Table of Contents

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

[mark one]
☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: September 30, 2024

□ 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 1-36598

CELLECTAR BIOSCIENCES, INC.

(*Exact name of registrant as specified in its charter*)

DELAWARE	**04-3321804**
(*State or other jurisdiction of incorporation or organization*)	(*IRS Employer Identification No.*)

100 Campus Drive
Florham Park, New Jersey 07932
(*Address of principal executive offices, including zip code*)

(608) 441-8120
(*Registrant's telephone number, including area code*)

(*Former name, former address and former fiscal year, if changed since last report)*

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.00001	CLRB	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 (§ 232.405 of this chapter) 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 ☒ Smaller reporting company ☒ Emerging growth 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 ☒

Number of shares outstanding of the issuer's common stock as of the latest practicable date: 41,269,830 shares of common stock, $0.00001 par value per share, as of November 14, 2024.

CELLECTAR BIOSCIENCES, INC.

FORM 10-Q INDEX

FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q of Cellectar Biosciences, Inc. (the "Company", "Cellectar", "we", "us", "our") contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. Examples of our forward-looking statements include:

- our current views with respect to our business strategy, business plan and research and development activities;
- the progress of our product development programs, including clinical testing and the timing of commencement and results thereof;
- our projected operating results, including research and development expenses;
- our ability to continue development plans for iopofosine I 131 (iopofosine, also known as CLR 131), CLR 1900 series, CLR 2000 series and CLR 12120;
- our ability to continue development plans for our Phospholipid Drug Conjugates (PDC)™;
- our ability to maintain orphan drug designation in the U.S. for iopofosine as a therapeutic for the treatment of multiple myeloma, neuroblastoma, osteosarcoma, rhabdomyosarcoma, Ewing's sarcoma and lymphoplasmacytic lymphoma, and the expected benefits of orphan drug status;
- any disruptions at our sole supplier of iopofosine;
- our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise;
- our ability to advance our technologies into product candidates;
- our enhancement and consumption of current resources along with ability to obtain additional funding;
- our current view regarding general economic and market conditions, including our competitive strengths;
- uncertainty and economic instability resulting from conflicts, military actions, terrorist attacks, natural disasters, public health crises, including the occurrence of a contagious disease or illness such as the COVID-19 pandemic, cyber-attacks and general instability;
- the future impacts of legislative and regulatory developments in the United States on the pricing and reimbursement of our product candidates;
- our ability to meet the continued listing standards of Nasdaq;
- assumptions underlying any of the foregoing; and
- any other statements that address events or developments that we intend or believe will or may occur in the future.

In some cases, you can identify forward-looking statements by terminology, such as “expects,” “anticipates,” “intends,” “estimates,” “plans,” “believes,” “seeks,” “may,” “should,” “could”, “would” or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Forward-looking statements also involve risks and uncertainties, many of which are beyond our control. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this quarterly report.

You should read this report completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this report is accurate as of the date hereof only. Because the risk factors referred to herein could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

This quarterly report on Form 10-Q contains trademarks and service marks of Cellectar Biosciences, Inc. Unless otherwise provided in this quarterly report on Form 10-Q, trademarks identified by ™ are trademarks of Cellectar Biosciences, Inc. All other trademarks are the property of their respective owners.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 34,263,371	$ 9,564,988
Prepaid expenses and other current assets	1,635,818	888,225
Total current assets	35,899,189	10,453,213
Property, plant & equipment, net	910,131	1,090,304
Operating lease right-of-use asset	454,166	502,283
Other long-term assets	29,780	29,780
TOTAL ASSETS	$ 37,293,266	$ 12,075,580
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 8,304,311	$ 9,178,645
Warrant liability	11,929,242	16,120,898
Lease liability, current	80,821	58,979
Total current liabilities	20,314,374	25,358,522
Long-term lease liability, net of current portion	431,929	494,003
TOTAL LIABILITIES	20,746,303	25,852,525
COMMITMENTS AND CONTINGENCIES (Note 7)		
MEZZANINE EQUITY:		
Series D preferred stock, 111.11 shares authorized, issued and outstanding as of September 30, 2024 and December 31, 2023	1,382,023	1,382,023
STOCKHOLDERS' EQUITY (DEFICIT):		
Series E-2 preferred stock, 1,225.00 shares authorized; 149.60 and 319.76 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	2,188,434	4,677,632
Series E-3 preferred stock, 2,205.00 shares authorized; 202.50 and 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	4,369,317	—
Series E-4 preferred stock, 1,715.00 shares authorized; 714.00 and 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	7,057,793	—
Common stock, $0.00001 par value; 170,000,000 shares authorized; 40,566,534 and 20,744,110 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	406	207
Additional paid-in capital	246,536,080	182,924,210
Accumulated deficit	(244,987,090)	(202,761,017)
Total stockholders' equity (deficit)	15,164,940	(15,158,968)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 37,293,266	$ 12,075,580

The accompanying notes are an integral part of these condensed consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
OPERATING EXPENSES:				
Research and development	$ 5,493,496	$ 7,034,656	$ 19,927,019	$ 19,528,898
General and administrative	7,834,181	2,378,804	19,105,853	6,883,866
Total operating expenses	13,327,677	9,413,460	39,032,872	26,412,764
LOSS FROM OPERATIONS	(13,327,677)	(9,413,460)	(39,032,872)	(26,412,764)
OTHER INCOME (EXPENSE):				
Warrant issuance expense	(7,743,284)	(470,000)	(7,743,284)	(470,000)
Gain (loss) on valuation of warrants	6,088,355	(7,688,028)	3,583,440	(8,254,649)
Interest income	317,887	51,110	966,643	247,925
Total other expense	(1,337,042)	(8,106,918)	(3,193,201)	(8,476,724)
NET LOSS	$ (14,664,719)	$ (17,520,378)	(42,226,073)	$ (34,889,488)
NET LOSS PER SHARE — BASIC	$ (0.37)	$ (1.55)	(1.21)	$ (3.09)
NET LOSS PER SHARE — DILUTED	$ (0.40)	$ (1.55)	(1.39)	$ (3.09)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC	39,335,924	11,308,738	34,850,441	11,277,231
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — DILUTED	39,794,220	11,308,738	35,545,500	11,277,231

The accompanying notes are an integral part of these condensed consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)

	Series D Preferred Stock		Preferred Stock		Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Par Amount	Paid-In Capital	Deficit	(Deficit) Equity
Balance at December 31, 2022	111.11	$ 1,382,023	—	$ —	9,385,272	$ 94	$ 168,143,557	$ (159,990,407)	$ 8,153,244
Conversion of pre-funded warrants into common stock	—	—	—	—	355,235	3	—	—	3
Stock-based compensation	—	—	—	—	—	—	408,206	—	408,206
Net loss	—	—	—	—	—	—	—	(7,190,470)	(7,190,470)
Balance at March 31, 2023	111.11	1,382,023	—	—	9,740,507	97	168,551,763	(167,180,877)	1,370,983
Stock-based compensation	—	—	—	—	—	—	419,757	—	419,757
Net loss	—	—	—	—	—	—	—	(10,178,640)	(10,178,640)
Balance at June 30, 2023	111.11	1,382,023	—	—	9,740,507	97	168,971,520	(177,359,517)	(8,387,900)
Issuance of Series E-1 preferred stock, net of issuance costs (Note 6)	1,225.00	17,820,000	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	497,878	—	497,878
Exercise of warrants into common stock	—	—	—	—	177,877	2	649,248	—	649,250
Reclassification of pre-funded warrants to liability	—	—	—	—	—	—	(3,239,112)	—	(3,239,112)
Net loss	—	—	—	—	—	—	—	(17,520,378)	(17,520,378)
Balance at September 30, 2023	1,336.11	$ 19,202,023	—	$ —	9,918,384	$ 99	$ 166,879,534	$ (194,879,895)	$ (28,000,262)
Balance at December 31, 2023	111.11	$ 1,382,023	319.76	$ 4,677,632	20,744,110	$ 207	$ 182,924,210	$ (202,761,017)	$ (15,158,968)
Stock-based compensation	—	—	—	—	—	—	454,363	—	454,363
Conversion of pre-funded warrants into common shares	—	—	—	—	1,079,132	11	3,972,529	—	3,972,540
Exercise of warrants for preferred stock, net of issuance costs (Note 2)	—	—	2,205.00	47,577,000	—	—	—	—	47,577,000
Conversion of Series E-3 preferred stock into common stock	—	—	(1,575.00)	(33,983,571)	9,890,099	100	33,983,471	—	—
Exercise of warrants for common stock	—	—	—	—	547,177	5	2,298,138	—	2,298,143
Conversion of Series E-2 preferred stock into common stock	—	—	(82.26)	(1,203,346)	903,956	9	1,203,337	—	—
Retired shares	—	—	—	—	(8)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(26,641,983)	(26,641,983)
Balance at March 31, 2024	111.11	1,382,023	867.50	17,067,715	33,164,466	332	224,836,048	(229,403,000)	12,501,095
Stock-based compensation	—	—	—	—	—	—	799,249	—	799,249
Conversion of Series E-3 preferred stock into common stock	—	—	(427.50)	(9,224,112)	2,684,458	26	9,224,086	—	—
Net loss	—	—	—	—	—	—	—	(919,371)	(919,371)
Balance at June 30, 2024	111.11	$ 1,382,023	440.00	$ 7,843,603	35,848,924	$ 358	$ 234,859,383	$ (230,322,371)	$ 12,380,973
Stock-based compensation							1,534,054	—	1,534,054
Issuance of E-4 preferred stock net of issuance costs	—	—	1,610.00	15,914,632	—	—	—	—	15,914,632
Conversion of Series E-2 preferred stock into common stock	—	—	(87.90)	(1,285,851)	965,934	10	1,285,841	—	—
Conversion of Series E-4 preferred stock into common stock	—	—	(896.00)	(8,856,840)	3,750,909	38	8,856,802	—	—
Stock option exercise into common stock	—	—	—	—	767	—	—	—	—
Net loss	—	—	—	—	—	—	—	(14,664,719)	(14,664,719)
Balance at September 30, 2024	111.11	$ 1,382,023	1,066.10	$ 13,615,544	40,566,534	$ 406	$ 246,536,080	$ (244,987,090)	$ 15,164,940

