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, 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** **87-0455038**

*(State or other jurisdiction (IRS Employer Identification No.)*

*of incorporation or organization)*

##### **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 12, 2024, 9,436,069 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, |  | December 31, |
|  |  |  |  | 2024 |  | 2023 |
|  | | |  | (unaudited) |  |  |
| ASSETS | | |  |  |  |  |
| Current assets: | | |  |  |  |  |
|  | Cash and cash equivalents | |  | $ 8,592,523 |  | $ 6,452,589 |
|  | Accounts receivable | |  | 547,574 |  | - |
|  | Prepaid expenses | |  | 1,729,326 |  | 1,433,153 |
| Total current assets | | |  | 10,869,423 |  | 7,885,742 |
| Property and equipment, net | | |  | 171,615 |  | 209,689 |
| Other assets | | |  | 71,010 |  | 1,187,788 |
|  |  |  |  |  |  |  |
| Total assets | | |  | $ 11,112,048 |  | $ 9,283,219 |
|  |  |  |  |  |  |  |
| LIABILITIES AND STOCKHOLDERS’ EQUITY | | |  |  |  |  |
| Current liabilities: | | |  |  |  |  |
|  | Accounts payable | |  | $ 2,147,952 |  | $ 2,802,950 |
|  | Accrued expenses | |  | 460,220 |  | 716,931 |
| Total current liabilities | | |  | 2,608,172 |  | 3,519,881 |
|  |  |  |  |  |  |  |
| Commitments (Note 5) | | |  |  |  |  |
|  |  |  |  |  |  |  |
| Stockholders’ equity: | | |  |  |  |  |
|  | Common stock, $.001 par value: | |  |  |  |  |
|  |  | Authorized shares – 150,000,000 and 600,000,000 at |  |  |  |  |
|  |  | September 30, 2024 and December 31, 2023, respectively |  |  |  |  |
|  |  | Issued and outstanding shares – 8,609,308 and 1,977,152 at |  |  |  |  |
|  |  | September 30, 2024 and December 31, 2023, respectively |  | 8,609 |  | 1,977 |
|  | Additional paid-in capital | |  | 129,588,694 |  | 110,125,146 |
|  | Accumulated deficit | |  | (121,093,427) |  | (104,363,785) |
| Total stockholders’ equity | | |  | 8,503,876 |  | 5,763,338 |
|  |  |  |  |  |  |  |
| Total liabilities and stockholders’ equity | | |  | $ 11,112,048 |  | $ 9,283,219 |
|  |  |  |  |  |  |  |

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, | | |
|  |  |  |  | 2024 |  | 2023 |  | 2024 |  | 2023 |
| Revenue from government contract | | | | $ 2,789,484 |  | $ - |  | $ 3,090,161 |  | $ - |
|  |  |  |  |  |  |  |  |  |  |  |
| Operating expenses: | | | |  |  |  |  |  |  |  |
|  | Research and development | | | 7,402,884 |  | 6,947,979 |  | 16,105,480 |  | 14,486,896 |
|  | General and administrative | | | 1,241,176 |  | 1,651,775 |  | 3,784,559 |  | 4,562,293 |
| Total operating expenses | | | | 8,644,060 |  | 8,599,754 |  | 19,890,039 |  | 19,049,189 |
|  |  |  |  |  |  |  |  |  |  |  |
| Loss from operations | | | | (5,854,576) |  | (8,599,754) |  | (16,799,878) |  | (19,049,189) |
|  |  |  |  |  |  |  |  |  |  |  |
| Other income (expense): | | | |  |  |  |  |  |  |  |
|  | Interest income | | | 53,191 |  | 190,936 |  | 91,611 |  | 674,835 |
|  | Interest expense | | | (14,083) |  | - |  | (21,375) |  | - |
| Total other income (expense) | | | | 39,108 |  | 190,936 |  | 70,236 |  | 674,835 |
|  |  |  |  |  |  |  |  |  |  |  |
| Net loss | | | | $ (5,815,468) |  | $ (8,408,818) |  | $ (16,729,642) |  | $ (18,374,354) |
|  |  |  |  |  |  |  |  |  |  |  |
| Basic and diluted: | | | |  |  |  |  |  |  |  |
| Net loss per common share | | | | $ (0.91) |  | $ (4.75) |  | $ (4.52) |  | $ (10.42) |
| Weighted average shares outstanding | | | | 6,404,797 |  | 1,769,604 |  | 3,701,145 |  | 1,762,856 |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

