

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 March 31, 2024

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 May 14, 2024, 2,308,309 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**

	March 31 2024 <u>(unaudited)</u>	December 31, 2023 <u></u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 768,859	\$ 6,452,589
Prepaid expenses	<u>2,093,519</u>	<u>1,433,153</u>
Total current assets	2,862,378	7,885,742
Property and equipment, net	190,113	209,689
Other assets	<u>305,691</u>	<u>1,187,788</u>
Total assets	<u>\$ 3,358,182</u>	<u>\$ 9,283,219</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,883,844	\$ 2,802,950
Accrued expenses	<u>1,420,063</u>	<u>716,931</u>
Total current liabilities	3,303,907	3,519,881
Commitments (Note 4)		
Stockholders' equity:		
Common stock, \$.001 par value:		
Authorized shares – 150,000,000 and 600,000,000 at		
March 31, 2024 and December 31, 2023, respectively		
Issued and outstanding shares – 2,308,309 and 1,977,152 at		
March 31, 2024 and December 31, 2023, respectively		
	2,308	1,977
Additional paid-in capital	110,265,884	110,125,146
Accumulated deficit	<u>(110,213,917)</u>	<u>(104,363,785)</u>
Total stockholders' equity	<u>54,275</u>	<u>5,763,338</u>
Total liabilities and stockholders' equity	<u>\$ 3,358,182</u>	<u>\$ 9,283,219</u>

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	4,425,728	2,819,189
General and administrative	1,457,353	1,451,425
Total operating expenses	5,883,081	4,270,614
Loss from operations	(5,883,081)	(4,270,614)
Other income:		
Interest income	32,949	232,698
Net loss	\$ (5,850,132)	\$ (4,037,916)
Basic and diluted:		
Net loss per common share	\$ (2.47)	\$ (2.30)
Weighted average shares outstanding	2,367,050	1,755,905

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31, 2024				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2023	1,977,152	\$ 1,977	\$ 110,125,146	\$(104,363,785)	\$ 5,763,338
Issuance of common stock for services	6,703	7	37,493	-	37,500
Issuance of common stock upon warrant exercise	269,032	269	(269)	-	-
Fractional share roundup following reverse split	55,422	55	(55)	-	-
Stock option expense	-	-	103,569	-	103,569
Net loss for the three months ended March 31, 2024	-	-	-	(5,850,132)	(5,850,132)
Balance at March 31, 2024	2,308,309	\$ 2,308	\$ 110,265,884	\$ (110,213,917)	\$ 54,275

	Three Months Ended March 31, 2023				
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2022	1,755,664	\$ 1,756	\$ 104,995,301	\$(78,397,023)	\$ 26,600,034
Issuance of common stock for services	7,246	7	74,993	-	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	1,762,910	\$ 1,763	\$ 105,298,333	\$ (82,434,939)	\$ 22,865,157

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (5,850,132)	\$ (4,037,916)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	19,576	17,319
Stock-based compensation expense	157,736	246,039
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(677,033)	(755,973)
Other assets	882,097	976,498
Accounts payable, accrued expenses and other liabilities	(215,974)	(208,839)
Total adjustments	166,402	275,044
Net cash used in operating activities	(5,683,730)	(3,762,872)
Cash flows from investing activities:		
None		
Cash flows from financing activities:		
None		
Net decrease in cash and cash equivalents	(5,683,730)	(3,762,872)
Cash and cash equivalents at beginning of period	6,452,589	27,612,732
Cash and cash equivalents at end of period	\$ 768,859	\$ 23,849,860

See accompanying notes to condensed consolidated financial statements.

GEOVAX LABS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2024
(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, 2023 those accounting policies that we consider significant in determining our results of operations and financial position. During the three months ended March 31, 2024, 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, 2023. 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 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. Our existing cash resources are insufficient to continue our planned operations beyond the second quarter of 2024 without additional funding, which we are actively pursuing. 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. 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.

The accompanying consolidated financial statements, and all share and per share information contained herein, have been retroactively restated to reflect the reverse stock split described in Note 5.

