

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2023

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-39563

GEOVAX LABS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation or organization)

87-0455038

(IRS Employer Identification No.)

**1900 Lake Park Drive, Suite 380
Smyrna, Georgia**

(Address of principal executive offices)

30080

(Zip Code)

(678) 384-7220

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each Class</u>	<u>Trading Symbol</u>	<u>Name of each Exchange on which Registered</u>
Common Stock \$0.001 par value	GOVX	The Nasdaq Capital Market
Warrants to Purchase Common Stock	GOVXW	The Nasdaq Capital Market

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Emerging growth company	<input type="checkbox"/>
Smaller reporting company	<input checked="" type="checkbox"/>		

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 accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):

Yes No

As of November 8, 2023, 26,695,287 shares of the Registrant's common stock, \$.001 par value, were issued and outstanding.

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Part I -- FINANCIAL INFORMATION

Item 1 Financial Statements

GEOVAX LABS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30 2023 <u>(unaudited)</u>	December 31, 2022 <u></u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,687,041	\$ 27,612,732
Prepaid expenses	2,113,249	1,325,998
Total current assets	<u>14,800,290</u>	<u>28,938,730</u>
Property and equipment, net	212,953	234,912
Other assets	<u>1,187,788</u>	<u>2,174,286</u>
Total assets	<u>\$ 16,201,031</u>	<u>\$ 31,347,928</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,213,295	\$ 1,747,682
Accrued expenses	2,868,390	3,000,212
Total current liabilities	<u>7,081,685</u>	<u>4,747,894</u>
Commitments (Note 4)		
Stockholders' equity:		
Common stock, \$.001 par value:		
Authorized shares – 600,000,000		
Issued and outstanding shares – 26,695,287 and 26,334,953 at September 30, 2023 and December 31, 2022, respectively		
	26,695	26,335
Additional paid-in capital	105,864,028	104,970,722
Accumulated deficit	<u>(96,771,377)</u>	<u>(78,397,023)</u>
Total stockholders' equity	<u>9,119,346</u>	<u>26,600,034</u>
Total liabilities and stockholders' equity	<u>\$ 16,201,031</u>	<u>\$ 31,347,928</u>

See accompanying notes to condensed consolidated financial statements.

GEOVAX LABS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Grant revenue	\$ -	\$ -	\$ -	\$ 81,526
Operating expenses:				
Research and development	6,947,979	2,721,196	14,486,896	5,358,917
General and administrative	<u>1,651,775</u>	<u>1,249,337</u>	<u>4,562,293</u>	<u>3,363,672</u>
Total operating expenses	<u>8,599,754</u>	<u>3,970,533</u>	<u>19,049,189</u>	<u>8,722,589</u>
Loss from operations	(8,599,754)	(3,970,533)	(19,049,189)	(8,641,063)
Other income:				
Interest income	<u>190,936</u>	<u>2,431</u>	<u>674,835</u>	<u>3,747</u>
Net loss	<u>\$ (8,408,818)</u>	<u>\$ (3,968,102)</u>	<u>\$(18,374,354)</u>	<u>\$ (8,637,316)</u>
Basic and diluted:				
Net loss per common share	\$ (0.32)	\$ (0.17)	\$ (0.69)	\$ (0.63)
Weighted average shares outstanding	26,544,058	23,461,665	26,442,847	13,818,315

See accompanying notes to condensed consolidated financial statements.

GEOVAX LABS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

Three-Month and Nine-Month Periods Ended September 30, 2023

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2022	26,334,953	\$ 26,335	\$ 104,970,722	\$(78,397,023)	\$ 26,600,034
Issuance of common stock for services	108,696	109	74,891	-	75,000
Stock option expense	-	-	228,039	-	228,039
Net loss for the three months ended March 31, 2023	-	-	-	(4,037,916)	(4,037,916)
Balance at March 31, 2023	26,443,649	26,444	105,273,652	(82,434,939)	\$ 22,865,157
Stock option expense	-	-	226,013	-	226,013
Net loss for the three months ended June 30, 2023	-	-	-	(5,927,620)	(5,927,620)
Balance at June 30, 2023	26,443,649	26,444	105,499,665	(88,362,559)	17,163,550
Issuance of common stock for services	251,638	251	137,249	-	137,500
Stock option expense	-	-	227,114	-	227,114
Net loss for the three months ended September 30, 2023	-	-	-	(8,408,818)	(8,408,818)
Balance at September 30, 2023	26,695,287	\$ 26,695	\$ 105,864,028	\$(96,771,377)	\$ 9,119,346