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, 2024 | | | | |
|  |  |  |  |  |  | Total |
|  |  | Common Stock | | Additional | Accumulated | Stockholders’ |
|  |  | Shares | Amount | Paid-in Capital | Deficit | Equity |
| 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 exercises |  | 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 |
| Sale of common stock and warrants for cash |  | 220,000 | 220 | 1,209,318 | - | 1,209,538 |
| Issuance of common stock upon warrant exercises |  | 1,650,391 | 1,651 | 1,387,712 | - | 1,389,363 |
| Stock option expense |  | - | - | 101,640 |  | 101,640 | |
| Net loss for the three months ended June 30, 2024 |  | - | - | - | (5,064,042) | (5,064,042) |
| Balance at June 30, 2024 |  | 4,178,700 | 4,179 | 112,964,554 | (115,277,959) | (2,309,226) |
| Sale of common stock and warrants for cash |  | 2,741,463 | 2,742 | 15,518,135 | - | 15,520,877 |
| Issuance of common stock upon warrant exercises |  | 1,689,145 | 1,688 | 976,082 | - | 977,770 |
| Stock option expense |  | - | - | 129,923 |  | 129,923 | |
| Net loss for the three months ended September 30, 2024 | | - | - | - | (5,815,468) | (5,815,468) |
| Balance at September 30, 2024 |  | 8,609,308 | $ 8,609 | $ 129,588,694 | $ (121,093,427) | $ 8,503,876 |
|  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | Three-Month and Nine-Month Periods Ended September 30, 2023 | | | | |
|  |  |  |  |  |  | Total |
|  |  | Common Stock | | Additional | Accumulated | Stockholders’ |
|  |  | Shares | Amount | Paid-in Capital | Deficit | Equity |
| 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 |
| Stock option expense |  | - | - | 226,013 |  | 226,013 |
| Net loss for the three months ended June 30, 2023 |  | - | - | - | (5,927,620) | (5,927,620) |
| Balance at June 30, 2023 |  | 1,762,910 | 1,763 | 105,524,346 | (88,362,559) | 17,163,550 |
| Issuance of common stock for services |  | 16,776 | 17 | 137,483 | - | 137,500 |
| Stock option expense |  | - | - | 227,114 |  | 227,114 |
| Net loss for the three months ended September 30, 2023 | | - | - | - | (8,408,818) | (8,408,818) |
| Balance at September 30, 2023 |  | 1,779,686 | $ 1,780 | $ 105,888,943 | $ (96,771,377) | $ 9,119,346 |
|  |  |  |  |  |  |  |

See accompanying notes to condensed consolidated financial statements.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **GEOVAX LABS, INC.**  **CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  **(Unaudited)** | | | | | | | | | | |
|  | | | | | | |  |  |  |  |
|  | | | | | | |  |  |  |  |
|  | | | | | | |  | Nine Months Ended September 30, | | |
|  | | | | | | |  | 2024 |  | 2023 |
| Cash flows from operating activities: | | | | | | |  |  |  |  |
|  | Net loss | | | | | |  | $ (16,729,642) |  | $ (18,374,354) |
|  | Adjustments to reconcile net loss to net cash | | | | | |  |  |  |  |
|  | used in operating activities: | | | | | |  |  |  |  |
|  |  | Depreciation and amortization expense | | | | |  | 73,727 |  | 51,956 |
|  |  | Stock-based compensation expense | | | | | | 389,299 |  | 813,499 |
|  |  | Changes in assets and liabilities: | | | | |  |  |  |  |
|  |  |  | | Accounts receivable | | | | (547,574) |  | - |
|  |  |  | | Prepaid expenses and other current assets | | | | (312,840) |  | (707,084) |
|  |  |  | | Other assets | | | | 1,116,778 |  | 986,498 |
|  |  |  | | Accounts payable and accrued expenses | | | | (911,709) |  | 2,333,791 |
|  |  |  | | Total adjustments | | |  | (192,319) |  | 3,478,660 |
|  | Net cash used in operating activities | | | | | |  | (16,921,961) |  | (14,895,694) |
|  |  |  | | |  |  |  |  |  |  |
| Cash flows from investing activities: | | | | | | |  |  |  |  |
|  | Purchase of equipment | | | | | | | (20,653) |  | (29,997) |
|  | Net cash used in investing activities | | | | | |  | (20,653) |  | (29,997) |
|  |  |  | | |  |  |  |  |  |  |
| Cash flows from financing activities: | | | | | | |  |  |  |  |
|  | Net proceeds from issuance of notes payable – related parties | | | | | | | 135,000 |  | - |
|  | Repayment of notes payable – related parties | | | | | | | (150,000) |  | - |
|  | Net proceeds from sale of common stock and warrants | | | | | | | 16,730,415 |  | - |
|  | Net proceeds from warrant exercise | | | | | |  | 2,367,133 |  | - |
|  | Net cash provided by financing activities | | | | | |  | 19,082,548 |  | - |
|  |  |  | | |  |  |  |  |  |  |
| Net increase (decrease) in cash and cash equivalents | | | | | | | | 2,139,934 |  | (14,925,691) |
| Cash and cash equivalents at beginning of period | | | | | | | | 6,452,589 |  | 27,612,732 |
|  |  | |  | |  |  |  |  |  |  |
| Cash and cash equivalents at end of period | | | | | | | | $ 8,592,523 |  | $ 12,687,041 |
|  |  | |  | |  |  |  |  |  |  |

Supplemental disclosure of non-cash financing activities:

During the nine months ended September 30, 2024, we issued 5,947 shares of common stock upon the cashless exercise of warrants.