The accompanying notes are an integral part of these condensed consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Nine Months Ended September 30,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (42,226,073)	$ (34,889,488)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	223,082	122,415
Stock-based compensation expense	2,787,666	1,325,841
Warrant issuance expense	7,743,284	470,000
Change in operating lease right-of-use asset	48,117	42,768
Change in fair value of warrants	(3,583,440)	8,254,649
Changes in:		
Prepaid expenses and other current assets	(747,593)	(408,790)
Lease liability	(40,232)	(34,815)
Accounts payable and accrued liabilities	(874,334)	2,336,146
Cash used in operating activities	(36,669,523)	(22,781,274)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant & equipment	(42,909)	(597,282)
Cash used in investing activities	(42,909)	(597,282)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of preferred stock and warrants, net of issuance costs	—	22,150,000
Proceeds from exercise of warrants, net of issuance costs	61,410,815	348,641
Cash provided by financing activities	61,410,815	22,498,641
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	24,698,383	(879,915)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	9,564,988	19,866,358
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 34,263,371	$ 18,986,443
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Settlement of warrants to equity	$ 7,410,000	$ —
Conversion of preferred stock to common stock	$ 54,553,720	$ —

The accompanying notes are an integral part of these condensed consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. NATURE OF BUSINESS AND ORGANIZATION

Cellectar Biosciences, Inc. (the Company) is a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, leveraging the Company's proprietary phospholipid drug conjugate™ (PDC™) delivery platform that specifically targets cancer cells and delivers improved efficacy and better safety as a result of fewer off-target effects.

Going Concern — As an emerging growth company, the Company has, by design, incurred significant recurring losses and used net cash in its operations since its inception as it devotes substantially all of its efforts towards researching, developing and seeking approval for its product candidates to be commercialized in the marketplace. As a result of these efforts, the Company had an accumulated deficit of approximately $244,987,000 as of September 30, 2024, and incurred a net loss of approximately $42,226,000 during the nine months ended September 30, 2024. The Company expects it will continue to generate significant losses and use net cash for the foreseeable future, until such time that one or more of its product candidates are approved and successfully commercialized in the marketplace. While management believes one or more of the Company's product candidates will be approved and successfully commercialized in the marketplace, no assurance can be provided any products will be approved or commercialized in a profitable manner.

To fund its research, development, and approval efforts, the Company has been heavily dependent on funding from private investors and public stockholders since its inception through the issuance of securities, such as common stock, convertible preferred stock, and warrants (outside capital). The Company expects to remain heavily dependent on outside capital to fund the Company's operations for the foreseeable future until such time that one or more of its product candidates are approved and successfully commercialized in the marketplace. While management believes additional outside capital will be secured as needed, no assurance can be provided that additional outside capital will be secured, or secured on terms that are acceptable to the Company.

As of the date the accompanying consolidated financial statements were issued (the "issuance date"), the Company's available liquidity to fund the Company's operations over the next twelve months beyond the issuance date was limited to approximately $28.6 million of unrestricted cash and cash equivalents. Absent further action taken by management to increase its liquidity, the Company may be unable to fund its operations under normal course beyond the second quarter of 2025. To improve the Company's liquidity, management plans to secure additional outside capital via the sale of equity and/or debt securities or execute a strategic transaction. Management also plans to preserve liquidity, as needed, by implementing temporary cost saving measures. While management believes their plans will be successful, no assurance can be provided such plans will be effectively implemented over the next twelve months beyond the issuance date. In the event management's plans are not effectively implemented, the Company will be required to seek other alternatives which may include, among others, the sale of the Company or its assets, discontinuance of certain operations, a wind-down of operations and/or filing for bankruptcy protection.

These uncertainties raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on the basis that the Company will continue to operate as a going concern, which contemplates it will be able to realize assets and settle liabilities and commitments in the normal course of business for the foreseeable future. Accordingly, the accompanying consolidated financial statements do not include any adjustments that may result from the outcome of these uncertainties.

The condensed consolidated financial statements have been prepared by Cellectar Biosciences, Inc. in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. Management believes the disclosures made in this document are adequate with respect to interim reporting requirements.

The accompanying Condensed Consolidated Balance Sheet as of December 31, 2023, has been derived from the Company's audited financial statements. The accompanying Condensed Consolidated Balance Sheet as of September 30, 2024, and the Condensed Consolidated Statements of Operations, Cash Flows, and the Consolidated Statements of Stockholders' Equity for the nine months ended September 30, 2024 and 2023, and the related interim information contained within the Notes to the Condensed Consolidated Financial Statements, have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and with the instructions, rules and regulations of the Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all the information and the notes required by U.S. GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all adjustments which are of a nature necessary for the fair presentation of the Company's consolidated financial position as of September 30, 2024, and consolidated results of its operations, cash flows, and stockholders' equity for the nine months ended September 30, 2024 and 2023. The results for the nine months ended September 30, 2024, are not necessarily indicative of future results.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes thereto included in the Company's Form 10-K/A for the fiscal year ended December 31, 2023, which was filed with the SEC on October 29, 2024.

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation. The Company consists of one reportable segment.

Use of Estimates — The preparation of the accompanying consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Significant estimates include the assumptions used in the accrual for potential liabilities, the valuation of the warrant liability, the valuation of debt and equity instruments, the valuation of stock options issued for services, and deferred tax valuation allowances. Actual results could differ from those estimates.

Property, Plant & Equipment — Property, plant & equipment are stated at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets (3 to 10 years). Leasehold improvements are depreciated over 64 months (their estimated useful life), which represents the full term of the lease at the time the leasehold improvements were capitalized. The Company's only long-lived assets are property, plant & equipment and right-of-use (ROU) assets. Periodically, and at a minimum annually, the Company evaluates long-lived assets for potential impairment. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. Such analyses necessarily involve judgement. The Company did not experience any events or changes in circumstances that indicate the carrying amount of the assets may not be recoverable as of September 30, 2024. There were no fixed asset impairment charges recorded during the nine months ended September 30, 2024 or 2023.

Right-of-Use (ROU) Asset and Lease Liabilities -The Company accounts for all material leases in accordance with FASB Accounting Standards Codification (ASC) Topic 842, Leases. ROU Assets are amortized over their estimated useful life, which represents the full term of the lease. See Note 8.

Stock-Based Compensation — The Company uses the Black-Scholes option-pricing model to calculate the grant-date fair value of stock option awards. The resulting compensation expense, net of forfeitures for awards that are not performance-based, is recognized on a straight-line basis over the service period of the award, which in the three and nine months ended September 30, 2024 and 2023, ranged from twelve months to three years.

Research and Development — Research and development costs are expensed as incurred. The Company recognizes revenue and cost reimbursements from government grants when it is probable that the Company will comply with the conditions attached to the grant arrangement and the grant proceeds will be received. Government grants are recognized on a systematic basis over the periods in which the Company recognizes the related costs for which the government grant is intended to compensate. Specifically, when government grants are related to reimbursements for cost of revenues or operating expenses, the government grants are recognized as a reduction of the related expense in the Condensed Consolidated Statements of Operations. The Company records government grants receivable in the Condensed Consolidated Balance Sheets in prepaid expenses and other current assets.

Income Taxes — Income taxes are accounted for using the liability method of accounting. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement basis and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more-likely-than-not that some portion of the deferred tax assets will not be realized. Management has provided a full valuation allowance against the Company's gross deferred tax asset. Tax positions taken or expected to be taken in the course of preparing tax returns are required to be evaluated to determine whether the tax positions are more-likely-than-not to be sustained by the applicable tax authority. Tax positions deemed not to meet a more-likely-than-not threshold would be recorded as tax expense in the current year. There are no uncertain tax positions that require accrual to or disclosure in the financial statements as of September 30, 2024 and December 31, 2023.