Three-Month and Nine-Month Periods Ended September 30, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2021	6,381,541	\$ 6,382	\$ 68,731,220	\$(64,375,898)	\$ 4,361,704
Sale of common stock and warrants for cash	707,484	707	9,228,541	-	9,229,248
Issuance of common stock upon warrant exercise	2,360,000	2,360	(2,336)	-	24
Stock option expense	-	-	190,191	-	190,191
Net loss for the three months ended March 31, 2022	-	-	-	(2,427,515)	(2,427,515)
Balance at March 31, 2022	9,449,025	9,449	78,147,616	(66,803,413)	11,353,652
Sale of common stock and warrants for cash	1,050,000	1,050	18,496,896	-	18,497,946
Issuance of common stock upon warrant exercise	5,671,214	5,671	(5,104)	-	567
Issuance of common stock for services	68,500	69	71,931	-	72,000
Stock option expense	-	-	190,191	-	190,191
Net loss for the three months ended June 30, 2022	-	-	-	(2,241,699)	(2,241,699)
Balance at June 30, 2022	16,238,739	16,239	96,901,530	(69,045,112)	27,872,657
Issuance of common stock upon warrant exercise	10,021,214	10,021	7,615,522	-	7,625,543
Issuance of common stock for services	75,000	75	60,675	-	60,750
Stock option expense	-	-	190,191	-	190,191
Net loss for the three months ended September 30, 2022	-	-	-	(3,968,102)	(3,968,102)
Balance at September 30, 2022	26,334,953	\$ 26,335	\$ 104,767,918	\$(73,013,214)	\$ 31,781,039

See accompanying notes to condensed consolidated financial statements.

GEOVAX LABS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (18,374,354)	\$ (8,637,316)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	51,956	42,213
Stock-based compensation expense	813,499	650,895
Changes in assets and liabilities:		
Grant funds receivable	-	49,006
Prepaid expenses and other current assets	(707,084)	(1,251,539)
Other assets	986,498	(2,173,276)
Accounts payable and accrued expenses	2,333,791	(645,955)
Total adjustments	3,478,660	(3,328,656)
Net cash used in operating activities	(14,895,694)	(11,965,972)
Cash flows from investing activities:		
Purchase of equipment	(29,997)	(134,258)
Net cash used in investing activities	(29,997)	(134,258)
Cash flows from financing activities:		
Net proceeds from sale of common stock and warrants	-	27,727,194
Net proceeds from warrant exercise	-	7,626,134
Net cash provided by financing activities	-	35,353,328
Net increase (decrease) in cash and cash equivalents	(14,925,691)	23,253,098
Cash and cash equivalents at beginning of period	27,612,732	11,423,870
Cash and cash equivalents at end of period	\$ 12,687,041	\$ 34,676,968

See accompanying notes to condensed consolidated financial statements.

GEOVAX LABS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2023
(unaudited)

1. Nature of Business

GeoVax Labs, Inc., headquartered in the Atlanta, Georgia metropolitan area, is a clinical-stage biotechnology company incorporated under the laws of the State of Delaware. GeoVax Labs, Inc. and its wholly owned subsidiary, GeoVax, Inc., a Georgia corporation, are collectively referred to herein as “GeoVax” or the “Company”.

The Company is focused on developing immunotherapies and vaccines against cancers and infectious diseases using novel vector vaccine platforms. GeoVax’s product pipeline includes ongoing human clinical trials for a next-generation COVID-19 vaccine and a gene-directed therapy for advanced head and neck cancer. Additional preclinical research and development programs include preventive vaccines against Mpox (monkeypox), hemorrhagic fever viruses (Ebola Zaire, Ebola Sudan, Marburg, and Lassa Fever) Zika virus, and malaria, as well as immunotherapies for solid tumors.

2. Summary of Significant Accounting Policies

We disclosed in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022 those accounting policies that we consider significant in determining our results of operations and financial position. During the nine months ended September 30, 2023, there have been no material changes to, or in the application of, the accounting policies previously identified and described in the Form 10-K.

Basis of Presentation

The accompanying financial statements include the accounts of GeoVax Labs, Inc. and GeoVax, Inc. All intercompany transactions have been eliminated in consolidation. The financial statements are unaudited, but include all adjustments, consisting of normal recurring entries, which we believe to be necessary for a fair presentation of interim periods presented. Interim results are not necessarily indicative of results for a full year. The financial statements should be read in conjunction with our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022. We expect our operating results to fluctuate for the foreseeable future; therefore, period-to-period comparisons should not be relied upon as predictive of the results in future periods.

We believe that our existing cash resources will be sufficient to continue our planned operations into the first quarter of 2024. We are devoting substantially all of our present efforts to research and development of our vaccine and immunotherapy candidates and will require additional funding to continue our research and development activities. We plan to pursue additional cash resources through public or private equity or debt financings, government grants/contracts, arrangements with strategic partners, or from other sources. There can be no assurance that additional funding will be available on favorable terms or at all. These factors collectively raise substantial doubt about the Company’s ability to continue as a going concern within one year from the date these financial statements are issued. Management believes that we will be successful in securing the additional capital required to continue the Company’s planned operations, but that our plans do not fully alleviate the substantial doubt about the Company’s ability to operate as a going concern.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

Recent Accounting Pronouncements

During the nine months ended September 30, 2023, there have been no new accounting pronouncements or changes in accounting pronouncements which we expect to have a material impact on our financial statements.