See accompanying notes to condensed consolidated financial statements.

**GEOVAX LABS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 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 human vaccines for many of the world’s most threatening infectious diseases and therapies for solid tumor cancers using novel proprietary platforms. GeoVax’s lead clinical program is GEO-CM04S1, a next-generation COVID-19 vaccine for which it was recently awarded a BARDA-funded contract to sponsor a 10,000-participant Phase 2b clinical trial to evaluate the efficacy of GEO-CM04S1 versus an approved COVID-19 vaccine. In addition, GEO-CM04S1 is currently in three Phase 2 clinical trials, being evaluated as (1) a primary vaccine for immunocompromised patients such as those suffering from hematologic cancers and other patient populations for whom the current authorized COVID-19 vaccines are insufficient, (2) a booster vaccine in patients with chronic lymphocytic leukemia (CLL) and (3) a more robust, durable COVID-19 booster among healthy patients who previously received the mRNA vaccines. The lead oncological clinical program is Gedeptin®, a novel oncolytic solid tumor gene-directed therapy, which is currently in a multicenter Phase 1/2 clinical trial for advanced head and neck cancers. Additional preclinical research and development programs include preventive vaccines against Mpox (formerly known as monkeypox), hemorrhagic fever viruses (Ebola Zaire, Ebola Sudan, and Marburg), and Zika virus, 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 nine months ended September 30, 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. We believe that our existing cash resources will be sufficient to continue our planned operations into the first quarter of 2025. We plan to pursue additional capital 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 6.

*Recent Accounting Pronouncements*

During the nine months ended September 30, 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:

|  |  |  |
| --- | --- | --- |
|  | September 30,  2024 | December 31,  2023 |
| Prepaid clinical trial costs (current portion) | $ 1,706,281 | $ 1,282,746 |
| Prepaid insurance premiums | - | 110,695 |
| Prepaid rent | 13,045 | 13,045 |
| Other prepaid expenses | 10,000 | 26,667 |
| Total prepaid expenses | $ 1,729,326 | $ 1,433,153 |

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

|  |  |  |
| --- | --- | --- |
|  | September 30,  2024 | December 31,  2023 |
| Equipment and furnishings | $ 795,411 | $ 774,758 |
| Leasehold improvements | 115,605 | 115,605 |
| Total property and equipment | 911,016 | 890,363 |
| Accumulated depreciation and amortization | (739,401) | (680,674) |
| Total property and equipment, net | $ 171,615 | $ 209,689 |

*Other Assets* – Other assets consist of the following:

|  |  |  |
| --- | --- | --- |
|  | September 30,  2024 | December 31,  2023 |
| Prepaid clinical trial costs (noncurrent portion) | $ - | $ 1,106,778 |
| Prepaid technology license fees | 60,000 | 70,000 |
| Deposits | 11,010 | 11,010 |
| Total other assets | $ 71,010 | $ 1,187,788 |

*Accrued Expenses* – Accrued expenses consist of the following:

|  |  |  |
| --- | --- | --- |
|  | September 30,  2024 | December 31,  2023 |
| Payroll-related liabilities | $ 169,719 | $ 114,337 |
| Accrued clinical trial costs | 220,501 | 490,635 |
| Other accrued expenses | 70,000 | 111,959 |
| Total accrued expenses | $ 460,220 | $ 716,931 |

4. Notes Payable – Related Parties

On May 10, 2024, we issued 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, in exchange for gross cash proceeds to us of $135,000. 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 (a “Qualified Financing Event”). On August 22, 2024, following the successful completion of a Qualified Financing Event, we repaid the aggregate principal amount of the Notes in full, together with accrued interest. Total interest expense recorded during the nine months ended September 30, 2024 was $21,375, consisting of $15,000 of debt discount amortization and $6,375 of accrued interest.