Recent Accounting Pronouncements

During the three months ended March 31, 2024, 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:

	March 31, 2024	December 31, 2023
Prepaid clinical trial costs (current portion)	\$ 1,996,677	\$ 1,282,746
Prepaid insurance premiums	73,797	110,695
Prepaid rent	13,045	13,045
Other prepaid expenses	10,000	26,667
Total prepaid expenses	\$ 2,093,519	\$ 1,433,153

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

	March 31, 2024	December 31, 2023
Equipment and furnishings	\$ 774,758	\$ 774,758
Leasehold improvements	115,605	115,605
Total property and equipment	890,363	890,363
Accumulated depreciation and amortization	(700,250)	(680,674)
Total property and equipment, net	\$ 190,113	\$ 209,689

Other Assets – Other assets consist of the following:

	March 31, 2024	December 31, 2023
Prepaid clinical trial costs (noncurrent portion)	\$ 224,681	\$ 1,106,778
Prepaid technology license fees	70,000	70,000
Deposits	11,010	11,010
Total other assets	\$ 305,691	\$ 1,187,788

Accrued Expenses – Accrued expenses consist of the following:

	March 31, 2024	December 31, 2023
Payroll-related liabilities	\$ 152,407	\$ 114,337
Other accrued expenses	1,267,656	602,594
Total accrued expenses	\$ 1,420,063	\$ 716,931

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 periods ended March 31, 2024 and 2023 was \$46,764 and \$45,414, respectively. Future minimum lease payments total \$140,292 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”) and contract manufacturing organizations (“CMOs”) for clinical trials services and production of materials for use in our clinical trials. 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

Reverse Stock Split and Reduction of Authorized Shares of Common Stock

At a special meeting of our stockholders held on January 16, 2024, our stockholders approved an amendment to our certificate of incorporation to (i) reduce our authorized shares of common stock from 600,000,000 to 150,000,000 and (ii) effect a one-for-fifteen reverse split of our common stock. The amendment to our certificate of incorporation was filed with the Delaware Secretary of State on January 30, 2024 and our common stock began trading on the split-adjusted basis on January 31, 2024. The accompanying consolidated financial statements, and all share and per share information contained herein, have been retroactively restated to reflect the reverse stock split.

Common Stock Transactions

During January 2024, we issued 6,703 shares of our common stock pursuant to a professional relations and consulting agreement and we issued 55,422 shares of our common stock for the roundup of fractional shares associated with the reverse stock split. In February and March 2024, we issued 133,032 and 136,000 shares of our common stock, respectively, pursuant to the exercise of prefunded warrants.

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 three months ended March 31, 2024, 961 stock options were cancelled and there were no new grants of stock options or other transactions related to the Plans. As of March 31, 2024, there are 133,648 stock options outstanding, with a weighted-average exercise price of \$28.39 per share and a weighted-average remaining contractual term of 7.9 years. Including the outstanding stock options, a total of 333,648 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. As described under "Common Stock Transactions" above, during the three months ended March 31, 2024, we issued 269,032 shares of our common stock pursuant to the exercise of prefunded warrants; there were no other transactions related to our stock purchase warrants. The table below summarizes information concerning warrants outstanding as of March 31, 2024.

<u>Issue Date</u>	<u>Number of Shares</u>	<u>Exercise Price</u>	<u>Expiration</u>
June 2020	8,000	\$ 6.21	June 2025
September 2020	159,781	75.00	September 2025
February 2021	4,800	103.13	August 2024
September 2021	6,668	195.00	September 2026
December 2023	238,000	-0-	n/a
December 2023	<u>1,408,998</u>	6.21	June 2029
Outstanding at March 31, 2024	<u>1,826,247</u>		

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 individuals to whom the awards are granted. Stock-based compensation expense related to stock option grants was \$103,569 and \$228,039 during the three-month periods ended March 31, 2024 and 2023, respectively, and as of March 31, 2024, there is \$451,023 of unrecognized compensation expense that we expect to recognize over a weighted-average period of 1.3 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 periods ended March 31, 2024 and 2023 we recorded stock-based compensation expense of \$54,167 and \$18,000, respectively, associated with common stock issued for consulting services.

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 1,721,895 and 1,029,529 shares at March 31, 2024 and 2023, respectively.

8. Income Taxes

No provision for income taxes was recorded in either of the three-month periods ended March 31, 2024 and 2023. The Company remains in a cumulative loss position with a full valuation allowance recorded against its net deferred income tax assets as of March 31, 2024.

9. Subsequent Events

On May 10, 2024, we conducted a bridge financing through the issuance and sale of 10% Original Issue Discount Promissory Notes (the "Notes") with an aggregate principal amount of \$150,000 to members of our Board of Directors and senior management. The Notes are unsecured, bear interest at a rate of 15% per annum, and mature upon the earlier of (i) six months from the issue date or (ii) three days following the date the Company completes an offering of its common stock with gross proceeds of not less than \$5 million.

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, 2023, which was filed with the Securities and Exchange Commission on February 29, 2024.

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, future governmental grants, 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, 2023. 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 Developments

GeoVax is a clinical-stage biotechnology company developing immunotherapies and vaccines against infectious diseases and solid tumor cancers 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 research and development programs include preventive vaccines against Mpox and smallpox, hemorrhagic fever viruses (Ebola Zaire, Ebola Sudan and Marburg), Zika virus and malaria, as well as immunotherapies for multiple 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/Cell Transplant Phase 2 Trial

- GEO-CM04S1 is undergoing a Phase 2 multi-site 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). Data published 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.