3. Balance Sheet Components

Prepaid Expenses – Prepaid expenses consist of the following:

	September 30, 2023	December 31, 2022
Prepaid clinical trial costs (current portion)	\$ 1,986,037	\$ 1,171,077
Prepaid insurance premiums	-	107,876
Prepaid rent	13,045	13,045
Other prepaid expenses	114,167	34,000
Total prepaid expenses	<u>\$ 2,113,249</u>	<u>\$ 1,325,998</u>

Property and Equipment – Property and equipment consist of the following:

	September 30, 2023	December 31, 2022
Equipment and furnishings	\$ 755,809	\$ 725,812
Leasehold improvements	115,605	115,605
Total property and equipment	871,414	841,417
Accumulated depreciation and amortization	(658,461)	(606,505)
Total property and equipment, net	<u>\$ 212,953</u>	<u>\$ 234,912</u>

Other Assets – Other assets consist of the following:

	September 30, 2023	December 31, 2022
Prepaid clinical trial costs (noncurrent portion)	\$ 1,106,778	\$ 2,083,276
Prepaid technology license fees	70,000	80,000
Deposits	11,010	11,010
Total other assets	<u>\$ 1,187,788</u>	<u>\$ 2,174,286</u>

Accrued Expenses – Accrued expenses consist of the following:

	September 30, 2023	December 31, 2022
Accrued technology license fees	\$ 2,000,000	\$ 2,000,000
Payroll-related liabilities	133,665	550,810
Other accrued expenses	734,725	449,402
Total accrued expenses	<u>\$ 2,868,390</u>	<u>\$ 3,000,212</u>

4. Commitments

Operating Lease

We lease approximately 8,400 square feet of office and laboratory space pursuant to an operating lease which expires on December 31, 2025. Rent expense for the three-month and nine-month periods ended September 30, 2023 was \$45,414 and \$136,242, respectively, as compared to \$44,089 and \$132,267, respectively, for the same periods of 2022. Future minimum lease payments total \$45,414 in 2023, \$187,056 in 2024, and \$192,708 in 2025 although the lease may be terminated at any time by either party with one hundred eighty days written notice.

License Agreements

We have entered into license agreements for various technologies and patent rights associated with our product development activities. These agreements may contain provisions for upfront payments, milestone fees due upon the achievement of selected development and regulatory events, minimum annual royalties or other fees, and royalties based on future net sales. Due to the uncertainty of the achievement and timing of the contingent events requiring payment under these agreements, the amounts to be paid by us in the future are not determinable.

Other Commitments

In the normal course of business, we enter into various contracts and purchase commitments including those with contract research organizations (“CROs”) for clinical trial services, contract manufacturing organizations (“CMOs”) for production of materials for use in our clinical trials, and other independent contractors or academic institutions for preclinical research

activities and other services and products. Most contracts are generally cancellable, with notice, at the Company's option. Payments due upon cancellation may consist of payments for services provided or expenses incurred to date, or cancellation penalties depending on the time of cancellation.

5. Stockholders' Equity

Common Stock Transactions

During March, August and September 2023 we issued 108,696, 178,253 and 73,385 shares of our common stock, respectively, pursuant to professional services and consulting agreements.

Stock Options

We have stock-based incentive plans (the "Plans") pursuant to which our Board of Directors may grant stock options and other stock-based awards to our employees, directors and consultants. During the nine months ended September 30, 2023, 40,000 stock options were cancelled and there were no new grants of stock options or other transactions related to the Plans. As of September 30, 2023, there are 2,018,800 stock options outstanding, with a weighted-average exercise price of \$1.89 per share and a weighted-average remaining contractual term of 7.5 years. Including the outstanding stock options, a total of 5,018,800 shares of our common stock are reserved for future issuance pursuant to the Plans.

Stock Purchase Warrants

We have issued stock purchase warrants in connection with past financing and licensing transactions. During the nine months ended September 30, 2023, there were no transactions related to our stock purchase warrants. As of September 30, 2023, there are 13,384,115 stock purchase warrants outstanding with a weighted-average exercise price of \$2.77 per share and a weighted-average remaining term of 3.8 years.

6. Stock-Based Compensation Expense

Stock-based compensation expense related to stock options is recognized on a straight-line basis over the requisite service period for the award and is allocated to research and development expense or general and administrative expense based upon the classification of the individual to whom the award is granted. Stock-based compensation expense related to stock option grants was \$227,114 and \$681,166 during the three-month and nine-month periods ended September 30, 2023, respectively, as compared to \$190,191 and \$570,573, respectively, during the same periods of 2022. As of September 30, 2023, there is \$738,281 of unrecognized compensation expense that we expect to recognize over a weighted-average period of 1.6 years.