5. Commitments

*Operating Lease.* We lease approximately 8,400 square feet of office and laboratory space pursuant to an operating lease which expires on December 31, 2025. Rent expense for the three-month and nine-month periods ended September 30, 2024 was $46,764 and $140,292, respectively, as compared to $45,414 and $136,242, respectively, for the same periods of 2023. Future minimum lease payments total $46,764 in 2024, and $192,708 in 2025 although the lease may be terminated at any time by either party with one hundred eighty days written notice.

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

*Other Commitments*. In the normal course of business, we enter into various contracts and purchase commitments including those with contract research organizations (“CROs”) for clinical trial services, contract manufacturing organizations (“CMOs”) for production of materials for use in our clinical trials, and other independent contractors or academic institutions for preclinical research activities and other services and products. Most contracts are generally cancellable, with notice, at the Company’s option. Payments due upon cancellation may consist of payments for services provided or expenses incurred to date, or cancellation penalties depending on the time of cancellation.

6. 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 and Warrant Offerings*

On May 21, 2024, we closed a registered direct offering of 220,000 shares of common stock and pre-funded warrants to purchase an aggregate of 582,844 shares of common stock (the “May 2024 Pre-Funded Warrants”). In a concurrent private placement, we issued common warrants to the purchaser to purchase up to 1,605,688 shares of common stock at an exercise price of $1.68 per share. Net proceeds after deducting placement agent commissions and other offering expenses were approximately $1.2 million.

On July 12, 2024, we closed a registered direct offering of 458,632 shares of common stock and pre-funded warrants to purchase an aggregate of 626,368 shares of common stock (the “July 2024 Pre-Funded Warrants”). In a concurrent private placement, we issued common warrants to the purchaser to purchase up to 2,170,000 shares of common stock at an exercise price of $2.86 per share. Net proceeds after deducting placement agent commissions and other offering expenses were approximately $2.8 million.

On August 21, 2024, we closed a registered direct offering of 1,360,731 shares of common stock and pre-funded warrants to purchase an aggregate of 339,269 shares of common stock (the “August 21, 2024 Pre-Funded Warrants”). In a concurrent private placement, we issued common warrants to the purchaser to purchase up to 1,700,000 shares of common stock at an exercise price of $5.00 per share. Net proceeds after deducting placement agent commissions and other offering expenses were approximately $7.9 million.

On August 30, 2024, we closed a registered direct offering of 837,500 shares of common stock and pre-funded warrants to purchase an aggregate of 138,110 shares of common stock (the “August 30, 2024 Pre-Funded Warrants”). In a concurrent private placement, we issued common warrants to the purchaser to purchase up to 975,610 shares of common stock at an exercise price of $5.00 per share. Net proceeds after deducting placement agent commissions and other offering expenses were approximately $4.6 million.

On September 25, 2024, we entered into a Sales Agreement and established an “At-the-Market” continuous offering program (the “ATM Program”), pursuant to which the Company may offer and sell, from time to time through its sales agent, shares of its common stock. During the third quarter of 2024 we sold 84,600 shares of our common stock through the ATM Program at a weighted-average price of $2.51 per share, raising $206,003 of net proceeds, after deducting commissions to the sales agent and other related expenses. As of September 30, 2024, we had $4,274,260 available under the ATM Program.

*Warrant Exercises*

During the first quarter of 2024, we issued 269,032 shares of our common stock upon the exercise of prefunded warrants issued in December 2023 (the “December 2023 Pre-Funded Warrants”).

During the second quarter of 2024, we issued (i) 238,000 and 582,844 shares of our common stock upon the exercise of the December 2023 Pre-Funded Warrants and the May 2024 Pre-Funded Warrants, respectively; (ii) 2,549 shares of our common stock upon the cashless exercise of 4,000 warrants issued in June 2020, and (iii) 826,998 shares of our common stock upon the exercise of common warrants issued in December 2023 (the “December 2023 Common Warrants”), with net cash proceeds to us of $1,389,363.

During the third quarter of 2024, we issued (i) 626,368, 339,269 and 138,110 shares of our common stock upon the exercise of the July 2024 Pre-Funded Warrants, the August 21, 2024 Pre-Funded Warrants, and the August 30, 2024 Pre-Funded Warrants respectively; (ii) 3,398 shares of our common stock upon the cashless exercise of 4,000 warrants issued in June 2020, and (iii) 582,000 shares of our common stock upon the exercise of the December 2023 Common Warrants, with net cash proceeds to us of $977,770.

*Other Common Stock Transactions*

During the first quarter of 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.