Fair Value of Financial Instruments — The guidance under ASC Topic 825, Financial Instruments, requires disclosure of the fair value of certain financial instruments. Financial instruments in the accompanying financial statements consist of cash equivalents, prepaid expenses and other assets, accounts payable and accrued liabilities, and long-term obligations. The carrying amount of cash equivalents, prepaid expenses, other current assets and accounts payable approximate their fair value as a result of their short-term nature. (See Notes 2 and 3)

Warrants — The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity and ASC 815, Derivatives and Hedging. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require net cash settlement in a fundamental transaction outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding (see Note 2). If the warrants are liability-classified, valuation changes, as well as the cost to issue the warrants, are included in Other Income (Expense) in the financial statements (see Note 3). If these instruments are initially classified as either liabilities or equity and a subsequent assessment determines that the classification has changed, the Company reflects that change in the financial statements.

Preferred Stock — The Company accounts for preferred stock based upon their specific terms and the authoritative guidance in ASC 480 and ASC 815, including whether they are freestanding instruments, whether any redemption or conversion aspects exist and how they are required to be settled (particularly if there is a cash settlement aspect), whether they contain characteristics that are predominantly debt-like or equity-like, whether they have embedded derivatives, and if they have redemption features. Based upon analysis of these criteria, the preferred stock will be classified as either debt, temporary (or "mezzanine") equity, or permanent equity. The resultant classification is then evaluated quarterly to determine whether any change to the classification is required.

Concentration of Credit Risk — Financial instruments that subject the Company to credit risk consist of cash and cash equivalents on deposit with financial institutions. The Company's excess cash as of September 30, 2024 and December 31, 2023 is on deposit in interest-bearing accounts with well-established financial institutions. At times, such amounts may exceed the FDIC insurance limits. As of September 30, 2024, and December 31, 2023, uninsured cash balances totaled approximately $33,814,000 and $9,123,000, respectively.

Government Assistance — Reimbursements of eligible expenditures pursuant to government assistance programs are recorded as reductions of operating costs when there is reasonable assurance that the Company will comply with the conditions attached to the grant arrangement and when the reimbursement has been claimed. The determination of the amount of the claim, and accordingly the receivable amount, requires management to make calculations based on its interpretation of eligible expenditures in accordance with the terms of the programs. The reimbursement claims submitted by the Company are subject to review by the relevant government agencies. The Company currently has a cancer treatment research award through the National Cancer Institute (NCI) totaling approximately $2.0 million over a period of approximately three years. In September 2022, the Company was awarded $1.98 million in additional grant funding to expand the Company's ongoing Phase 1 study of iopofosine I 131 in children and adolescents with inoperable relapsed or refractory high-grade gliomas (HGGs). The grant was awarded by the NCI based upon the initial signals of efficacy in the Phase 1 study, which is an international, open-label, dose escalation, safety study. The funding allows for an expansion from Part 1a into the Part 1b portion of the ongoing Phase 1 pediatric study.

During the nine months ended September 30, 2024 and 2023, the Company received approximately $602,000 and $1,314,000 in NCI grant funding under the grants described above, respectively, all of which was reported as a reduction of research and development expenses.

Recently Adopted Accounting Pronouncements Not Yet Adopted — In December 2023, the FASB issued Accounting Standards Update (ASU) No. 2023-09, Income Taxes (Topic 740)—Improvements to Income Tax Disclosures, which is intended to enhance the transparency and decision usefulness of income tax disclosures. Public business entities are required to adopt this standard for annual fiscal periods beginning after December 15, 2024, and early adoption is permitted. The Company is evaluating the impact the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280). The amendments in this update expand segment disclosure requirements, including new segment disclosure requirements for entities with a single reportable segment among other disclosure requirements. This update is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact that the adoption of ASU 2023 - 07 will have on its condensed consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. The amendments in ASU 2024-03 address investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating this guidance to determine the impact it may have on its condensed consolidated financial statements.

The Company evaluates all ASUs issued by the FASB for consideration of their applicability to the financial statements. The Company has assessed all ASUs issued but not yet adopted and concluded that those not disclosed are not relevant to the Company or are not expected to have a material impact.

Restatement of Previously Issued Consolidated Financial Statements — During the third quarter of 2024 the Company determined that it was necessary to re-evaluate its accounting treatment for certain previously issued warrants and preferred stock. Additionally, the Company identified certain operating costs previously presented as research and development expenses which are more appropriately classified as general and administrative. In accordance with Staff Accounting Bulletins No. 99 (SAB No. 99) Topic 1.M, “Materiality” and SAB No. 99 Topic 1.N “Considering the Effects of Misstatements when Quantifying Misstatements in the Current Year Financial Statements,” the Company assessed the materiality of these errors to its previously issued consolidated financial statements. Based upon the Company’s evaluation of both quantitative and qualitative factors, the Company concluded the errors were material to the Company’s previously issued consolidated financial statements for the fiscal years ended December 31, 2023 and 2022, as well as those for the first quarter of 2024. Accordingly, this Form 10-Q presents the Company’s Restated Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2023 as reflected in the Company’s Form 10-K/A for the year ended December 31, 2023.

2. STOCKHOLDERS’ EQUITY

July 2024 Warrant Inducement

On July 21, 2024, the Company, entered into a warrant exercise inducement (the “Inducement”) with certain holders of its September 2023 Tranche B warrants, pursuant to which the holders agreed to exercise the warrants to purchase 1,610 shares of the Company’s Series E-4 Convertible Voting Preferred Stock, par value $0.00001 per share (the “Series E-4 preferred stock”) which is convertible to 6,739,918 shares of the Company’s common stock in the aggregate, at a reduced, as-converted common stock price of $2.52 per share, in exchange for the Company’s issuance of new warrants (the “Inducement Warrants”), with varying termination dates and exercise prices. The Company received gross proceeds of $19.4 million and net proceeds of $17.5 million.

The Inducement Warrants have the following terms:

- The 2024 Tranche A warrants have an exercise price of $2.52 and expire at the earlier of (i) ten (10) trading days following the date of the Company’s public announcement that the FDA has assigned a Prescription Drug User Fee Act goal date for review of iopofosine I 131, and (ii) July 21, 2029.

- The 2024 Tranche B warrants have an exercise price of $4.00 and expire at the earlier of (i) ten (10) trading days following the date of the Company's public announcement of its receipt of written approval from the FDA of its New Drug Application for iopofosine I 131, and (ii) July 21, 2029.

- The 2024 Tranche C warrants have an exercise price of $5.50 and expire at the earlier of (i) ten (10) trading days following the date of the Company's public announcement that it has recorded quarterly gross revenues from sales of iopofosine I 131 in the United States in excess of $10 million and (ii) July 21, 2029.

Due to a cash settlement feature that requires cash settlement in event of a fundamental transaction that is outside the Company's control resulting in a form of settlement inconsistent with that which would be received by other security holders, the warrants do not qualify under the equity classification guidance. As a result, and in accordance with the guidance in ASC 815, the warrants issued in July 2024 are deemed to be liabilities. All such liabilities are required to be presented at fair value, with changes reflected in financial results for the period. See Note 3 for the related valuation.

In accordance with the guidance above, the Company recorded the Inducement Warrants and preferred stock at their respective fair values. Utilizing valuation techniques described in Note 3 below, the Company computed the fair value of the Inducement Warrants as $12.0 million and recorded the preferred stock at approximately $15.9 million, which represented its fair value of $17.0 million less allocated issuance costs. The value of the preferred stock and Inducement Warrants sold exceeded the proceeds received by the Company and the fair value of the Tranche B warrants that were exercised in the transaction, which was approximately $2.6 million at the time of exercise. The value in excess of the net proceeds and the fair value of the Tranche B warrants of approximately $7.7 million is reflected in Other Expense.

Subsequent to the issuance of the Series E-4 preferred stock and prior to September 30, 2024, investors who held 896.00 shares of Series E-4 preferred stock converted them into 3,750,909 shares of common stock. There remain 714.00 shares of Series E-4 preferred stock outstanding as of September 30, 2024.

September 2023 Private Placement

On September 8, 2023, in a private placement with certain institutional investors, the Company issued 1,225 shares of Series E-1 preferred stock, along with Tranche A warrants to purchase 2,205 shares of Series E-3 preferred stock and Tranche B warrants to purchase 1,715 shares of Series E-4 preferred stock. Shares of Series E preferred stock were issued at a fixed price of $20,000 per share, resulting in gross proceeds of $24.5 million and net proceeds of approximately $22.2 million after placement agent fees and other customary expenses.

The conversion prices for the preferred stock are as follows: for the Series E-1 or E-2 preferred stock, $1.82 per share of common stock, or a total of 13,461,538 shares of common stock; for the Series E-3 preferred stock, $3.185 per share of common stock, or a total of 13,846,154 shares of common stock; and for the Series E-4 preferred stock, $4.7775 per share of common stock, or a total of 7,179,487 shares of common stock, in each case subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization. The warrants were exercisable as follows:

- Tranche A warrants, for an aggregate exercise price of $44.1 million, exercisable for Series E-3 preferred stock until the earlier of September 6, 2026, or 10 trading days after the Company's announcement of positive topline data from the Waldenstrom's macroglobulinemia CLOVER WaM pivotal trial; and,

- Tranche B warrants, for an aggregate exercise price of $34.3 million, exercisable for Series E-4 preferred stock until the earlier of September 6, 2028, or 10 days following the Company's public announcement of its receipt of written approval from the FDA of its New Drug Application for iopofosine I 131.