We have also issued shares of our restricted common stock to consultants and recognize the related expense over the terms of the related agreements. During the three-month and nine-month periods ended September 30, 2023 we recorded stock-based compensation expense of \$70,833 and \$132,333, respectively, associated with common stock issued for consulting services, as compared to \$48,375 and \$80,322, respectively, for the same periods of 2022. As of September 30, 2023, there is \$104,167 recorded as a prepaid expense for these arrangements, which will be recognized as expense over the term of the related agreements.

7. Net Loss Per Share

Basic and diluted loss per common share are computed based on the weighted average number of common shares outstanding. The Company's potentially dilutive securities, which include stock options and stock purchase warrants, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive. The securities that could potentially dilute basic earnings per share in the future and that have been excluded from the computation of diluted net loss per share totaled 15,402,915 and 14,346,415 shares at September 30, 2023 and 2022, respectively.

8. Income Taxes

No provision for income taxes was recorded in either of the nine-month periods ended September 30, 2023 and 2022. The Company remains in a cumulative loss position with a full valuation allowance recorded against its net deferred income tax assets as of September 30, 2023.

Item 2 Management’s Discussion and Analysis of Financial Condition And Results of Operations

The following Management’s Discussion and Analysis of Financial Condition and Results of Operations (“MD&A”) is intended to help the reader understand our results of operations and financial condition. This MD&A is provided as a supplement to, and should be read in conjunction with, our condensed consolidated financial statements and the accompanying notes thereto and other disclosures included in this Quarterly Report on Form 10-Q (this “Report”), and our audited financial statements and the accompanying notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the Securities and Exchange Commission on March 23, 2023.

Forward-Looking Statements

Information included in this Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Forward-looking statements are not statements of historical facts, but rather reflect our current expectations concerning future events and results. We generally use the words “believes,” “expects,” “intends,” “plans,” “anticipates,” “likely,” “will” and similar expressions to identify forward-looking statements. All statements in this Report, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, expectations and objectives could be forward-looking statements. Such forward-looking statements, including those concerning our expectations, involve risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and factors include, but are not limited to, those factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022. We operate in a highly competitive, highly regulated and rapidly changing environment and our business is constantly evolving. Therefore, it is likely that new risks will emerge, and that the nature and elements of existing risks will change, over time. It is not possible for management to predict all such risk factors or changes therein, or to assess either the impact of all such risk factors on our business. We assume no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this Report.

Overview and Recent Events

GeoVax is a clinical-stage biotechnology company developing immunotherapies and vaccines against cancers and infectious diseases using novel vector vaccine platforms. GeoVax’s product pipeline includes ongoing human clinical trials for a next-generation COVID-19 vaccine and a gene-directed therapy against advanced head and neck cancer. Additional preclinical research and development programs include preventive vaccines against Mpox (monkeypox), hemorrhagic fever viruses (Ebola Zaire, Ebola Sudan, Marburg, and Lassa), Zika virus, and malaria, as well as immunotherapies for solid tumors.

Our corporate strategy is to advance, protect and exploit our differentiated vaccine/immunotherapy technologies leading to the successful development of preventive and therapeutic vaccines and immunotherapies against infectious diseases and various cancers. Our goal is to advance products through to human clinical testing, and to seek partnership or licensing arrangements for achieving regulatory approval and commercialization. We also leverage third party resources through collaborations and partnerships for preclinical and clinical testing with multiple government, academic and corporate entities.

Our programs are in various stages of development, the most significant of which are summarized below along with recent developments:

GEO-CM04S1 – Immunocompromised Trial

- GEO-CM04S1 is currently undergoing a Phase 2 clinical trial (ClinicalTrials.gov Identifier: NCT04977024), evaluating its safety and efficacy, compared to either the Pfizer/BioNTech or Moderna mRNA-based vaccine, as a preventive COVID-19 vaccine in high-risk immunocompromised patients (e.g. patients who have previously received either an allogeneic hematopoietic cell transplant, an autologous hematopoietic cell transplant or chimeric antigen receptor (CAR) T cell therapy).
- In September 2023, the journal, *Vaccines*, published data from the open-label safety portion of the trial indicating that GEO-CM04S1 is highly immunogenic, inducing both antibody responses, including neutralizing antibodies, and T cell responses.