*Stock Options*

We have stock-based incentive plans (the “Plans”) pursuant to which our Board of Directors may grant stock options and other stock-based awards to our employees, directors and consultants. During the nine months ended September 30, 2024, we granted 200,000 new stock options with a weighted-average exercise price of $2.23 per share and 961 stock options were cancelled. As of September 30, 2024, there are 333,648 stock options outstanding, with a weighted-average exercise price of $12.71 per share and a weighted-average remaining contractual term of 7.2 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*

The table below summarizes information concerning warrants outstanding as of September 30, 2024.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Issue Date | | Number  of Shares | | Exercise  Price | | Expiration | |
| September 2020 | 159,781 | | $ 75.00 | | September 2025 | |
| September 2021 | 6,668 | | 195.00 | | September 2026 | |
| May 2024 | 1,605,688 | | 1.68 | | May 2029 | |
| July 2024 | 2,170,000 | | 2.86 | | November 2029 | |
| August 2024 | 2,675,610 | | 5.00 | | August 2029 | |
| Outstanding at September 30, 2024 | 6,617,747 | |  | |  | |

**7. Stock-Based Compensation Expense**

Stock-based compensation expense related to stock options is recognized on a straight-line basis over the requisite service period for the award and is allocated to research and development expense or general and administrative expense based upon the classification of the individual to whom the award is granted. Stock-based compensation expense related to stock option grants was $129,923 and $335,132 during the three-month and nine-month periods ended September 30, 2024, respectively, as compared to $227,114 and $681,166, respectively, during the same periods of 2023. As of September 30, 2024, there is $655,314 of unrecognized compensation expense that we expect to recognize over a weighted-average period of 1.9 years.

We have also issued shares of our restricted common stock to consultants and recognize the related expense over the terms of the related agreements. During the three-month and nine-month periods ended September 30, 2024 we recorded stock-based compensation expense of $-0- and $54,167, respectively, associated with common stock issued for consulting services, as compared to $70,833 and $132,333, respectively, for the same periods of 2023.

8. Revenue from Government Contract

On June 12, 2024, GeoVax was awarded a contract (the “BARDA Contract”) through the Rapid Response Partnership Vehicle (RRPV) to advance the clinical development of GEO-CM04S1, the Company’s next-generation COVID-19 vaccine. The RRPV is a consortium funded by 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).

Under the BARDA Contract, GeoVax will sponsor a 10,000-participant, randomized, Phase 2b double-blinded clinical trial to assess the efficacy, safety, and immunogenicity of GEO-CM04S1 compared with a U.S. Food and Drug Administration (FDA)-approved mRNA COVID-19 vaccine. The direct award to GeoVax, currently approximately $26.2 million and which may increase to as much as $45 million, is funding the manufacturing of clinical materials and support for the Phase 2b clinical trial, including regulatory activities. BARDA has made a separate award through its Clinical Studies Network to fully fund the execution of the study by Allucent, a global clinical research organization; the funding provided directly to Allucent will not be recognized in GeoVax’s financial statements.

GeoVax’s role in the project is being funded in whole or in part with federal funds from BARDA under Other Transaction 75A50123D00005. Allucent’s role in the project is being funded in whole or in part with federal funds from BARDA under contract 75A50120D00016/75A50123F33005.

During the three-month and nine-month periods ending September 30, 2024, GeoVax recognized revenue of $2,789,484 and $3,090,161, respectively, associated with the BARDA contract. We record revenue associated with this contract as the reimbursable costs are incurred.

9. 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 6,951,395 and 1,026,862 shares at September 30, 2024 and 2023, respectively.

10. Income Taxes

No provision for income taxes was recorded in either of the nine-month periods ended September 30, 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 September 30, 2024.

11. Subsequent Events

During October 2024 we issued 826,761 shares of our common stock through the ATM Program at a weighted-average price of $2.20 per share, raising $1,761,309 of net proceeds, after deducting commissions to the sales agent and other related expenses. On October 15, 2024, we increased the maximum aggregate offering price of the shares issuable under the ATM Program from $4,486,846 to $30,000,000.

## 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 “Quarterly 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 (the “SEC”) on February 29, 2024.*

**Forward-Looking Statements**

*Information included in this Quarterly 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 Quarterly 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 Quarterly Report.*