As of December 31, 2023, the Tranche A and Tranche B warrants did not qualify as derivatives; however, they did not meet the requirements necessary to be considered indexable in the Company's stock. As a result, and in accordance with the guidance in FASB ASC 815, the warrants were deemed to be liabilities. As of September 30, 2024, the Tranche B warrants do not qualify as derivatives and meet the requirements necessary to be considered indexable in the Company's stock. However, due to a cash settlement feature that requires cash settlement in event of a fundamental transaction that is outside the Company's control resulting in a form of settlement inconsistent with that which would be received by other security holders, the warrants do not qualify under the equity classification guidance. As a result, and in accordance with the guidance in ASC 815, the Tranche B warrants continue to be deemed

liabilities. All such liabilities are required to be presented at fair value, with changes reflected in financial results for the period. As discussed above, the majority of the Tranche B warrants were exercised in July 2024. See Note 3 for the related valuation.

When issued, the Series E-1 preferred stock had a redemption feature; therefore, it was classified as mezzanine equity as of September 30, 2023. The Series E-1 preferred stock also had a liquidation preference, which was calculated as an amount per share equal to the greater of (i) two times (2X) the Original Per Share Price, together with any declared, unpaid dividends, or (ii) such amount per share as would have been payable had all shares of Series E-1 preferred stock been converted into Common Stock immediately prior to such Liquidation. While the Series E-1 preferred was outstanding, this resulted in both the Tranche A and Tranche B warrants being considered puttable by virtue of the liquidation preference impacting the disposition of these warrants in the event of a liquidation. In accordance with the guidance in ASC 480, a puttable warrant is deemed to be a liability. These features only applied to the Series E-1 preferred stock when it was outstanding; upon stockholder approval of the transaction, which was obtained by the Company at a special meeting of stockholders held on October 25, 2023, the Series E-1 preferred stock immediately converted into either Series E-2 preferred stock and/or common stock, dependent upon the beneficial ownership position of the holder.

The net proceeds from the September 2023 Private Placement were allocated first to the fair value of the Tranche A and Tranche B warrants, which had a fair value upon issuance of $4,800,000, with the remainder, or $17,820,000, allocated to the Series E-1 preferred stock. Upon stockholder approval of the transaction, the entire amount that had been assigned to mezzanine equity was reclassified to Series E-2 preferred stock and is a component of permanent equity, as is reflected in the financial statements. As a result of the stockholder approval, Series E-1 preferred stock was fully extinguished in accordance with the terms of the financing. The outstanding shares of Series E preferred stock were classified as permanent equity upon issuance.

Series E preferred stock is convertible to common stock at the request of the holder, subject to the holder not exceeding certain beneficial ownership percentages as stipulated in the financing agreement. Subsequent to the issuance of the Series E-2 preferred stock and prior to December 31, 2023, preferred holders converted 905.24 shares of preferred stock into 9,947,684 shares of common stock at the stated rate of $1.82 per common share, resulting in 319.76 shares of Series E-2 preferred stock outstanding as of December 31, 2023.

During the nine months ended September 30, 2024, 170.16 shares of Series E-2 preferred stock were converted into 1,869,890 shares of common stock. There remain 149.60 shares of Series E-2 preferred stock outstanding as of September 30, 2024.

In January 2024, the Company released topline data from its pivotal, Phase 2b CLOVER WaM trial. In accordance with the terms of the Tranche A warrant, the warants' expiration accelerated to 10 trading days after the topline data release. Warrant holders exercised the Tranche A warrants in their entirety, resulting in the Company issuing 2,205.00 shares of Series E-3 preferred stock, which are convertible to common stock at the stated rate of $3.185 per share, and receiving gross proceeds of $44.1 million and net proceeds of $42.8 million (see Note 3).

During the nine months ended September 30, 2024, investors who held 2,002.50 shares of Series E-3 preferred stock converted them into 12,574,557 shares of common stock. There remain 202.50 shares of Series E-3 preferred stock outstanding as of September 30, 2024.

October 2022 Public Offering and Private Placement

On October 25, 2022, the Company completed a registered direct offering of 3,275,153 shares of the Company's common stock at $2.085 per share and warrants to purchase up to an aggregate of 3,275,153 shares of common stock in a concurrent private placement priced at-the-market under Nasdaq rules. In a separate concurrent private placement transaction, the Company offered and sold pre-funded warrants to purchase an aggregate of 1,875,945 shares of common stock and warrants to purchase an aggregate of 1,875,945 shares of common stock. The warrants are immediately exercisable at an exercise price of $1.96 per share and will expire on the fifth anniversary of the closing date. Each pre-funded warrant had a purchase price of $2.08499, is immediately exercisable at an exercise price of $0.00001 per share and will not expire until exercised in full. The registered direct offering and private placements resulted in total gross proceeds of approximately $10.7 million with net proceeds to the Company of approximately $9.6 million after deducting estimated offering expenses.

During the nine months ended September 30, 2024, 1,079,132 pre-funded warrants were converted into 1,079,132 shares of common stock, and 547,177 warrants issued in October 2022 were exercised for net proceeds of approximately $1.1 million. There were no such conversions or exercises in the nine months ended September 30, 2023.

Warrants

The following table summarizes information with regard to outstanding warrants to purchase stock as of September 30, 2024:

Offering	Number of Common Shares Issuable Upon Exercise of Outstanding Warrants	Exercise Price	Expiration Date
2024 Tranche A Warrants	6,739,918	$ 2.52	July 21, 2029
2024 Tranche B Warrants	8,214,278	$ 4.00	July 21, 2029
2024 Tranche C Warrants	4,267,152	$ 5.50	July 21, 2029
2023 Tranche B Preferred Warrants	439,560	$ 4.7775	September 8, 2028
2022 Common Warrants	4,201,044	$ 1.96	October 25, 2027
June 2020 Series H Common Warrants	720,796	$ 12.075	June 5, 2025
October 2017 Series D Common Warrants	31,085	$ 178.00	October 14, 2024
Total	24,613,833		

All warrants in the table above are liability-classified.

3. FAIR VALUE

In accordance with the Fair Value Measurements and Disclosures Topic of ASC 820, the Company groups its financial assets and financial liabilities generally measured at fair value in three levels, based on the markets in which the assets and liabilities are traded, and the reliability of the assumptions used to determine fair value:

- Level 1: Input prices quoted in an active market for identical financial assets or liabilities.
- Level 2: Inputs other than prices quoted in Level 1, such as prices quoted for similar financial assets and liabilities in active markets, prices for identical assets, and liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data.
- Level 3: Input prices quoted that are significant to the fair value of the financial assets or liabilities which are not observable or supported by an active market.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. The carrying value of cash and cash equivalents approximates fair value as maturities are less than three months. The carrying amounts reported for other current financial assets and liabilities approximate fair value because of their short-term nature. As of September 30, 2024, the Company does not have any Level 1 or Level 2 liabilities.

July 2024 Warrants

As part of the July 2024 financing the Company issued Tranche A, B, and C warrants (the 2024 Warrants) to purchase shares of common stock (see Note 2). The fair value of the 2024 warrants was determined using a probability-weighted expected return method (PWERM) with a scenario-based Monte Carlo simulation and Black-Scholes model. The PWERM is a scenario-based methodology that estimates the fair value of the Company's different classes of equity based upon an analysis of future values for the Company, assuming various outcomes. Under both models, assumptions and estimates are used to value the warrants. The Company assesses these assumptions and estimates on a quarterly basis as additional information that impacts the assumptions is obtained. The quantitative elements associated with the inputs impacting the fair value measurement of the 2024 Warrants include the value per share of the underlying common stock, the timing, form and overall value of the expected exits for the stockholders, the risk-free interest rate, the expected dividend yield and the expected volatility of the Company's shares. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared cash dividends. Expected volatility was determined based upon the historical volatility of the Company's common stock.

The 2024 Warrants are classified within the Level 3 hierarchy because of the nature of these inputs and the valuation technique utilized, and had a fair value of $12,000,000 and $6,900,000 as of July 21, 2024, the date of issuance, and September 30, 2024, respectively, which is included in the warrant liability caption on the accompanying balance sheets.

The following table summarizes the modified option-pricing assumptions used on September 30, 2024 and December 31, 2023:

	July 21, 2024	September 30, 2024
Volatility	75.9-82.0 %	80.6-83.0 %
Risk-free interest rate	4.10-4.20 %	3.50-3.60 %
Expected life (years)	0.7-5.0	0.5-4.8
Dividend	0 %	0 %

September 2023 Warrants

As part of the September 2023 financing (see Note 2) the Company issued Tranche A and Tranche B warrants (the 2023 Warrants) to purchase shares of preferred stock which, on an as-converted basis, represented an aggregate of 21,025,641 shares of common stock. The fair value of the Tranche A and B warrants was determined using a probability-weighted expected return method (PWERM) with a scenario-based Monte Carlo simulation and Black-Scholes model. The PWERM is a scenario-based methodology that estimates the fair value of the Company's different classes of equity based upon an analysis of future values for the Company, assuming various outcomes. Under both models, assumptions and estimates are used to value the preferred stock warrants. The Company assesses these assumptions and estimates on a quarterly basis as additional information that impacts the assumptions is obtained. The quantitative elements associated with the inputs impacting the fair value measurement of the 2023 Warrants include the value per share of the underlying common stock, the timing, form and overall value of the expected exits for the stockholders, the risk-free interest rate, the expected dividend yield and the expected volatility of the Company's shares. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared cash dividends. Expected volatility was determined based upon the historical volatility of the Company's common stock.

