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, 2022

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	**87-0455038**
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification No.)*
1900 Lake Park Drive, Suite 380 Smyrna, Georgia	**30080**
(Address of principal executive offices)	*(Zip Code)*

(678) 384-7220
(Registrant's telephone number, including area code)

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

Title of each Class	Trading Symbol	Name of each Exchange on which Registered
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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Emerging growth company	☐
Smaller reporting company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial 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 9, 2022, 26,334,953 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, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,676,968	$ 11,423,870
Grant funds receivable	-	49,006
Prepaid expenses	1,460,207	156,240
Total current assets	36,137,175	11,629,116
Property and equipment, net	248,983	156,938
Other assets	2,184,286	11,010
Total assets	$ 38,570,444	$ 11,797,064
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,079,421	$ 2,057,534
Accrued expenses	3,709,984	3,377,826
Total current liabilities	4,789,405	5,435,360
Other liabilities	2,000,000	2,000,000
Total liabilities	6,789,405	7,435,360
Commitments (Note 4)		
Stockholders' equity:		
Common stock, $.001 par value:		
Authorized shares – 600,000,000		
Issued and outstanding shares – 26,334,953 and 6,381,541 at September 30, 2022 and December 31, 2021, respectively	26,335	6,382
Additional paid-in capital	104,767,918	68,731,220
Accumulated deficit	(73,013,214)	(64,375,898)
Total stockholders' equity	31,781,039	4,361,704
Total liabilities and stockholders' equity	$ 38,570,444	$ 11,797,064

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Grant and collaboration revenue	$ -	$ 30,414	$ 81,526	$ 220,539
Operating expenses:				
Research and development	2,721,196	1,224,362	5,358,917	2,659,980
General and administrative	1,249,337	757,432	3,363,672	2,562,641
Total operating expenses	3,970,533	1,981,794	8,722,589	5,222,621
Loss from operations	(3,970,533)	(1,951,380)	(8,641,063)	(5,002,082)
Other income (expense):				
Interest income	2,431	877	3,747	3,998
Interest expense	-	-	-	(1,286)
Gain on debt extinguishment	-	-	-	172,056
Total other income (expense)	2,431	877	3,747	174,768
Net loss	$ (3,968,102)	$ (1,950,503)	$ (8,637,316)	$ (4,827,314)
Basic and diluted:				
Net loss per common share	$ (0.17)	$ (0.31)	$ (0.63)	$ (0.80)
Weighted average shares outstanding	23,461,665	6,349,297	13,818,315	6,005,032

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, 2022						
	Preferred Stock		Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Equity
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 exercises	-	-	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 exercises	-	-	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

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

	Three-Month and Nine-Month Periods Ended September 30, 2021						
	Preferred Stock		Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Equity
Balance at December 31, 2020	100	$ 76,095	3,834,095	$ 3,834	$ 55,294,504	$(45,805,581)	$ 9,568,852
Sale of common stock for cash	-	-	1,644,000	1,644	9,407,276	-	9,408,920
Issuance of common stock upon warrant exercise	-	-	835,900	836	3,173,320	-	3,174,156
Issuance of common stock for services	-	-	1,472	1	5,999	-	6,000
Stock option expense	-	-	-	-	56,190	-	56,190
Net loss for the three months ended March 31, 2021	-	-	-	-	-	(1,562,778)	(1,562,778)
Balance at March 31, 2021	100	76,095	6,315,467	6,315	67,937,289	(47,368,359)	20,651,340
Repurchase of preferred stock	(100)	(76,095)	-	-	75,095	-	(1,000)
Issuance of common stock for services	-	-	12,235	13	65,828	-	65,841
Stock option expense	-	-	-	-	56,190	-	56,190
Net loss for the three months ended June 30, 2021	-	-	-	-	-	(1,314,033)	(1,314,033)
Balance at June 30, 2021	-	-	6,327,702	6,328	68,134,402	(48,682,392)	19,458,338
Issuance of common stock upon warrant exercise	-	-	53,839	54	229,946	-	230,000
Stock option expense	-	-	-	-	56,190	-	56,190
Issuance of warrant for technology license	-	-	-	-	209,825	-	209,825
Net loss for the three months ended September 30, 2021	-	-	-	-	-	(1,950,503)	(1,950,503)
Balance at September 30, 2021	-	$ -	6,381,541	$ 6,382	$ 68,630,363	$ (50,632,895)	$ 18,003,850

See accompanying notes to consolidated financial statements.