- In September 2023, preclinical vaccine efficacy data for GEO-CM02 were presented during the Keystone Symposia on Molecular and Cellular Biology, *Vaccinology During and After COVID-19*, demonstrating that our multi-antigen SARS-CoV-2 vaccine, GEO-CM02, induced efficacious immune responses against the original Wuhan strain and BA.1 Omicron variant with a single dose. The data generated in the GEO-CM02 studies validate our hypothesis that vaccines such as GEO-CM04S1, which are designed to induce both antibodies and T-cells to multiple viral structural proteins, can address the issue of viral variation and escape from the immune system.
- In October 2023, we announced commencement of the planned site expansion for this trial to accelerate patient enrollment. In addition to study enrollments completed at the City of Hope Medical Center (Duarte, California), the trial is now open to eligible patients at Wake Forest Baptist Medical Center (Winston Salem, North Carolina), the University of Massachusetts Medical Center (Worcester, Massachusetts), and the Fred Hutchinson Cancer Center (Seattle, Washington).

GEO-CM04S1 – Healthy Booster Trial

- GEO-CM04S1 is undergoing the Phase 2 portion of a Phase 1/2 trial (ClinicalTrials.gov Identifier: NCT04639466), evaluating its use as a universal COVID-19 booster vaccine to current FDA-approved two-shot mRNA vaccines from Pfizer/BioNTech and Moderna.
- In September 2023, we announced the completion of patient enrollment for this trial.

GEO-CM04S1 – CLL Trial

- In July 2023, an investigator-initiated Phase 2 clinical trial (ClinicalTrials.gov Identifier: NCT05672355) of GEO-CM04S1 began, evaluating its use as a COVID-19 booster vaccine in patients with chronic lymphocytic leukemia (CLL), compared to the Pfizer/BioNTech mRNA-based vaccine.

Gedepin® – Advanced Head and Neck Cancer Trial

- Gedepin® is currently undergoing a Phase 1/2 clinical trial (ClinicalTrials.gov Identifier: NCT03754933) for treatment of patients with advanced head and neck squamous cell carcinoma (HNSCC). This trial is being funded in part by the U.S. Food & Drug Administration (FDA) pursuant to its Orphan Products Clinical Trials Grants Program. The trial is designed to inform the design of a larger patient trial 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.
- In July 2023, interim data were presented at the American Association for Cancer Research (AACR) and the American Head and Neck Society (AHNS) joint Head and Neck Cancer Conference, indicating that administration of Gedepin® is safe and feasible, with observation of tumor growth impairment in a majority of the patients.

Advanced Vaccine Manufacturing Process Development

- In September 2023, GeoVax and ProBioGen AG announced the signing of a commercial license agreement for ProBioGen’s AGE1.CR.pIX® suspension cell line. The agreement enhances our manufacturing capabilities for our entire Modified Vaccinia Ankara (MVA)-based vaccine portfolio. This follows the May 2023 execution of a Master Services Agreement with Advanced Bioscience Laboratories, Inc. (ABL) to support current Good Manufacturing Practices (cGMP) production of our vaccine candidates through late-stage development toward eventual commercialization. These agreements move the Company toward fully implementing a continuous cell line manufacturing system that will provide lower-cost, scalable versatility for our entire MVA-based vaccine portfolio.

Intellectual Property Development

- In October 2023, the U.S. Patent and Trademark Office issued a Notice of Allowance to GeoVax for Patent Application No. 17/584,231 titled “*Replication Deficient Modified Vaccinia Ankara (MVA) Expressing Marburg Virus Glycoprotein (GP) and Matrix Protein (VP40)*.” The allowed claims generally cover GeoVax’s vector platform for expressing Marburg virus antigens in virus-like particles (VLPs) utilizing an MVA viral vector.
- In October 2023, the U.S. Patent and Trademark Office issued a Notice of Allowance to GeoVax for Patent Application No. 17/409,574 titled “*Multivalent HIV Vaccine Boost Compositions and Methods of Use*.” The allowed claims generally cover a priming vaccination with a DNA vector encoding multiple HIV antigens in virus-like particles (VLPs), followed by a boost vaccination with GeoVax’s vector platform for expressing HIV-1 antigens in VLPs utilizing an MVA viral vector.
- In August 2023, the U.S. Patent and Trademark Office issued a Notice of Allowance to GeoVax for Patent Application No. 17/726,254 titled “*Compositions and Methods for Generating an Immune Response to Treat or Prevent Malaria*”. The allowed claims cover compositions comprising GeoVax’s modified vaccinia Ankara (MVA) vector expressing Plasmodium antigens and methods of inducing an immune response to malaria utilizing the compositions. The compositions and methods covered in the allowed claims are useful both prophylactically and therapeutically and may be used to prevent and/or treat malaria.

- In July 2023, the U.S. Patent and Trademark Office issued Patent No. 11,701,418 B2 to GeoVax, pursuant to the Company's patent application No. 15/543,139 titled "*Replication-Deficient Modified Vaccinia Ankara (MVA) and Matrix Protein (VP40)*", covering GeoVax's vector platform for expressing ebolavirus antigens in virus-like particles (VLPs) utilizing an MVA viral vector. The claims encompass multiple ebolavirus strains, including Sudan ebolavirus, Zaire ebolavirus, Tai Forest ebolavirus, and Reston ebolavirus.