As previously described, all of the Tranche A warrants were exercised in January 2024. Additionally, in July 2024, the holders of the Tranche B warrants exercised all but 105.00 of the Tranche B warrants outstanding. As a result, those warrants were marked-to-market on July 21, 2024, the date of the exercise and subsequent settlement.

The 2023 Warrants are classified within the Level 3 hierarchy because of the nature of these inputs and the valuation technique utilized, and had a fair value of $30,000 and $4,200,000 as of September 30, 2024 and December 31, 2023, respectively, which is included in the warrant liability caption on the accompanying balance sheets.

The following table summarizes the modified option-pricing assumptions used on September 30, 2024 and December 31, 2023:

	September 30, 2024	December 31, 2023
Volatility	81.0-85.0 %	82.0-83.0 %
Risk-free interest rate	4.41 %	3.80-5.40 %
Expected life (years)	0.8-4.2	0.3-4.7
Dividend	0 %	0 %

At the time the Tranche A warrants were exercised, their fair value, calculated as the difference between the common stock conversion rate in the Series E-3 preferred stock and the trading price of the stock when the warrants were exercised, was determined to be $4,800,000. Due to the settlement of the Tranche A warrants relieving the Company of any further related obligation, the liability was reclassified to equity in accordance with ASC 815. The Tranche B warrants continue to be classified as a liability due to a cash settlement feature in the agreement.

October 2022 Warrants

In October 2022 the Company issued a total of 5,151,098 common warrants that are immediately exercisable with a five-year life and a strike price of $1.96 for shares of common stock (the 2022 Common Warrants), and 1,875,941 pre-funded warrants (the 2022 Pre-Funded Warrants) to acquire shares of common stock (see Note 6). The 2022 Pre-Funded Warrants are exercisable by the holder upon payment of the par value of the common stock and are classified as Level 2 liabilities as their value is equal to the Company's common stock value less the par value.

The fair value of the 2022 Common Warrants was determined by utilizing a Black-Scholes option-pricing model. The quantitative elements associated with the inputs impacting the fair value measurement of the 2022 Common Warrants include the value per share of the underlying common stock, the risk-free interest rate, the expected dividend yield and the expected volatility of the Company's shares. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared cash dividends. Expected volatility was determined based upon the historical volatility of the Company's common stock. These warrants are classified within the Level 3 hierarchy because of the nature of these inputs and the valuation technique utilized. The following table summarizes the assumptions used at each financial reporting date:

	September 30, 2024	December 31, 2023
Volatility	78.3 %	81.1 %
Risk-free interest rate	3.58 %	3.84 %
Expected life (years)	3.1	3.8
Dividend	0 %	0 %

The following table summarizes the changes in the fair market value of the warrants which are classified within the Level 3 fair value hierarchy.

	Level 3
Fair value of Level 3 liabilities as of December 31, 2023	$ 13,131,691
Change in warrant fair value	(4,566,773)
Issuance of July 2024 Inducement Warrants	12,000,000
Settlement of 2023 Tranche A Warrants to equity	(4,800,000)
Settlement of 2023 Tranche B Warrants to equity	(2,610,000)
Exercise of October 2022 Warrants	(1,225,676)
June 30, 2024, fair value of Level 3 liabilities	$ 11,929,242

4. STOCK-BASED COMPENSATION

Accounting for Stock-Based Compensation

2021 Stock Incentive Plans

The Company maintains the 2021 Stock Incentive Plan (the "2021 Plan"). The Company utilizes stock-based compensation incentives as a component of its employee and non-employee director and officer compensation philosophy. A committee of the Board of Directors determines the terms of the awards granted and may grant various forms of equity-based incentive compensation. Currently, these incentives consist principally of stock options and restricted shares. All outstanding awards under the 2015 Stock Incentive Plan (the "2015 Plan") remained in effect according to the terms of the 2015 Plan. Any shares that are currently available under the 2015 Plan and any shares underlying 2015 Plan awards which are forfeited, cancelled, reacquired by the Company or otherwise terminated are added to the shares available for grant under the 2021 Plan.

Under the current stock option award program, all options become exercisable between one and three years after issuance and expire after ten years. The fair value of each stock option award is estimated on the grant date using the Black-Scholes option-pricing model. Volatility is based on the Company's historical common stock volatility. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time. The expected term of stock options granted is based on an estimate of when options will be exercised in the future. Forfeitures are recorded as they occur. No dividends have been recorded historically.

At the annual meeting of stockholders held on June 14, 2024, the Company's stockholders approved an increase in the number of shares of common stock available for issuance under the 2021 Stock Incentive Plan by 7,000,000 to 9,368,900.

The following table summarizes amounts charged to expense for stock-based compensation related to employee and director stock option grants:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Employee and director stock option grants:				
Research and development	$ 309,933	$ 89,172	$ 453,158	$ 227,896
General and administrative	1,224,121	408,706	2,334,508	1,097,945
Total stock-based compensation	$ 1,534,054	$ 497,878	$ 2,787,666	$ 1,325,841

In December 2023, the Company granted 2,776,000 contingent, non-statutory stock option awards at an exercise price of $2.65 per share to employees and directors, and in March 2024 the Company granted 200,000 contingent, non-statutory stock option awards at an exercise price of $3.63 and $3.35 per share to our employees. Each of these grants was contingent on approval of an increase in the shares available in the 2021 Stock Incentive Plan that was approved by the stockholders at the annual meeting of stockholders held on June 14, 2024. In accordance with the removal of the contingency, the Company began recognizing the expense for these awards in June 2024.

Assumptions Used in Determining Fair Value

Valuation and amortization method. The fair value of each stock award is estimated on the grant date using the Black-Scholes option-pricing model. The estimated fair value of employee stock options is amortized to expense using the straight-line method over the required service period which is generally the vesting period. The estimated fair value of the non-employee options is amortized to expense over the period during which a non-employee is required to provide services for the award (usually the vesting period).

Volatility. The Company estimates volatility based on the Company's historical volatility since its common stock is publicly traded.

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption.

Expected term. The expected term of stock options granted is based on an estimate of when options will be exercised in the future. The Company applies the simplified method of estimating the expected term of the options, as described in the SEC's Staff Accounting Bulletins 107 and 110, as the historical experience is not indicative of the expected behavior in the future. The expected term, calculated under the simplified method, is applied to groups of stock options that have similar contractual terms. Using this method, the expected term is determined using the average of the vesting period and the contractual life of the stock options granted. The Company applied the simplified method to non-employees who have a truncation of term based on termination of service and utilizes the contractual life of the stock options granted for those non-employee grants which do not have a truncation of service.

Forfeitures. The Company records stock-based compensation expense only for those awards that are expected to vest and accounts for forfeitures as they occur.

Dividends. The Company has not historically recorded dividends related to stock options.

Exercise prices for all grants made during the nine months ended September 30, 2024 and September 30, 2023, were equal to the market value of the Company's common stock on the date of grant.

5. INCOME TAXES

The Company accounts for income taxes in accordance with the liability method of accounting. Deferred tax assets or liabilities are computed based on the difference between the financial statement and income tax basis of assets and liabilities, and net operating loss carryforwards ("NOLs"), using the enacted tax rates. Deferred income tax expense or benefit is based on changes in the asset or liability from period to period. The Company did not record a provision or benefit for federal, state or foreign income taxes for the nine months ended September 30, 2024 or 2023 because the Company has experienced losses on a tax basis since inception. Management has provided a full allowance against the value of its gross deferred tax assets in light of the continuing losses and uncertainty associated with the utilization of the NOLs in the future.

The Company also accounts for the uncertainty in income taxes related to the recognition and measurement of a tax position taken or expected to be taken in an income tax return. The Company follows the applicable accounting guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition related to the uncertainty in income tax positions. No uncertain tax positions have been identified.

6. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock and pre-funded warrants outstanding during the period. The pre-funded warrants are considered common shares outstanding for the purposes of the basic net loss per share calculation due to the nominal cash consideration and lack of other contingencies for issuance of the underlying common shares. Diluted net loss attributable to common stockholders per share is computed by dividing net loss attributable to common stockholders, as adjusted, by the sum of the weighted average number of shares of common stock and the dilutive potential common stock equivalents then outstanding. Potential common stock equivalents consist of stock options, warrants, and convertible preferred shares. In accordance with ASC Topic 260, Earnings per Share, diluted earnings per share are the amount of earnings for the period available to each share of common stock outstanding during the reporting period and to each share that would have been outstanding assuming the issuance of common shares for all dilutive potential common shares outstanding during the reporting period. In the quarter ended September 30, 2024, the common warrants issued in October 2022 were dilutive. In all other periods presented, all outstanding warrants were antidilutive.