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (8,637,316)	$ (4,827,314)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	42,213	26,806
Stock-based compensation expense for employees and directors	570,573	168,570
Stock-based compensation expense for consultants	80,322	80,733
Warrant issued for technology license	-	209,825
Gain on debt extinguishment	-	(172,056)
Changes in assets and liabilities:		
Grant funds and other receivables	49,006	182,663
Prepaid expenses and other current assets	(1,251,539)	106,979
Deposits and other assets	(2,173,276)	-
Accounts payable and accrued expenses	(645,955)	(289,477)
Total adjustments	(3,328,656)	314,043
Net cash used in operating activities	(11,965,972)	(4,513,271)
Cash flows from investing activities		
Purchase of equipment	(134,258)	(47,718)
Net cash used in investing activities	(134,258)	(47,718)
Cash flows from financing activities:		
Net proceeds from sale of common stock and warrants	27,727,194	9,408,920
Net proceeds from warrant exercises	7,626,134	3,404,156
Repurchase of preferred stock	-	(1,000)
Principal repayment of note payable	-	(27,864)
Net cash provided by financing activities	35,353,328	12,784,212
Net increase in cash and cash equivalents	23,253,098	8,223,223
Cash and cash equivalents at beginning of period	11,423,870	9,883,796
Cash and cash equivalents at end of period	$ 34,676,968	$ 18,107,019

Supplemental disclosure of non-cash financing activities:

During the nine months ended September 30, 2021, we issued 149,705 shares of common stock upon the cashless exercise of stock purchase warrants, and $172,056 of principal and accrued interest related to a note payable was extinguished upon the loan's forgiveness.

GEOVAX LABS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2022
(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 as "GeoVax" or the "Company".

The Company is focused on developing immunotherapies and vaccines against infectious diseases and cancers using novel vector vaccine platforms. GeoVax's product pipeline includes ongoing human clinical trials for vaccines against COVID-19 and a therapy for advanced head and neck cancer. Additional research and development programs include preventive vaccines against hemorrhagic fever viruses (Ebola Zaire, Ebola Sudan, Marburg, and Lassa Fever) 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, 2021 those accounting policies that we consider significant in determining our results of operations and financial position. During the nine months ended September 30, 2022, 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 condensed consolidated 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, 2021. 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.

Our financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. As of the date these financial statements are issued, the Company expects its existing cash and cash equivalents to be sufficient to fund its operations for at least the next twelve months. Since inception, the Company's activities have consisted primarily of performing research and development to advance its technologies. The Company expects to continue to generate operating losses in the foreseeable future and will require additional funding to continue its research and development activities. The Company may seek funds through further equity financings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements.

Recent Accounting Pronouncements – During the nine months ended September 30, 2022, 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, 2022	December 31, 2021
Prepaid clinical trial costs (current portion)	$ 1,231,337	$ -
Prepaid insurance premiums	143,450	123,248
Prepaid rent	13,045	13,045
Other prepaid expenses	72,375	19,947
Total prepaid expenses	$ 1,460,207	$ 156,240

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

	September 30, 2022	December 31, 2021
Equipment and furnishings	$ 725,812	$ 591,554
Leasehold improvements	115,605	115,605
Total property and equipment	841,417	707,159
Accumulated depreciation and amortization	(592,434)	(550,221)
Total property and equipment, net	$ 248,983	$ 156,938

Other Assets – Other assets consist of the following:

	September 30, 2022	December 31, 2021
Prepaid clinical trial costs (noncurrent portion)	$ 2,083,276	$ -
Prepaid technology license fees	90,000	-
Deposits	11,010	11,010
Total other assets	$ 2,184,286	$ 11,010

Accrued Expenses – Accrued expenses consist of the following:

	September 30, 2022	December 31, 2021
Accrued technology license fees – current portion	$ 3,000,000	$ 3,000,000
Accrued compensation	-	269,000
Other accrued expenses	709,984	108,826
Total accrued expenses	$ 3,709,984	$ 3,377,826

Other Liabilities – Other liabilities were $2,000,000 at September 30, 2022 and December 31, 2021 and consist of the noncurrent portion of accrued technology license fees.

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, 2022, but which we expect to extend. Rent expense for the three-month and nine-month periods ended September 30, 2022 was $44,089 and $132,267, respectively, as compared to $42,803 and $128,410, respectively, for the same periods of 2021. Future minimum lease payments total $44,089 in 2022.