General Corporate

- In June 2023, we received notice from the Listing Qualifications Department of the Nasdaq Stock Market ("Nasdaq") granting our request for a second 180-day period, or until December 4, 2023, to regain compliance with the \$1.00 bid price per share requirement for continued inclusion on The Nasdaq Capital Market. If the Company does not meet the bid price requirement prior to the compliance date, Nasdaq will notify the Company that the Company's common stock will be subject to delisting. At that time, the Company may appeal the delisting determination to the Nasdaq Hearings Panel. There can be no assurance that if the Company does appeal a delisting determination, that such appeal will be successful.

Financial Overview

Revenue

We have not generated any revenue from product sales to date. Our product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that we advance to clinical testing will require regulatory approval prior to commercial use and will require significant costs for commercialization. Our grant revenue relates to grants and contracts from agencies of the U.S. government in support of our vaccine development activities. We record revenue associated with these grants as the related costs and expenses are incurred.

Research and development expenses

Since our inception, we have focused and we continue to focus significant resources on our research and development activities, including developing our vector platform and analytical testing methods, conducting preclinical studies, developing manufacturing processes, and conducting clinical trials. Research and development costs are expensed as incurred and consist primarily of the following:

- personnel costs in our research, development and regulatory functions;
- expenses incurred with contract research organizations ("CROs") that conduct clinical trials on our behalf;
- expenses incurred with contract manufacturing organizations ("CMOs") that manufacture product used in our clinical trials;
- expenses incurred in procuring materials and for analytical testing services required to produce vaccine candidates;
- expenses incurred internally and externally to improve the efficiency and yield of our vaccine manufacturing process;
- laboratory supplies, vendor expenses and other third-party contract expenses related to preclinical research activities;
- technology license fees;
- consultant expenses for services supporting our clinical, regulatory and manufacturing activities; and
- facilities, depreciation and other general overhead expenses.

We expect our research and development expenditures to increase as we advance our existing and future product candidates into and through clinical trials and pursue regulatory approval, especially with regard to the ongoing Gedeptin and GEO-CM04S1 clinical programs. We do not provide forward-looking estimates of costs and time to complete our research programs due to the many uncertainties associated with biotechnology research and development. Due to these uncertainties, our future expenditures are likely to be highly volatile in future periods depending on the outcomes of the trials and studies. As we obtain data from preclinical studies and clinical trials, we may elect to discontinue or delay certain development programs to focus our resources on more promising product candidates. Completion of preclinical studies and human clinical trials may take several years or more, but the length of time can vary substantially depending upon several factors. The duration and the cost of future clinical trials may vary significantly over the life of the project because of differences arising during development of the human clinical trial protocols, including the length of time required to enroll suitable patient subjects, the number of patients that ultimately participate in the clinical trial, the duration of patient follow-up, and the number of clinical sites included in the clinical trials.

General and administrative expenses

Our general and administrative expenses consist primarily of personnel costs in our executive, finance and investor relations, business development and administrative functions. Other general and administrative expenses include consulting fees, professional service fees for accounting and legal services, lease expenses related to our offices, insurance premiums, intellectual property costs incurred in connection with filing and prosecuting patent applications, depreciation and other costs. We expect our general and administrative expenses to continue to increase in the future as we support expanded research and development activities, prepare for potential commercialization of our current and future product candidates, and other general corporate activities.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates and adjusts the estimates as necessary. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

For a description of critical accounting policies that require significant judgments and estimates during the preparation of our financial statements, refer to the Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2022. There have been no significant changes to our critical accounting policies from those disclosed in our 2022 Annual Report.

Recent Accounting Pronouncements – Information regarding recent accounting pronouncements is contained in Note 2 to the condensed consolidated financial statements, included in this Quarterly Report.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that are likely or reasonably likely to have a material effect on our financial condition or results of operations, other than the operating lease for our office and laboratory space.

Results of Operations

The following table summarizes our results of operations for the three-month and nine-month periods ended September 30, 2023 and 2022:

	Three Months Ended September 30,		
	2023	2022	Change
Grant revenue	\$ -	\$ -	\$
Operating expenses:			
Research and development	6,947,979	2,721,196	4,226,783
General and administrative	1,651,775	1,249,337	402,438
Total operating expenses	8,599,754	3,970,533	4,629,221
Loss from operations	(8,599,754)	(3,970,533)	(4,629,221)
Interest income	190,936	2,431	188,505
Net loss	<u>\$ (8,408,818)</u>	<u>\$ (3,968,102)</u>	<u>\$ (4,440,716)</u>