Periods ended September 30, 2024	**Three Months**	**Nine Months**
Net loss	$ (14,664,719)	$ (42,226,073)
Dilutive effect of warrant liability	(1,428,355)	(7,283,786)
Net loss allocated to common shares	$ (16,093,074)	$ (49,509,859)
Weighted average common shares outstanding - basic	39,335,924	34,850,441
Dilutive effect of warrant liability	458,296	695,060
Weighted average common shares outstanding - diluted	39,794,220	35,545,500
Net loss per share - diluted	$ (0.40)	$ (1.39)

The following potentially dilutive securities have been excluded from the computation of diluted net loss per share since their inclusion would be antidilutive:

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2024	**2023**	**2024**	**2023**
Warrants	20,412,789	27,148,243	20,412,789	27,148,243
Preferred shares on an as-converted-into-common-stock basis	6,015,662	111,111	6,015,662	111,111
Stock options	5,359,624	2,280,756	5,359,624	2,280,756
Total potentially dilutive shares	31,788,075	29,540,110	31,788,075	29,540,110

7. COMMITMENTS AND CONTINGENCIES

Legal

The Company may be involved in legal matters and disputes in the ordinary course of business. It is not anticipated that the outcome of such matters and disputes will materially affect the Company’s financial statements.

8. LEASES

Operating Lease Liability

In June 2018, the Company executed an agreement for office space in the Borough of Florham Park, Morris County, New Jersey to be used as its headquarters (HQ Lease). The HQ Lease commenced upon completion of certain improvements in October 2018.

On December 30, 2022, the Company entered into an Amended Agreement of Lease of the HQ Lease (Amended HQ Lease), with CAMPUS 100 LLC (the "Landlord"). Under the Amended HQ Lease, which was accounted for as a modification of the initial lease, the Company will continue to lease 3,983 square feet of rentable area on the second floor of a building located at 100 Campus Drive in Florham Park, New Jersey, commencing on March 1, 2023 until April 30, 2029. The Company also has an option to extend the term of the Amended HQ Lease for one additional 60-month period.

Under the terms of the Amended Lease, the Company Company's previously paid security deposit of $75,000 will be reduced to $23,566, and the aggregate rent due over the term of the Amended Lease is approximately $918,000, which will be reduced to approximately $893,000 after certain rent abatements. The Company will also be required to pay its proportionate share of certain operating expenses and real estate taxes applicable to the leased premises. After rent abatements, the rent is approximately $11,800 per month for the first year and then escalates thereafter by 2% per year for the duration of the term. The Company has not entered into any leases with related parties.

Discount Rate

The Company has determined an appropriate interest rate to be used in evaluating the present value of the Amended Lease liability considering factors such as the Company's credit rating, borrowing terms offered by the U.S. Small Business Administration, amount of lease payments, quality of collateral and alignment of the borrowing term and lease term. The Company considers 14% per annum as reasonable to use as the incremental borrowing rate for the purpose of calculating the liability under the Amended Lease.

Maturity Analysis of Short-Term and Operating Leases

The following table approximates the dollar maturity of the Company's undiscounted payments for its short-term leases and operating lease liabilities as of September 30, 2024:

Years ending September 30,		
Remaining period of 2024	$	36,000
2025		146,000
2026		150,000
2027		153,000
2028		155,000
Thereafter		53,000
Total undiscounted lease payments		693,000
Less: Imputed interest		(180,000)
Present value of lease liabilities	$	513,000

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited financial information and notes thereto included in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, include forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section in our Annual Report on Form 10-K/A for the year ended December 31, 2023, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

We are a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer. Our core objective is to leverage our proprietary phospholipid ether drug conjugate™ (PDC™) delivery platform to develop PDCs that are designed to specifically target cancer cells and deliver improved efficacy and better safety as a result of fewer off-target effects. We believe that our PDC platform possesses the potential for the discovery and development of the next generation of cancer-targeting treatments, and we plan to develop PDCs both independently and through research and development collaborations.

Our lead PDC therapeutic, iopofosine I 131 (iopofosine) is a small-molecule PDC designed to provide targeted delivery of iodine-131 directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates iopofosine from many traditional on-market treatments and radiotherapeutics. Our CLOVER-WaM Phase 2 pivotal study of iopofosine in patients with relapsed/refractory (r/r) Waldenstrom's macroglobulinemia (WM) has completed, and our Phase 2b studies in r/r multiple myeloma (MM) patients and r/r central nervous system lymphoma (CNSL) are ongoing. The CLOVER-2 Phase 1a study for a variety of pediatric cancers has concluded and a Phase 1b study in pediatric patients with high grade glioma is enrolling. Additionally, a Phase 1 Investigator-initiated study conducted by the University of Wisconsin Madison of iopofosine I 131 in combination with external beam radiation in patients with recurrent head and neck cancer has also completed. As with all clinical trials, adverse events, serious adverse events or fatalities may arise during a clinical trial resulting from medical problems that may not be related to clinical trial treatments.

The U.S. Food and Drug Administration (FDA) granted iopofosine Fast Track Designation for lymphoplasmacytic lymphoma (LPL) and WM patients having received two or more prior treatment regimens, as well as r/r MM and r/r diffuse large B-cell lymphoma (DLBCL). Orphan Drug Designations (ODDs) have been granted for LPL/WM, MM, neuroblastoma, soft tissue sarcomas including rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Iopofosine was also granted Rare Pediatric Disease Designation (RPDD) for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. The European Commission granted ODD to iopofosine for treatment of r/r MM and WM, as well as PRIME designation for WM.

Additionally, in June 2020, the European Medicines Agency (EMA) granted us Small and Medium-Sized Enterprise (SME) status by the EMA's Micro, Small and Medium-sized Enterprise office. SME status allows us to participate in significant financial incentives that include a 90% to 100% EMA fee reduction for scientific advice, clinical study protocol design, endpoints and statistical considerations, quality inspections of facilities and fee waivers for selective EMA pre-and post-authorization regulatory filings, including orphan drug and PRIME designations. We are also eligible to obtain EMA certification of quality and manufacturing data prior to review of clinical data. Other financial incentives include EMA-provided translational services of all regulatory documents required for market authorization, further reducing the financial burden of the market authorization process.

Our product pipeline also includes a PDC-based targeted alpha-emitter therapy utilizing actinium-225 as the payload (CLR121225) currently in IND enabling studies. We are also evaluating other alpha emitting isotopes such as astatine-211 and lead-212 preclinical studies. Additionally, we have preclinical PDC programs seeking to deliver conjugated small molecule chemotherapeutic compounds, oligonucleotides and peptides to solid tumors.

We have leveraged our PDC platform to establish three ongoing collaborations featuring four unique payloads and mechanisms of action. Through research and development collaborations, our strategy is to generate near-term capital, supplement internal resources, gain access to novel molecules or payloads, accelerate product candidate development, and broaden our proprietary and partnered product pipelines.

Our PDC platform is designed to provide selective delivery of a diverse range of oncologic payloads to cancerous cells, whether a hematologic cancer or solid tumor; a primary tumor, or a metastatic tumor; and cancer stem cells. The PDC platform's mechanism of

entry is designed not to rely upon a specific cell surface epitope or antigen as are required by other targeted delivery platforms but rather a unique change in the tumor cell membrane. Our PDC platform takes advantage of a metabolic pathway (beta oxidation) utilized by nearly all tumor cell types in all stages of the tumor cycle. Tumor cells modify the cell membrane to create specific, highly organized microdomains by which to transport lipids and long chain fatty acids into the cytoplasm, as a result of the utilization of this metabolic pathway. Our PDCs are designed to bind to these regions and directly enter the intracellular compartment. This mechanism allows the PDC molecules to accumulate in tumor cells over time, which we believe can enhance drug efficacy. The direct intracellular delivery allows our molecules to avoid the specialized, highly acidic cellular compartment known as lysosomes, which allows a PDC to deliver payloads that previously could not be delivered in this targeted manner. Additionally, molecules targeting specific cell surface epitopes face challenges in completely eliminating a tumor because the targeted antigens are limited in the total number presented on the cell surface, limiting total potential uptake and resulting in heterogenous uptake across the tumor, have longer cycling time from internalization to relocation on the cell surface, again diminishing their availability for binding, and are not present on all of the tumor cells because of the heterogenous nature of cancer cells, further increasing the unequal distribution of the drug across the tumor. This means a subpopulation of tumor cells always exists that cannot be addressed by therapies targeting specific surface epitopes. Additionally, many epitopes utilized are also present on other normal tissue, resulting in off-target toxicities.

Beyond the benefits provided by the mechanism of entry, the PDC platform features include the capacity to link with almost any molecule, provide a significant increase in targeted oncologic payload delivery, a more uniform delivery, and the ability to target virtually all types of tumor cells. As a result, we believe that we can create PDCs to treat a broad range of cancers with the potential to improve the therapeutic index of oncologic drug payloads, enhance or maintain efficacy while also reducing adverse events by minimizing drug delivery to healthy cells, and increasing delivery to cancerous cells and cancer stem cells.

We employ a drug discovery and development approach that allows us to efficiently design, research and advance drug candidates. Our iterative process allows us to rapidly and systematically produce multiple generations of incrementally improved targeted drug candidates without the expense of having to generate significant compound libraries.