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. Unrecorded future minimum payments under these agreements (excluding milestone and royalty payments due upon contingent future events) are approximately $409,000 in the aggregate.

Clinical Trial Commitments – We have entered into agreements with contract research organizations ("CROs") and with testing sites to conduct clinical trials of our products under development. Contracts with CROs are generally cancellable with notice. We have also entered into arrangements with contract manufacturing organizations ("CMOs") to produce materials for use in our clinical trials. These contracts generally provide for non-cancellable obligations or cancellation penalties depending on the time of cancellation. As of September 30, 2022, the total non-cancellable obligations under contracts with CMOs were approximately $1.2 million.

Other Commitments – In the normal course of business, we enter into various firm purchase commitments and other contractual obligations related to production and testing of our product candidates, conduct of clinical trials and preclinical research studies, and other activities. As of September 30, 2022, there are approximately $612,000 of unrecorded noncancelable purchase commitments to our vendors and subcontractors.

5. Stockholders' Equity

January 2022 Private Placement – On January 19, 2022, we closed a private placement of 707,484 shares of common stock, a pre-funded warrant to purchase 2,360,000 shares of common stock for a nominal exercise price per share (the "Jan 2022 Pre-Funded Warrant"), and a warrant to purchase up to 3,067,484 shares of common stock at an exercise price of $3.26 per share (the "Jan 2022 Common Warrant"). Net proceeds after deducting placement agent commissions and other

offering expenses were approximately $9.2 million. During March 2022, the Jan 2022 Pre-Funded Warrant was exercised in full. The Jan 2022 Common Warrant is currently exercisable and will expire on February 10, 2027.

May 2022 Private Placement – On May 27, 2022, we closed a private placement of 1,050,000 shares of common stock, pre-funded warrants to purchase an aggregate of 11,071,214 shares of common stock for a nominal exercise price per share (the "May 2022 Pre-Funded Warrants"), and preferred investment options to purchase up to an aggregate of 12,121,214 shares of common stock at an exercise price of $1.65 per share (the "May 2022 Preferred Investment Options"). Net proceeds after deducting placement agent commissions and other offering expenses were approximately $18.5 million.

The May 2022 Pre-Funded Warrants were exercised as to 1,980,304 shares concurrent with the closing and during June and July the remaining 9,090,910 were fully exercised. During August, the May 2022 Preferred Investment Options were exercised as to 4,621,214 shares, resulting in net proceeds to us of approximately $7,626,000.

Other Common Stock Transactions – During May and July, we issued 68,500 and 75,000 shares, respectively, of our common stock pursuant to consulting agreements.

Stock Options – We have a stock-based incentive plan (the "2020 Plan") pursuant to which our Board of Directors may grant stock options and other stock-based awards to our employees, directors and consultants. A total of 1,500,000 shares of our common stock are reserved for issuance pursuant to the 2020 Plan. During the nine months ended September 30, 2022, there were no stock option transactions related to the 2020 Plan. As of September 30, 2022, there are 962,300 stock options outstanding, with a weighted-average exercise price of $3.18 per share and a weighted-average remaining term of 8.6 years.

Stock Purchase Warrants – The table below presents summary information about our warrants outstanding as of September 30, 2022.

Warrant Description	Number of Shares	Exercise Price	Expiration
2020 Warrants	120,000	$ 1.65	Jun 2025
2020 Unit Warrants	2,396,631	5.00	Sep 2025
2020 Representative Warrants	128,000	5.50	Mar 2024
2021 Representative Warrants	72,000	6.875	Aug 2024
2021 Warrants	100,000	13.00	Sep 2026
Jan 2022 Common Warrants	3,067,484	3.26	Feb 2027
May 2022 Preferred Investment Options	7,500,000	1.65	May 2028
Total Warrants Outstanding at September 30, 2022	13,384,115		

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. As of September 30, 2022, there is $849,571 of unrecognized compensation expense that we expect to recognize over a weighted-average period of 1.7 years.

We also have issued shares of restricted common stock to consultants and recognize the related expense over the terms of the related agreements. As of September 30, 2022, there is $72,375 recorded as a prepaid expense for these arrangements, which will be recognized as expense over the terms of the related agreements.