	Nine Months Ended September 30,		
	2023	2022	Change
Grant revenue	\$ -	\$ 81,526	\$ (81,526)
Operating expenses:			
Research and development	14,486,896	5,358,917	9,127,979
General and administrative	4,562,293	3,363,672	1,198,621
Total operating expenses	19,049,189	8,722,589	10,326,600
Loss from operations	(19,049,189)	(8,641,063)	(10,408,126)
Interest income	674,835	3,747	671,088
Net loss	<u>\$(18,374,354)</u>	<u>\$ (8,637,316)</u>	<u>\$ (9,737,038)</u>

Grant Revenue

There were no grant revenues during either of the three-month periods ended September 30, 2023 and 2022. Grant revenue decreased by \$81,526 (100%) for the nine-month period ended September 30, 2023 compared to the nine-month period ended September 30, 2022, reflective of the wind-down of the Company's grant from the U.S. Department of Defense for our Lassa Fever vaccine program. As of September 30, 2023, all approved grant funds have been utilized.

Research and Development Expenses

For the three-month and nine-month periods ending September 30, 2023, research and development expenses increased by \$4,226,783 (155%) and \$9,127,979 (170%), respectively, versus the comparable 2022 periods. The overall increase during the 2023 periods relates primarily to costs of conducting clinical trials for GEO-CM04S1 and Gedepetin, costs of manufacturing materials for use in our clinical trials, technology license fees, personnel costs, costs of preclinical research activities and higher travel costs. Research and development expense for the three-month and nine-month periods of 2023 included stock-based compensation expense of \$77,873 and \$232,516, respectively; as compared to \$54,293 and \$162,878 respectively, for the comparable 2022 periods.

General and Administrative Expenses

For the three-month and nine-month periods ending September 30, 2023, general and administrative expenses increased by \$402,438 (32%) and \$1,198,621 (36%), respectively, versus the comparable 2022 periods. The overall increase during the 2023 periods relates primarily to higher personnel costs, investor relations consulting costs, legal fees, patent costs and travel expenses. General and administrative expense for the three-month and nine-month periods of 2023 included stock-based compensation expense of \$220,075 and \$580,983, respectively; as compared to \$184,273 and \$488,017, respectively, for the comparable periods of 2022.

Other Income

Interest income for the three-month and nine-month periods ended September 30, 2023 was \$190,936 and \$674,835, respectively, as compared to \$2,431 and \$3,747, respectively, for comparable periods of 2022. The variances between periods are primarily attributable to cash available for investment and higher interest rates.

Liquidity and Capital Resources

The following tables summarize our liquidity and capital resources as of September 30, 2023 and December 31, 2022, and our cash flows for the nine-month periods ended September 30, 2023 and 2022:

Liquidity and Capital Resources	September 30, 2023	December 31, 2022
Cash and cash equivalents	\$ 12,687,041	\$ 27,612,732
Working capital	7,718,605	24,190,836

Cash Flow Data	Nine Months Ended September 30,	
	2023	2022
Net cash provided by (used in):		
Operating activities	\$ (14,895,694)	\$ (11,965,972)
Investing activities	(29,997)	(134,258)
Financing activities	-	35,353,328
Net increase (decrease) in cash and cash equivalents	\$ (14,925,691)	\$ 23,253,098

Operating Activities – Net cash used in operating activities of \$14,895,694 for the nine months ended September 30, 2023, was primarily due to our net loss of \$18,374,354, offset by non-cash items such as depreciation expense and stock-based compensation expense, and by changes in our working capital accounts. Net cash used in operating activities of \$11,965,972 for the nine months ended September 30, 2022, was primarily due to our net loss of \$8,637,316, also offset by non-cash charges such as depreciation and stock-based compensation expense, and by changes in our working capital accounts.

Investing Activities – Net cash used in investing activities was \$29,997 and \$134,258 for the nine-month periods ended September 30, 2023 and 2022, respectively, and relates primarily to purchases of laboratory equipment

Financing Activities – Net cash provided by financing activities was \$0- and \$35,353,328 for the nine-month periods ended September 30, 2023 and 2022, respectively. Net cash provided by financing activities for the 2022 period relates primarily to net proceeds from offerings of our common stock and warrants.

Funding Requirements and Sources of Capital

To date, we have not generated any product revenue. We do not know when, or if, we will generate any product revenue and we do not expect to generate significant product revenue unless and until we obtain regulatory approval and commercialize one of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to all of the risks incident to the development of new products, and may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. We anticipate that we will need substantial additional funding in connection with our continuing operations. We have funded our operations to date primarily from sales of our equity securities and from government grants and clinical trial assistance.