A description of our PDC product candidates follows:

Clinical Pipeline

Our lead PDC therapeutic, iopofosine, is a small-molecule PDC designed to provide targeted delivery of iodine-131 directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates iopofosine from many traditional on-market treatments and treatments in development. Iopofosine was recently evaluated in the completed CLOVER-WaM Phase 2 pivotal study in patients with r/r WM, while evaluation is ongoing in a Phase 2b study in r/r MM and CNS lymphoma patients and the CLOVER-2 Phase 1b study for pediatric patients with high grade gliomas. Adverse events across all studies have been largely restricted to fatigue (39%), and cytopenias; specifically, thrombocytopenia (75%), anemia (61%), neutropenia (54%), leukopenia (56%), and lymphopenia (34%). Fatalities have occurred in patients post-treatment with iopofosine.

The CLOVER-WaM pivotal Phase 2b study completed enrollment of WM patients that have received at least two previous lines of therapy including those that failed or had a suboptimal response to a BTKi therapy in 4Q 2023. Topline safety data was reported on 45 patients meeting the criteria for the mITT population with a data cut-off date of January 3, 2024. Topline efficacy evaluable population (n=41) was defined as patients who were in the mITT and had follow up of at least 60 days post last dose. The CLOVER-WaM study met its primary endpoint with a MRR of 61% (95% confidence interval [44.50%, 75.80%, two-sided p value < 0.0001]) exceeding the agreed-upon statistical hurdle of 20%. The ORR in evaluable patients was 75.6%, and 100% of patients experienced disease control. Responses were durable, with median duration of response not reached and 76% of patients remaining progression free at a median follow-up of eight months. These outcomes exceed real world data, which demonstrate a 4-12% MRR and a duration of response of approximately six months or less despite continuous treatment in a patient population that is less pretreated and not refractory to multiple classes of drugs. Notably, iopofosine monotherapy achieved a 7.3% complete remission (CR) rate in this highly refractory WM population. Iopofosine I 131 was well tolerated and its toxicity profile was consistent with the Company's previously reported safety data. There were no treatment-related adverse events (TRAEs) leading to discontinuation. The rates of Grade 3 or greater TRAEs observed in more than 10% of patients included thrombocytopenia (55%), neutropenia (37%), and anemia (26%). All patients recovered from cytopenias with no reported aplastic sequalae. Importantly, there were no clinically significant bleeding events, and the rate of febrile neutropenia was 2%. There were no treatment-related deaths in the study.

The CLOVER-1 Phase 2 study met the primary efficacy endpoints from the Part A dose-finding portion, conducted in r/r B-cell malignancies, and is now enrolling an MM and CNSL expansion cohort (Phase 2b). The Phase 2b study will evaluate highly refractory MM patients in triple class, quad- and penta-drug refractory patients, including post-BCMA immunotherapy patients and r/r CNSL

patients. The initial Investigational New Drug (IND) application was accepted by the FDA in March 2014 with multiple INDs submitted since that time. The Phase 1 study was designed to assess the compound's safety and tolerability in patients with r/r MM and to determine maximum tolerated dose (MTD) and was initiated in April 2015. The study completed enrollment and the final clinical study report is expected in the first half of 2025. Initiated in March 2017, the primary goal of the Phase 2a study was to assess the compound's efficacy in a broad range of hematologic cancers.

The CLOVER-2 Phase 1a pediatric study was conducted internationally at seven leading pediatric cancer centers. The study was an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of iopofosine in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). The maximum tolerated dose was determined to be greater than 60mCi/m^2 administered as a fractionated dose. CLOVER-2 Phase 1b study is an open-label, international dose-finding study evaluating two different doses and dosing regiments of iopofosine in r/r pediatric patients with high grade gliomas. These cancer types were selected for clinical, regulatory and commercial rationales, including the radiosensitive nature and continued unmet medical need in the r/r setting, and the rare disease determinations made by the FDA based upon the current definition within the Orphan Drug Act.

In December 2014, the FDA granted ODD for iopofosine for the treatment of MM. In 2018, the FDA granted ODD and RPDD for iopofosine for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma, and osteosarcoma. In May 2019, the FDA granted Fast Track Designation for iopofosine for the treatment of MM and in July 2019 for the treatment of DLBCL. In September 2019 iopofosine received ODD from the European Union for MM. In December 2019, the FDA and the European Union each granted ODD for iopofosine for the treatment of WM. In September 2023, the European Union granted PRIME designation for iopofosine for the treatment of r/r WM. The FDA granted Fast Track designation for iopofosine for the treatment of r/r LPL and WM in May 2020.

As the result of iopofosine's RPDD designation, we may be eligible to receive a priority review voucher (PRV) if the product receives approval for any of the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma, or osteosarcoma. The FDA may award PRV to sponsors of a product application for a RPDD that meet its specified criteria. The key criteria to receiving PRV is that the drug be approved for a rare pediatric disease and treat a serious or life-threatening manifestation of the disease or condition that primarily affects individuals under the age of 18. In order to receive a PRV, a sponsor must obtain approval of a "rare pediatric disease product application," which is a human drug application for prevention or treatment of a rare pediatric disease and which contains no active ingredient, including any ester or salt thereof, that has been approved by the FDA; is deemed eligible for priority review; is submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) or section 351(a) of the Public Health Service Act (PHSA); relies on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population; does not seek approval for an adult indication in the original rare pediatric disease application; and is approved after September 30, 2016. Under this program, a sponsor who receives an approval for a drug or biologic for a rare pediatric disease can receive a PRV that can be redeemed to receive a priority review of a subsequent marketing application for a different product. Additionally, the PRV's can be exchanged or sold to other companies so that the receiving company may use the voucher. Congress has only authorized the rare pediatric disease priority review voucher program until September 30, 2024. However, if a drug candidate receives RPDD before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026.

CLOVER-WaM: Phase 2 Pivotal Study in: Patients with r/r Waldenstrom's Macroglobulinemia

We participated in a Type C guidance meeting with the FDA in September 2020. The results of that guidance meeting provided us with an agreed upon path for conducting the CLOVER-WaM study; a single arm, pivotal study in WM patients that have received and relapsed or were refractory to two prior lines of therapy, including having failed or had a suboptimal response to BTKi therapy. WM is a rare, indolent, and incurable form of non-Hodgkin's lymphoma (NHL) that is composed of a patient population in need of new and better treatment options.

The study enrolled 65 WM patients who have received at least two prior lines of therapy, failed both lines of therapy including having failed or had a suboptimal response to a BTKi (i.e. ibrutinib). Patients in the trial received 4-doses of iopofosine over two cycles (cycle one: days 1, 15, and cycle two: days 57, 71) with each dose administered as a 15mCi/m^2 infusion. The primary endpoint of the trial is major response rate (MRR) defined as a partial response (a minimum of a 50% reduction in IgM) or better in patients that receive a minimum total body dose (TBD) of 60 mCi with secondary endpoints of treatment-free survival (treatment-free remission), duration of response and progression-free survival. An independent data monitoring committee (iDMC) performed an interim safety and futility evaluation on the first 10 patients enrolled. If three of the 10 patients experienced a Clinically Significant Toxicity (CST) then the dose would have been reduced to 12.5 mCi/m^2. We believe this design aligned with the feedback received from the FDA during the guidance meeting held in September 2020 and subsequent interactions. The FDA accepted the dose to be tested, our proposal for a safety and futility assessment to be conducted on the first 10 patients, the endpoint to be assessed, the statistical analysis plan and study size of approximately 50 patients in the mITT population ($\geq$60mCi TBD). Based upon this agreement, the pivotal study was initiated. The interim futility and safety assessment occurred in 2022 and the iDMC determined the study exceeded the futility threshold and that the CST threshold was not met, therefore the study should continue to enroll with no change to the dosing regimen. The study achieved full enrollment in the fourth quarter 2023 and topline safety data was reported on 45 patients meeting the criteria for the mITT population with a data cut-off date of January 3, 2024. Among mITT patients, median age was 71 years, median IgM level prior to treatment with iopofosine was 2,185, 90% were refractory to either a BTKi (18/36 50%) or anti-CD20 therapy (18/41 40%), with 26.7% multiclass refractory, and 80% of patients were previously treated with a BTKi therapy. Topline efficacy evaluable population (n=41) was defined as patients who were in the mITT and had follow up of at least 60 days post last dose. The CLOVER WaM study met its primary endpoint with a major response rate (MRR) of 61% (95% confidence interval [44.50%, 75.80%, two-sided p value < 0.0001]) exceeding the agreed upon statistical hurdle of 20%. The overall response rate (ORR) in evaluable patients was 75.6%, and 100% of patients experienced disease control. Responses were durable, with median duration of response not reached and 76% of patients remaining progression free at a median follow-up of eight months. These outcomes exceed real world data, which demonstrate a 4-12% MRR and a duration of response of approximately six months or less despite continuous treatment in a patient population that is less pretreated and not refractory to multiple classes of drugs. Notably, iopofosine monotherapy achieved an 7.3% complete remission (CR) rate in this highly refractory WM population. Iopofosine I 131 was well tolerated and its toxicity profile was consistent with the Company's previously reported safety data. There were no treatment-related adverse events (TRAEs) leading to discontinuation. The rates of Grade 3 or greater TRAEs observed in more than 10% of patients included thrombocytopenia (55%), neutropenia (37%), and anemia (26%). All patients recovered from cytopenias with no reported aplastic sequalae. Importantly, there were no clinically significant bleeding events, and the rate of febrile neutropenia was 2%. There were no treatment-related deaths in the study.