GEO-CM04S1 – Healthy Booster Phase 2 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. Patient enrollment was completed in September 2023.
- In February 2024, we announced positive interim safety and immune responses findings following vaccine administration. Consolidated data from all subjects tested one-month post-vaccination, documented statistically significant increases in neutralizing antibody responses against multiple SARS-CoV-2 variants, ranging from the original Wuhan strain through Delta and Omicron XBB 1.5.

GEO-CM04S1 – Immunocompromised/CLL Trial Phase 2 Trial

- GEO-CM04S1 is undergoing an investigator-initiated Phase 2 clinical trial (ClinicalTrials.gov Identifier: NCT05672355), 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 Phase 1/2 Trial

- Gedepin® is 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.
- Interim data presented at the American Association for Cancer Research (AACR) and the American Head and Neck Society (AHNS) joint Head and Neck Cancer Conference in July 2023, indicated that administration of Gedepin® is safe and feasible, with observation of tumor growth impairment in a majority of the patients.
- In January 2024, we announced closure of patient enrollment for this trial. Allowing time for the maximum number of cycles of Gedepin therapy and patient follow-up, we expect to complete the study by the third quarter of 2024. Our intent is to discuss a follow-on protocol with the FDA for a Phase 2 or Phase 2/3 trial among patients with advanced head and neck cancer in whom current therapeutic options are suboptimal, in conjunction with a complete review of the results of the current trial. We expect that such discussions will include addressing the opportunity and basis for an expedited approval pathway.

MVA-Based Vaccine Manufacturing Process Development

- In March 2024, we announced a significant milestone toward implementation of a validated chicken embryonic fibroblast (CEF) based production system for our MVA-based vaccines, with the release of the first lot of GEO-CM04S1 produced with a commercial manufacturing platform. This marked the successful completion of the transfer and scale-up of manufacturing to Oxford Biomedica, the Company’s cGMP (current Good Manufacturing Procedures) manufacturing partner.

Intellectual Property Development

- In January 2024, the U.S. Patent and Trademark Office issued Patent No. 11,857,611 to GeoVax, pursuant to 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 February 2024, the U.S. Patent and Trademark Office issued Patent No. 11,896,657 to GeoVax, pursuant to 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 February 2024, the U.S. Patent and Trademark Office issued Patent No. 11,897,919 to GeoVax, pursuant to 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 February 2024, the Japanese Patent Office issued a Decision of Grant notifying GeoVax of the allowance of the Company's Patent Application No. 2022-153352 titled "*Compositions and Methods for Generating an Immune Response to a Tumor Associated Antigen.*" The allowed claims are directed to recombinant MVA viral vectors comprising specific MUC-1 nucleic sequences used in GeoVax's MUC-1 tumor-associated antigen immunotherapy program. Pharmaceutical compositions for inducing immune responses, preventing or reducing neoplasm growth, or treating cancer are also covered by the granted claims. This represents an extension of the GeoVax MVA-VLP platform that was originally developed for vaccines targeting infectious diseases.

General Corporate

Effective January 31, 2024, following approval by our stockholders at a special meeting held on January 16, 2024, we effected a reverse stock split of our common stock at a ratio of 1-for-15. The purpose of the reverse split was to regain compliance with the \$1.00 minimum bid price required for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). On the effective date, every fifteen issued and outstanding shares of our common stock was converted automatically into one share of the Company's Common Stock without any change in the par value per share, and our publicly-traded warrants were adjusted to require fifteen warrants to be exercised to receive one share of common stock at a price of \$75 per share.

Financial Overview

Revenue

We have not generated any revenues to date from the sale of the products we are developing. 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.

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, which include salaries, benefits and stock-based compensation;
- expenses incurred under agreements with contract research organizations ("CROs"), that conduct clinical trials on our behalf;
- expenses incurred under agreements with contract manufacturing organizations ("CMOs"), that manufacture product used in the clinical trials;
- expenses incurred in procuring materials and for analytical and release testing services required to produce vaccine candidates used in clinical trials;
- process development expenses incurred internally and externally to improve the efficiency and yield of the bulk vaccine;
- 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 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, including stock-based compensation. 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, maintain compliance with requirements of Nasdaq and the Securities and Exchange Commission, 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, 2023. There have been no significant changes to our critical accounting policies from those disclosed in our 2023 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 periods ended March 31, 2024 and 2023:

	<u>Three Months Ended March 31,</u>		<u>Change</u>
	<u>2024</u>	<u>2023</u>	
Operating expenses:			
Research and development	\$ 4,425,728	\$ 2,819,189	\$ 1,606,539
General and administrative	1,457,353	1,451,425	5,928
Total operating expenses	<u>5,883,081</u>	<u>4,270,614</u>	<u>1,612,467</u>
Loss from operations	(5,883,081)	(4,270,614)	(1,612,467)
Interest income	32,949	232,698	(199,749)
Net loss	<u>\$ (5,850,132)</u>	<u>\$ (4,037,916)</u>	<u>\$ (1,812,216)</u>

Research and Development Expenses

Our research and development expenses were \$4,425,728 for the three-month period ended March 31, 2024, as compared to \$2,819,189 for the comparable 2023 period, representing an increase of \$1,606,539 (57%). The increase during 2024 relates primarily to costs of manufacturing materials for use in our clinical trials and other related costs, personnel costs, and costs of preclinical research activities. Research and development expense for 2024 and 2023 includes stock-based compensation expense of \$53,099 and \$77,873, respectively, associated with employee stock options.

General and Administrative Expenses

Our general and administrative expenses were \$1,457,353 for the three-month period ended March 31, 2024, as compared to \$1,451,425 for the comparable 2023 period, representing an increase of \$5,928 (0.4%). General and administrative expense for 2024 and 2023 includes stock-based compensation expense of \$104,637 and \$168,166, respectively, associated with employee and consultant stock options and stock awards.

Other Income

Interest income for the three-month periods ended March 31, 2024 and 2023 was \$32,949 and \$232,698, respectively. The decrease during 2024 is attributable to lower cash balances.

Liquidity and Capital Resources

The following tables summarize our liquidity and capital resources as of March 31, 2024 and December 31, 2023, and our cash flows for the three-month periods ended March 31, 2024 and 2023:

Liquidity and Capital Resources	March 31, 2024	December 31, 2023
Cash and cash equivalents	\$ 768,859	\$ 6,452,589
Working capital (deficit)	(441,529)	4,365,861

Cash Flow Data	Three Months Ended March 31,	
	2024	2023
Net cash provided by (used in):		
Operating activities	\$ (5,683,730)	\$ (3,762,872)
Investing activities	-	-
Financing activities	-	-
Net decrease in cash and cash equivalents	\$ (5,683,730)	\$ (3,762,872)

Operating Activities – Net cash used in operating activities of \$5,683,730 for the three months ended March 31, 2024 was primarily due to our net loss of \$5,850,132, offset by non-cash charges such as depreciation and stock-based compensation expense, and by changes in our working capital accounts. Net cash used in operating activities of \$3,762,872 for the three months ended March 31, 2023 was primarily due to our net loss of \$4,037,916, offset by non-cash charges such as depreciation and stock-based compensation expense, and by changes in our working capital accounts.

Investing and Financing Activities – There were no cash flows from investing or financing activities for the three-month periods ended March 31, 2024 and 2023.

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.

On May 10, 2024, we conducted a bridge financing through the issuance and sale of 10% Original Issue Discount Promissory Notes (the “Notes”) with an aggregate principal amount of \$150,000 to members of our Board of Directors and senior management. The Notes are unsecured, bear interest at a rate of 15% per annum, and mature upon the earlier of (i) six months from the issue date or (ii) three days following the date the Company completes an offering of its common stock with gross proceeds of not less than \$5 million.

As of the date of this Quarterly Report, our existing cash and cash equivalents are insufficient to fund our operations beyond the second quarter of 2024 without additional funding, which we are actively pursuing. 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. We also continue to be in advanced discussions with the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS), for a potential award as part of Project NextGen, an initiative to advance a pipeline of new, innovative vaccines and therapeutics providing broader and more durable protection for COVID-19. We are highly encouraged by the negotiations with BARDA thus far, but there is no assurance that such an award may be made.

There can be no assurance that necessary 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. 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.

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. We may fund a significant portion of our ongoing operations through partnering and collaboration agreements which, while reducing our risks and extending our cash runway, will also reduce our share of eventual revenues, if any, from our vaccine candidates. We may be able to fund certain activities with assistance from government programs.

The sale of additional equity would result in additional dilution to our stockholders. We may also fund our operations through debt financing, which would result in debt service obligations, and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market vaccine candidates that we would otherwise prefer to develop and market ourselves. Any of these actions could harm our business, results of operations and prospects.

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. Our 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.

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.

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 March 31, 2024 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 January 2, 2024, we issued 6,703 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

3.1*	Restated Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on April 12, 2024
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

(1) These interactive data files shall not be deemed filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, or Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under these sections.

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: May 14, 2024

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