**Overview**

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

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

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

* GEO-CM04S1 – Next Generation COVID-19 Vaccine:
  + On June 12, 2024, GeoVax was awarded a contract (the “BARDA Contract”) through the Rapid Response Partnership Vehicle (RRPV) to advance the clinical development of GEO-CM04S1. The RRPV is a Consortium funded by 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). Under the agreement, GeoVax will sponsor a 10,000-participant, randomized, Phase 2b double-blinded study to assess the clinical efficacy, safety, and immunogenicity of GEO-CM04S1 compared with a U.S. Food and Drug Administration (FDA)-approved mRNA COVID-19 vaccine. The direct award to GeoVax, currently approximately $26.2 million and which may increase to as much as $45 million, is funding the manufacturing of clinical materials and support for the Phase 2b clinical trial, including regulatory activities. BARDA has made a separate award of approximately $343 million through its Clinical Studies Network to Allucent, a global clinical research organization, to execute the clinical trial as part of BARDA’s Clinical Studies Network. Target clinical sites are confirmed and manufacturing activities are underway for production of the vaccine product needed for study activation.
  + GEO-CM04S1 is currently undergoing a Phase 2 clinical trial (ClinicalTrials.gov Identifier: NCT04977024), evaluating its safety and efficacy as a preventive COVID-19 vaccine in high-risk immunocompromised patients (i.e. patients with blood cancers 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 safety lead-in portion of the trial indicates that GEO-CM04S1 is highly immunogenic in these patients, inducing broad and durable neutralizing antibody and T cell responses.
  + GEO-CM04S1 is also undergoing the Phase 2 portion of a Phase 1/2 trial (ClinicalTrials.gov Identifier: NCT04639466), evaluating two vaccine dose levels as a heterologous COVID-19 booster vaccine to current FDA-approved mRNA vaccines from Pfizer/BioNTech and Moderna. In February 2024, we announced positive interim safety and immune responses findings following vaccine administration. Consolidated data (blinded to vaccine dose) 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.
  + An investigator-initiated Phase 2 clinical trial (ClinicalTrials.gov Identifier: NCT05672355) of GEO-CM04S1 is evaluating its use as a COVID-19 vaccine booster in patients with chronic lymphocytic leukemia (CLL) compared to the Pfizer/BioNTech mRNA-based vaccine.
* Gedeptin®:
  + Gedeptin recently completed a Phase 1/2 clinical trial (PNP-002) (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.
  + In July 2024, we announced that a special clinical advisory board completed a comprehensive review of the PNP-002 trial results, together with the previously completed Phase 1 trial (PNP-001). This review concluded that Gedeptin demonstrated an acceptable safety and efficacy profile to support continued development. In addition, the therapy has demonstrated sufficient tumor stabilization/reduction activity to support plans to advance clinical development of Gedeptin therapy in an expanded Phase 2 clinical trial.
  + We have initiated activities in support of a Phase 2 trial in first-recurrence head and neck cancer. The primary goal of this trial will be to establish efficacy of neoadjuvant Gedeptin therapy combined with an immune checkpoint inhibitor in squamous cell head and neck cancer. This trial is anticipated to be a single cycle trial with surgery to follow in approximately 36 patients with pathologic response rate as the primary endpoint. We have initiated the necessary planning activities, including protocol development, manufacturing and CRO selection, with the trial activation anticipated during the first half of 2025.
* GEO-MVA:
  + GEO-MVA is the Company vaccine candidate in development for protection against Mpox and Smallpox. MVA is the vaccine recommended by both the World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention (CDC) against both Mpox and Smallpox, recognized for its safety and efficacy among all patient populations, including pregnant women, children and immunocompromised individuals. MVA is the vaccine currently used and stockpiled in the United States Strategic National Stockpile for immunization against potential bioterrorism threats based on the smallpox virus.
  + We have produced and released the cGMP Master Seed Virus for GEO-MVA and are currently producing the cGMP Working Virus Seed (WVS) bank. We expect to complete cGMP production of a clinical batch of GEO-MVA before year-end 2024, which will then be reviewed with stakeholders for potential clinical use.
* Our additional research programs for vaccines and immunotherapies at various stages of preclinical development.
* General Corporate:
  + On May 23, 2024, we received a notice from the Listing Qualifications Department of the Nasdaq Stock Market (“Nasdaq”) notifying the Company that it no longer complied with the $2,500,000 minimum stockholders’ equity required for continued listing pursuant to Nasdaq Listing Rule 5550(b)(1) (the “Stockholders’ Equity Requirement”), because the Company’s stockholders’ equity as reported in its Form 10-Q for the period ended March 31, 2024 did not meet the required minimum. On July 18, 2024, we received notice from Nasdaq granting our request for an extension of time to regain compliance with the Stockholders’ Equity Requirement until November 19, 2024. As a result of several financing transactions completed during the quarter ended September 30, 2024, we believe that, as of the date of this Quarterly Report, the Company has regained compliance with the Stockholders’ Equity Requirement. Nasdaq will continue to monitor our ongoing compliance with the Stockholders’ Equity Requirement and, if at the time of our next periodic report, we do not evidence compliance, the Company may be subject to delisting.