As of the date of this Quarterly Report, we expect our existing cash and cash equivalents will be sufficient to fund our operations into the first quarter of 2024. This projection takes into consideration contractual commitments we have made, and expect to make, in the normal course of operating our business, which include (i) obligations to our employees, (ii) our lease obligations, (iii) payments due under license agreements for various technologies and patent rights associated with our product development activities, (iv) arrangements with contract research organizations (“CROs”), contract manufacturing organizations (“CMOs”), and other third-party vendors for clinical trials services and production of materials for use in our clinical trials, and (v) other various firm purchase commitments and contractual obligations related to production and testing of our product candidates and the general operation of our business.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties and is based on assumptions that may prove to be wrong; actual results could vary materially.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect, and we may use our available capital resources sooner than we expect. Our future capital requirements will depend on many factors, which include but are not limited to:

- the timing and costs of our ongoing and planned clinical trials;
- the timing and costs of manufacturing material for use in clinical trials;
- the number and scope of our research programs and the speed at which they are advanced;
- the progress and success of our preclinical and clinical development activities;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights;
- the costs to attract and retain skilled personnel;
- the costs to maintain and expand our infrastructure to support our operations, our product development, and planned future commercialization efforts;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the costs associated with any products or technologies that we may in-license or acquire; and
- the costs and timing of regulatory approvals.

We will need to continue to raise additional capital to support our future operating activities, including progression of our development programs, preparation for commercialization, and other operating costs. Financing strategies we may pursue include, but are not limited to, the public or private sale of equity, debt financings or funds from other capital sources, such as government funding, collaborations, strategic alliances or licensing arrangements with third parties. There can be no assurance additional capital will be available to secure additional financing, or if available, that it will be sufficient to meet our needs on favorable terms. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development of one or more of our product candidates.

Item 3 Quantitative and Qualitative Disclosures About Market Risk

Not applicable to smaller reporting companies.

Item 4 Controls and Procedures

Evaluation of disclosure controls and procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that the information required to be disclosed in reports filed or submitted under the Securities Exchange Act of 1934, as amended (Exchange Act), is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to management, including the Chief Executive Officer and Principal Financial and Accounting Officer, as appropriate to allow timely decisions regarding required disclosure.

Our management has carried out an evaluation, under the supervision and with the participation of our Principal Executive Officer and our Principal Financial and Accounting Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rules 13a-15 or 15d-15 as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

Changes in internal control over financial reporting

There were no significant changes in our internal control over financial reporting that occurred during the three months ended September 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

PART II -- OTHER INFORMATION

Item 1 **Legal Proceedings**

None.

Item 1A **Risk Factors**

For information regarding factors that could affect our results of operations, financial condition or liquidity, see the risk factors discussed under “Risk Factors” in Item 1A of our most recent Annual Report on Form 10-K. See also “Forward-Looking Statements,” included in Part I - Item 2 of this Quarterly Report on Form 10-Q. As a smaller reporting company (as defined in Rule 12b-2 of the Exchange Act), we are not required to provide the information called for by this Item 1A concerning any material changes from the risk factors previously disclosed in our most recent Annual Report on Form 10-K.

Item 2 **Unregistered Sales of Equity Securities and Use of Proceeds**

On August 10, 2023, we issued 178,253 shares of our restricted common stock to Outside the Box Capital, Inc. pursuant to a professional services agreement. The Company relied on an exemption from the registration requirements of the Securities Act afforded by Section 4(a) (2) thereof and Rule 506 of Regulation D.

On September 28, 2023, we issued 73,385 shares of our restricted common stock to Acorn Management Partners, LLC pursuant to a professional relations and consulting agreement. The Company relied on an exemption from the registration requirements of the Securities Act afforded by Section 4(a) (2) thereof and Rule 506 of Regulation D.

There were no other sales of unregistered securities during the period covered by this report that have not previously been reported on Form 8-K.

Item 3 **Defaults Upon Senior Securities**

None.

Item 4 **Mine Safety Disclosures**

Not applicable.

Item 5 **Other Information**

During the period covered by this report, none of our directors or executive officers adopted or terminated any “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement” (as each term is defined in Item 408(a) of Regulation S-K).

During the period covered by this report, there was no information required to be disclosed by us in a Current Report on Form 8-K that was not so reported, nor were there any material changes to the procedures by which our security holders may recommend nominees to our board of directors.

Item 6 Exhibits

Exhibit

Number Description

10.1	At The Market Offering Agreement, by and between GeoVax Labs, Inc. and H.C. Wainwright & Co., LLC, dated July 18, 2023 (1)
31.1*	Certification pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
31.2*	Certification pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
32.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document (1)
101.SCH	Inline XBRL Taxonomy Extension Schema Document (1)
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document (1)
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document (1)
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document (1)
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document (1)
104	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q and included in the Exhibit 101 Inline XBRL Document Set (1)

* Filed herewith

** Indicates a management contract or compensatory plan or arrangement

(1) Incorporated by reference from the registrant's Current Report on Form 8-K filed July 19, 2023.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this quarterly report on Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

GEOVAX LABS, INC.
(Registrant)

Date: November 8, 2023

By: /s/ Mark W. Reynolds
Mark W. Reynolds
Chief Financial Officer
(duly authorized officer and principal
financial officer)