The following table summarizes our total stock-based compensation expense for employees, directors and consultants:

	Three Months Ended Sep. 30,		Nine Months Ended Sep. 30,	
	2022	2021	2022	2021
Stock options:				
Research and development	$ 54,293	$ 21,468	$ 162,878	$ 64,404
General and administrative	135,898	34,722	407,695	104,166
Total stock option expense	190,191	56,190	570,573	168,570
Stock awards (consultants):				
General and administrative	48,375	29,560	80,322	80,733
Total stock-based compensation expense	$ 238,566	$ 85,750	$ 650,895	$ 249,303

During September 2021, we recorded $209,825 of expense associated with the issuance of a stock purchase warrant in connection with our entering into a technology licensing agreement; such amount was recorded as research and development expense.

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 additional 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 14,346,415 and 3,418,631 shares at September 30, 2022 and 2021, respectively.

8. Income Taxes

No provision for income taxes was recorded in either of the nine-month periods ended September 30, 2022 and 2021. 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, 2022.

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, 2021, which was filed with the Securities and Exchange Commission on March 9, 2022.

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, 2021. 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

GeoVax is a clinical-stage biotechnology company developing immunotherapies and vaccines against infectious diseases and cancers using novel vector vaccine platforms. GeoVax's product pipeline includes ongoing human clinical trials in COVID-19 and head and neck cancer. Additional research and development programs include preventive vaccines against Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa) and malaria, as well as immunotherapies for solid tumors.

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

- GEO-CM04S1 is currently undergoing a Phase 2 clinical trial (NCT04977024), evaluating its safety and efficacy as a preventive COVID-19 vaccine in patients who have previously received either an allogeneic hematopoietic cell transplant, an autologous hematopoietic cell transplant or chimeric antigen receptor (CAR) T cell therapy. GEO-CM04S1 is the only COVID-19 vaccine that includes both SARS-CoV-2 spike and nucleocapsid proteins to advance to a Phase 2 trial in cancer patients. The trial is also the first to compare an investigational multi-antigenic COVID-19 vaccine to the current Food and Drug Administration (FDA)-approved mRNA vaccine from Pfizer/BioNTech in people who are immunocompromised.
- GEO-CM04S1 is also undergoing the Phase 2 portion of a Phase 1/2 trial (NCT04639466), evaluating its use as a universal booster vaccine to current FDA-approved two-shot mRNA vaccines from Pfizer/BioNTech and Moderna.
- Gedeptin® is currently undergoing a Phase 1/2 clinical trial (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.
- GEO-CM02 (our pan-coronavirus vaccine) has shown promising results in preclinical studies to date. Building on these earlier findings, we have initiated additional studies to prepare for an Investigational New Drug application and subsequent human clinical trials.
- Our research program for treatment of solid tumors (MVA-VLP-MUC1) is progressing with additional preclinical studies recently initiated. The initial animal studies of our MVA-VLP-MUC1 vaccine and ICI combination have been encouraging, showing that a combination of our MVA-VLP-MUC1 vaccine candidate with a MUC1 synthetic peptide was capable of breaking tolerance to human MUC1 in transgenic mice and inducing immune responses with efficacy against challenge in a lymphoma tumor model. Our studies also demonstrated a significant reduction of the tumor burden in a mouse model for colorectal cancer. We have initiated studies to determine the optimal course and schedule of vaccination to define a protocol that can be evaluated in a Phase 1 clinical trial.
- Our additional research programs for vaccines against hemorrhagic fever viruses (Ebola Zaire, Ebola Sudan, Marburg and Lassa Fever) and malaria are at various stages of preclinical development.

Financial Overview

Revenues

We have not generated any revenues 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 revenues relate 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, 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 track our external research and development costs on a program-by-program basis. We do not track our internal research and development expenses on a program-by-program basis as they primarily relate to shared costs deployed across multiple projects under development.

Our research and development expenses can fluctuate considerably on a period-to-period basis. We expect our research and development expenses to increase substantially in the future as we advance our existing and future product candidates into and through clinical trials and pursue regulatory approval. The process of conducting the necessary clinical studies to obtain regulatory approval is costly and time-consuming. Clinical trials generally become larger and more costly to conduct as they advance into later stages.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of any product candidates that we develop from our programs. We are also unable to predict when, if ever, material net cash inflows will commence from sales of product candidates we develop, if at all. This is due to the numerous risks and uncertainties associated with developing product candidates.

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 expand our operating activities and prepare for potential commercialization of our current and future product candidates, increase our headcount and investor relations activities and maintain compliance with requirements of Nasdaq and the Securities and Exchange Commission.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our condensed 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 Item 7 in Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 2 to our Consolidated Financial Statements contained in our Annual Report on Form 10-K for the year ended December 31, 2021. There have been no significant changes to our critical accounting policies from those disclosed in our 2021 Annual Report.