**Financial Overview**

*Revenue*

Our revenues to date have been related to government grants and contracts and other collaborative arrangements in support of our product development activities. We have not generated any revenue 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 and development functions, including salaries, benefits and stock-based compensation;

• expenses incurred under agreements with contract research organizations (“CROs”), for the conduct of clinical trials;

• expenses incurred under agreements with contract manufacturing organizations (“CMOs”), that manufacture product used in 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 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 SEC, 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 and nine-month periods ended September 30, 2024 and 2023:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | Three Months Ended September 30, | |  |
|  |  |  |  |  | 2024 | 2023 | Change |
| Revenue from government contract | | | |  | $ 2,789,484 | $ - | $ 2,789,484 |
| Operating expenses: | | | |  |  |  |  |
|  | Research and development | | |  | 7,402,884 | 6,947,979 | 454,905 |
|  | General and administrative | | |  | 1,241,176 | 1,651,775 | (410,599) |
| Total operating expenses | | | |  | 8,644,060 | 8,599,754 | 44,306 |
| Loss from operations | | | |  | (5,854,576) | (8,599,754) | 2,745,178 |
| Interest income | | | |  | 53,191 | 190,936 | (137,745) |
| Interest expense | | | |  | (14,083) | - | (14,083) |
| Net loss | | | |  | $ (5,815,468) | $ (8,408,818) | $ 2,593,350 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | Nine Months Ended September 30, | |  |
|  |  |  |  |  | 2024 | 2023 | Change |
| Revenue from government contract | | | |  | $ 3,090,161 | $ - | $ 3,090,161 |
| Operating expenses: | | | |  |  |  |  |
|  | Research and development | | |  | 16,105,480 | 14,486,896 | 1,618,584 |
|  | General and administrative | | |  | 3,784,559 | 4,562,293 | (777,734) |
| Total operating expenses | | | |  | 19,890,039 | 19,049,189 | 840,850 |
| Loss from operations | | | |  | (16,799,878) | (19,049,189) | 2,249,311 |
| Interest income | | | |  | 91,611 | 674,835 | (583,224) |
| Interest expense | | | |  | (21,375) | - | (21,375) |
|  | | | |  | $ (16,729,642) | $ (18,374,354) | $ 1,644,712 |

*Revenue from Government Contract*

During the three-month and nine-month periods ending September 30, 2024, we reported $2,789,484 and $3,090,161, respectively, of revenues associated with the BARDA Contract. There were no revenues reported during the comparable 2023 periods.

*Research and Development Expenses*

For the three-month and nine-month periods ending September 30, 2024, research and development expenses increased by $454,905 (6.5%) and $1,618,584 (11.2%), respectively, versus the comparable 2023 periods. The overall increase during the nine-month period of 2024 versus 2023 relates primarily to costs of manufacturing materials for use in our clinical trials of GEO-CM04S1 and other costs associated with the BARDA Contract. Research and development expenses for the three-month and nine-month periods of 2024 include stock-based compensation expense of $59,384 and $163,654, respectively; as compared to $77,873 and $232,516, respectively, for the comparable 2023 periods.

*General and Administrative Expenses*

For the three-month and nine-month periods ending September 30, 2024, general and administrative expenses decreased by $410,599 (24.9%) and $777,734 (17%), respectively, versus the comparable 2023 periods. The overall decrease during the 2024 periods relates primarily to lower stock-based compensation expense, consulting costs, legal and patent costs and franchise tax cost. General and administrative expenses for the three-month and nine-month periods of 2024 includes stock-based compensation expense of $70,538 and $225,645, respectively; as compared to $220,075 and $580,983, respectively, for the comparable periods of 2023.

*Other Income*

Interest income for the three-month and nine-month periods ended September 30, 2024 was $53,191 and $91,611, respectively, as compared to $190,936 and $674,835, respectively, for comparable periods of 2023. The overall decrease during the 2024 periods is primarily attributable to cash available for investment. Interest expense for the three-month and nine-month periods ended September 30, 2024 was $14,083 and $21,375, respectively, associated with certain notes payable issued during May 2024 and repaid in August 2024. There was no interest expense during the comparable periods of 2023.

**Liquidity and Capital Resources**

The following tables summarize our liquidity and capital resources as of September 30, 2024 and December 31, 2023, and our cash flows for the nine-month periods ended September 30, 2024 and 2023:

|  |  |  |  |
| --- | --- | --- | --- |
| Liquidity and Capital Resources |  | September 30, 2024 | December 31, 2023 |
| Cash and cash equivalents |  | $ 8,592,523 | $ 6,452,589 |
| Working capital |  | 8,261,251 | 4,365,861 |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Nine Months Ended September 30, | |
| Cash Flow Data |  | 2024 | 2023 |
| Net cash provided by (used in): |  |  |  |
| Operating activities |  | $ (16,921,961) | $ (14,895,694) |
| Investing activities |  | (20,653) | (29,997) |
| Financing activities |  | 19,082,548 | - |
| Net increase (decrease) in cash and cash equivalents | | $ 2,139,934 | $ (14,925,691) |

*Operating Activities* – Net cash used in operating activities of $16,921,961 for the nine months ended September 30, 2024, was due to our net loss of $16,729,642, offset by non-cash items such as depreciation and amortization expense and stock-based compensation expense, and by changes in our working capital accounts. Net cash used in operating activities of $14,895,694 for the nine months ended September 30, 2023, was due to our net loss of $18,374,354, offset by non-cash items such as depreciation expense and stock-based compensation expense, and by changes in our working capital accounts.