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 tables summarize our results of operations for the three-month and nine-month periods ended September 30, 2022 and 2021:

	Three Months Ended September 30,		
	2022	2021	Change
Grant revenue	$ -	$ 30,414	$ (30,414)
Operating expenses:			
Research and development	2,721,196	1,224,362	1,496,834
General and administrative	1,249,337	757,432	491,905
Total operating expenses	3,970,533	1,981,794	1,988,739
Loss from operations	(3,970,533)	(1,951,380)	(2,019,153)
Total other income (expense), net	2,431	877	1,554
Net loss	$ (3,968,102)	$ (1,950,503)	$ (2,017,599)

	Nine Months Ended September 30,		
	2022	2021	Change
Grant revenue	$ 81,526	$ 220,539	$ (139,013)
Operating expenses:			
Research and development	5,358,917	2,659,980	2,698,937
General and administrative	3,363,672	2,562,641	801,031
Total operating expenses	8,722,589	5,222,621	3,499,968
Loss from operations	(8,641,063)	(5,002,082)	(3,638,981)
Total other income (expense), net	3,747	174,768	(171,021)
Net loss	$ (8,637,316)	$ (4,827,314)	$ (3,810,002)

Grant Revenues

The following table summarizes our grant revenues for the three-month and nine-month periods ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Lassa Fever – U.S. Army Grant	$ -	$ -	$ 81,526	$ -
COVID-19 – NIH SBIR Grant	-	30,414	-	220,539
Total	$ -	$ 30,414	$ 81,526	$ 220,539

Total grant revenues decreased by $81,526 (100%) for the three-month period ended September 30, 2022 and by $139,013 (63%) for the nine-month period ended September 30, 2022, versus the comparable 2021 periods, attributable to the differing mix of active grants as shown in the table above, as well as the timing of expenditures related to such grants. As of September 30, 2022, all grant funds approved for direct use by GeoVax have been utilized.

Research and Development Expenses

For the three-month and nine-month periods ended September 30, 2022, research and development expenses increased by $1,496,834 (122%) and $2,698,937 (101%), respectively, versus the comparable 2021 periods. The overall increase during the 2022 periods relates primarily to higher personnel costs (including the use of external consultants), costs of conducting clinical trials for GEO-CM04S1 and Gedeptin, costs of manufacturing materials for use in our clinical trials, and a generally higher level of activity. Research and development expense for the three-month and nine-month periods of 2022 included stock-based compensation expense of $54,293 and $162,878, respectively; as compared to $21,468 and $64,404, respectively, for the comparable 2021 periods.

General and Administrative Expenses

For the three-month and nine-month periods ended September 30, 2022, general and administrative expenses increased by $491,905 (65%) and $801,031 (31%), respectively, versus the comparable 2021 periods. The overall increase during the 2022 periods relates primarily to higher personnel costs (including the use of external consultants), patent costs, investor relations consulting costs, and travel expenses. General and administrative expense for the three-month and nine-month periods of 2022 included stock-based compensation expense of $184,273 and $488,017, respectively; as compared to $64,282 and $184,899, respectively, for the comparable periods of 2021.

Other Income (Expense)

Interest income for the three-month and nine-month periods ended September 30, 2022 was $2,431 and $877, respectively, as compared to $3,747 and $3,998, respectively, for comparable periods of 2021. The variances between periods are primarily attributable to cash available for investment and interest rate fluctuations.

No interest expense was recorded during the three-month and nine-month periods ended September 30, 2022. Interest expense for the three-month and nine-month periods ended September 30, 2021 was $-0- and $1,286, respectively.

During the nine-month period ended September 30, 2021, we recorded a $172,056 one-time gain on debt extinguishment associated with the forgiveness of the principal and accrued interest related to our Paycheck Protection Program (PPP) loan.