*Investing Activities* – Net cash used in investing activities was $20,653 and $29,997 for the nine-month periods ended September 30, 2024 and 2023, respectively, and relates primarily to purchases of laboratory equipment.

*Financing Activities* – Net cash provided by financing activities was $19,082,548 and $-0- for the nine-month periods ended September 30, 2024 and 2023, respectively. Net cash provided by financing activities for the 2024 period primarily relates to offerings of our common stock and warrants and exercise of previously issued warrants.

**Funding Requirements and Sources of Capital**

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

During the nine months ended September 30, 2024, we closed four registered direct offerings of our common stock and warrants, as well as established the ATM Program (see footnote 6 to the financial statements included in this Quarterly Report). Net proceeds to us from these offerings, after deducting commissions to the placement agent and sales agent, as applicable, and other related offering expenses, were approximately $16.7 million. We also received approximately $2.4 million upon the exercise of warrants.

As of the date of this Quarterly Report, we believe that our existing cash and cash equivalents are sufficient to fund our operations into the first quarter of 2025. 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 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 (the “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 SEC’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, 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

## Legal Proceedings

None.

### 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.

## Unregistered Sales of Equity Securities and Use of Proceeds

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

## Defaults Upon Senior Securities

None.

## Mine Safety Disclosures

Not applicable.

## 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 filed April 12, 2024 (2)](https://www.sec.gov/Archives/edgar/data/832489/000143774924016605/ex_671452.htm)

3.2. [Bylaws (3)](https://www.sec.gov/Archives/edgar/data/832489/000143774924018144/ex_679029.htm)

4.1 [Form of Pre-Funded Warrant, dated July 12, 2024 (4)](https://www.sec.gov/Archives/edgar/data/832489/000143774924022656/ex_697615.htm)

4.2 [Form of Common Warrant, dated July 12, 2024 (4)](https://www.sec.gov/Archives/edgar/data/832489/000143774924022656/ex_697669.htm)

4.3 [Form of Pre-Funded Warrant, dated August 21, 2024 (5)](https://www.sec.gov/Archives/edgar/data/832489/000143774924027483/ex_717268.htm)

4.4 [Form of Common Warrant, dated August 21, 2024 (5)](https://www.sec.gov/Archives/edgar/data/832489/000143774924027483/ex_717269.htm)

4.5 [Form of Pre-Funded Warrant, dated August 30, 2024 (6)](https://www.sec.gov/Archives/edgar/data/832489/000143774924028138/ex_719853.htm)

4.6 [Form of Common Warrant, dated August 30, 2024 (6)](https://www.sec.gov/Archives/edgar/data/832489/000143774924028138/ex_719854.htm)

10.1 [Securities Purchase Agreement, dated July 11, 2024 (4)](https://www.sec.gov/Archives/edgar/data/832489/000143774924022656/ex_697617.htm)

10.2 [Securities Purchase Agreement, dated August 20, 2024 (5)](https://www.sec.gov/Archives/edgar/data/832489/000143774924027483/ex_717272.htm)

10.3 [Securities Purchase Agreement, dated August 28, 2024 (6)](https://www.sec.gov/Archives/edgar/data/832489/000143774924028138/ex_719856.htm)

10.4 [Sales Agreement, by and between the Company and A.G.P./Alliance Global Partners, dated September 25, 2024 (7)](https://www.sec.gov/Archives/edgar/data/832489/000143774924029998/ex_727127.htm)

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 registrants Quarterly Report on Form 10-Q filed May 14, 2024.
3. Incorporated by reference from the registrant’s Current Report on Form 8-K filed May 23, 2024.
4. Incorporated by reference from the registrant’s Current Report on Form 8-K filed July 12, 2024.
5. Incorporated by reference from the registrant’s Current Report on Form 8-K filed August 21, 2024.
6. Incorporated by reference from the registrant’s Current Report on Form 8-K filed August 30, 2024.
7. Incorporated by reference from the registrant’s Current Report on Form 8-K filed September 25, 2024.

**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 12, 2024 By: /s/ Mark W. Reynolds

Mark W. Reynolds

Chief Financial Officer

(duly authorized officer and principal  
financial officer)