Liquidity, Capital Resources and Cash Flows

The following tables summarize our liquidity and capital resources as of September 30, 2022 and December 31, 2021, and our cash flows for the nine-month periods ended September 30, 2022 and 2021:

Liquidity and Capital Resources	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 34,676,968	$ 11,423,870
Working capital	31,347,770	6,193,756

	Nine Months Ended September 30,	
Cash Flow Data	2022	2021
Net cash provided by (used in):		
Operating activities	$ (11,965,972)	$ (4,513,271)
Investing activities	(134,258)	(47,718)
Financing activities	35,353,328	12,784,212
Net increase in cash and cash equivalents	$ 23,253,098	$ 8,223,223

Operating Activities – 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, as adjusted 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 $4,513,271 for the nine months ended September 30, 2021, was primarily due to our net loss of $4,827,314, also adjusted 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 $134,258 and $47,718 for the nine-month periods ended September 30, 2022 and 2021, respectively, and relates primarily to purchases of laboratory equipment.

Financing Activities – Net cash provided by financing activities was $35,353,328 for the nine-month period ended September 30, 2022, consisting of (i) net proceeds of $27,727,194 from sales of our common stock and warrants, and (ii) net proceeds of $7,626,134 from the exercise of warrants, as described in Note 5 to the condensed consolidated financial statements included in this Quarterly Report. Net cash provided by financing activities was $12,784,212 for the nine-month period ended September 30, 2021, consisting of (i) net proceeds of $9,408,920 from a public offering of our common stock, (ii) $3,404,156 of net proceeds from the exercise of warrants, and (iii) $28,864 in principal repayments of a note payable and repurchase of preferred stock.

Funding Requirements

We have no products approved for commercial sale. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize our product candidates. We do not know when, or if, this will occur. As of September 30, 2022, we have an accumulated deficit of approximately $73 million and we expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. We have funded our operations to date primarily from sales of our equity securities and from government grants and clinical trial assistance.

Our primary uses of capital are for personnel costs, costs of conducting clinical trials, manufacturing costs for materials used in clinical trials, third-party research services, laboratory and related supplies, technology license fees, legal and other

regulatory expenses, and general overhead costs. We expect these costs will continue to be the primary operating capital requirements for the near future.

Our future expenditures are likely to be highly volatile in future periods depending on the outcomes of our clinical trials and preclinical studies. We expect our research and development costs to increase as we continue development of our various programs and as we move toward later stages of development, especially with regard to the ongoing clinical trials for Gedeptin and GEO-CM04S1. We expect our general and administrative expenses to increase commensurately in support of expanded research and development efforts.

As of the date of this Quarterly Report, we expect our existing cash and cash equivalents will be sufficient to fund our operations over at least the next twelve months.

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 assurances 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, 2022 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

During July 2022, we issued 75,000 shares of our common stock to a consultant in exchange for services. The shares were valued at $60,750 as of the date of issuance and were granted as a restricted stock award under our 2020 Stock Incentive Plan. We 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, 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	Securities Purchase Agreement, dated January 14, 2022 (2)
10.2	Registration Rights Agreement, dated January 14, 2022 (2)
10.3	Form of Common Warrant, dated January 19, 2022 (2)
10.4	Form of PIPE Securities Purchase Agreement, dated May 25, 2022 (4)
10.5	Form of RD Securities Purchase Agreement, dated May 25, 2022 (4)
10.6	Form of Registration Rights Agreement, dated May 25, 2022 (4)
10.7	Form of PIPE Pre-Funded Warrant, dated May 27, 2022 (4)
10.8	Form of PIPE Preferred Investment Options, dated May 27, 2022 (4)
10.9	Form of RD Preferred Investment Options, dated May 27, 2022 (4)
10.10**	Employment Agreement between GeoVax, Inc. and Mark J. Newman, PhD, as Amended and Restated March 9, 2022 (3)
10.11**	Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and Mark J. Newman, PhD (5)
10.12**	Employment Agreement between GeoVax, Inc. and John W. Sharkey, PhD (5)
10.13**	Amendment No. 1 to Employment Agreement between GeoVax Labs, Inc. and John W. Sharkey, PhD (5)
10.14**	Consulting Agreement by and between GeoVax, Inc. and Kelly T. McKee, MD, dated December 22, 2021 (3)
10.15	Summary of the GeoVax Labs, Inc. Director Compensation Plan (3)
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)

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* Filed herewith

** Indicates a management contract or compensatory plan or arrangement

(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.

(2) Incorporated by reference from the registrant's Current Report on Form 8-K filed January 20, 2022.

(3) Incorporated by reference from the registrant's Annual Report on Form 10-K filed March 9, 2022.

(4) Incorporated by reference from the registrant's Current Report on Form 8-K filed May 27, 2022.

(5) Incorporated by reference from the registrant's Quarterly Report on Form 10-Q filed August 3, 2022.

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 9, 2022

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