CLOVER-1: Phase 2 Study in Select B-Cell Malignancies

The Phase 2 CLOVER-1 study was an open-label study designed to determine the efficacy and safety of CLR 131 in select B-cell malignancies (multiple myeloma (MM), indolent chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), lymphoplasmacytic lymphoma (LPL)/Waldenstrom's macroglobulinemia (WM), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), DLBCL, and central nervous system lymphoma (CNSL) who have been previously treated with standard therapy for their underlying malignancy. As of March 2022, the study arms for CLL/SLL, LPL/WM, MZL, MCL, and DLBCL were closed. Dosing of patients varied by disease state cohort and was measured in terms of TBD.

In July 2016, we were awarded a $2,000,000 National Cancer Institute (NCI) Fast-Track Small Business Innovation Research grant to further advance the clinical development of iopofosine. The funds supported the Phase 2 study initiated in March 2017 to define the clinical benefits of iopofosine in r/r MM and other niche hematologic malignancies with unmet clinical need. These niche hematologic malignancies include CLL, SLL, MZL, LPL/WM and DLBCL. The study was conducted in approximately 10 U.S. cancer centers in patients with orphan-designated relapse or refractory hematologic cancers. The planned study enrollment was up to 80 patients.

The study's primary endpoint was clinical benefit response (CBR), with secondary endpoints of ORR, PFS, time to next treatment (TtNT), median Overall Survival (mOS), DOR and other markers of efficacy following patients receiving one of three TBDs of iopofosine (<50mCi, ~50mCi and >60mCi), with the option for a second cycle approximately 75-180 days later. Dosages were provided either as a single bolus or fractionated (the assigned dose level split into two doses) given day 1 and day 15. Over the course of the study the dosing regimen of iopofosine advanced from a single bolus dose to two cycles of fractionated administrations of 15 mCi/m^2 per dose on days 1, 15 (cycle 1), and days 57, 71 (cycle 2). Adverse events occurring in at least 25% of subjects were fatigue (39%) and cytopenias, specifically, thrombocytopenia (75%), anemia (61%), neutropenia (54%), leukopenia (51%), and lymphopenia (25%). Serious adverse events occurring in greater than 5% of subjects were restricted to thrombocytopenia (9%) and febrile neutropenia (7.5%).

Phase 2a Study: Patients with r/r Waldenstrom's Macroglobulinemia Cohort

Patients in the r/r WM cohort all received TBD of ≥ 60 mCi (25 mCi/m^2 single bolus, 31.25 mCi/m^2 fractionated, 37.5 mCi/m^2 fractionated, or two cycles of mCi/m^2 fractionated) either as a bolus dose or fractionated. Current data from our Phase 2a CLOVER-1 clinical study show a 100% ORR in six WM patients and an 83.3% major response rate with one patient achieving a complete response (CR), which reached 39 months post-last treatment. While median treatment free survival (TFS), also known as treatment free remission (TFR), and DOR have not been reached, the average treatment TFS/TFR is currently at 330 days. We believe this may represent an important improvement in the treatment of r/r WM as we believe no approved or late-stage development treatments for second- and third-line patients have reported a CR to date. Based on study results to date, patients continue to tolerate iopofosine well, with the most common adverse events being cytopenias and fatigue.

Phase 2a Study: Patients with r/r Multiple Myeloma Cohort

In September 2020, we announced that a 40% ORR was observed in the subset of refractory MM patients deemed triple class refractory who received 60 mCi or greater TBD. Triple class refractory is defined as patients that are refractory to immunomodulatory, proteasome inhibitors and anti-CD38 antibody drug classes. The 40% ORR (6/15 patients) represents triple class refractory patients enrolled in Part A of Cellectar's CLOVER-1 study and additional patients enrolled in Part B from March through May 2020 and received ≥60mCi TBD (25 mCi/m2 single bolus, 31.25 mCi/m2 fractionated, 37.5 mCi/m2 fractionated, or two cycles of mCi/m2 fractionated) either as a bolus dose or fractionated. Patients with MM received 40 mg of dexamethasone concurrently beginning within 24 hours of the first CLR 131 infusion. All MM patients enrolled in the expansion cohort are required to be triple class refractory. The additional six patients enrolled in 2020 were heavily pre-treated with an average of nine prior multi-drug regimens. Three patients received a TBD of ≥ 60 mCi and three received less than 60 mCi. Consistent with the data released in February 2020, patients receiving ≥ 60 mCi typically exhibit greater responses. Based on study results to date, patients continue to tolerate iopofosine well, with the most common and almost exclusive treatment-emergent adverse events are cytopenias, such as thrombocytopenia, neutropenia, and anemia.

In December 2021, we presented data from 11 MM patients from our ongoing Phase 2 CLOVER-1 study in a poster at the American Society of Hematology (ASH) Annual Meeting and Exposition. The MM patients were at least triple class refractory (defined as refractory to an immunomodulatory agent, proteasome inhibitor and monoclonal antibody) with data current as of May 2021. Patients had a median of greater than 7 prior therapies with 50% classified as high risk. Initial results in these patients showed an ORR of 45.5%, a CBR of 72.7%, and a disease control rate (DCR) of 100%. Median PFS was 3.4 months. In a subset of five quad/penta drug refractory patients, efficacy increased, demonstrating an ORR of 80% and CBR of 100% in this highly treatment refractory group. The most commonly observed treatment emergent adverse events were cytopenias that included Grade 3 or 4 thrombocytopenia (62.5%), anemia (62.5%), neutropenia (62.5%) and decreased white blood cell count (50%). Treatment emergent adverse events were mostly limited to bone marrow suppression in line with prior observations. No patients experienced treatment emergent adverse events of neuropathy, arrhythmia, cardiovascular event, bleeding, ocular toxicities, renal function, alterations in liver enzymes, or infusion-site reactions or adverse events. We continue to enrich the r/r MM patient cohort with patients that are even more refractory, specifically enrolling patients that are quad-class refractory (triple class plus refractory to any of the recent approved product classes) and have relapsed post-BCMA immunotherapy. We reported in the Blood Cancer Journal in August 2022 that iopofosine demonstrated a 50% ORR in patients receiving ≥60mCi total administered dose (3/6 patients).

Phase 2a: Patients with r/r non-Hodgkin's lymphoma Cohort

In February 2020, we announced positive data from our Phase 2a CLOVER-1 study in patients with NHL patients were treated with three different doses (<50mCi, ~50mCi and ≥60mCi TBD. Patients in the r/r NHL cohort received TBD of either ≥ 60 mCi or < 60 mCi (25 mCi/m2 single bolus, 31.25 mCi/m2 fractionated, 37.5 mCi/m2 fractionated, or two cycles of mCi/m2 fractionated) either as a bolus dose or fractionated. Patients with r/r NHL who received <60mCi TBD and the ≥60mCi TBD had a 42% and 43% ORR, respectively and a combined rate of 42%. These patients were also heavily pre-treated, having a median of three prior lines of treatment (range, 1 to 9) with the majority of patients being refractory to rituximab and/or ibrutinib. The patients had a median age of 70 with a range of 51 to 86. All patients had bone marrow involvement with an average of 23%. In addition to these findings, subtype assessments were completed in the r/r B-cell NHL patients. Patients with DLBCL demonstrated a 30% ORR with one patient achieving a CR, which continues at nearly 24 months post-treatment. The ORR for CLL/SLL and MZL patients was 33%.

Based upon the dose response observed in the Phase 2a study for patients receiving TBDs of 60mCi or greater, we determined that patient dosing of iopofosine in the pivotal study would be ≥60mCi TBD. Therefore, patients are now grouped as receiving <60mCi or ≥60mCi TBD.

The most frequently reported adverse events in all patients were cytopenias, which followed a predictable course and timeline. The frequency of adverse events did not increase as doses were increased and the profile of cytopenias remained consistent. Importantly, our assessment is that these cytopenias have had a predictable pattern to initiation, nadir and recovery and are treatable. The most common grade ≥3 events at the highest dose (75mCi TBD) were hematologic toxicities including thrombocytopenia (65%), neutropenia (41%), leukopenia (30%), anemia (24%) and lymphopenia (35%). No patients experienced cardiotoxicities, neurological toxicities, infusion site reactions, peripheral neuropathy, allergic reactions, cytokine release syndrome, keratopathy, renal toxicities, or changes in liver enzymes. The safety and tolerability profile in patients with r/r NHL was similar to r/r MM patients except for fewer cytopenias of any grade. Based upon iopofosine being well tolerated across all dose groups, the observed response rate, and especially in difficult to treat patients such as high risk and triple class refractory or penta-refractory, and corroborating data showing the potential to further improve upon current ORRs and durability of those responses, the study has been expanded to test a two-cycle dosing optimization regimen with a target TBD ≥60 mCi/m^2 of iopofosine.

In May 2020, we announced that the FDA granted Fast Track Designation for iopofosine in WM in patients having received two or more prior treatment regimens.

Phase 1 Study in Patients with r/r Multiple Myeloma

In February 2020, final results from a multicenter, Phase 1 dose escalation clinical trial of iopofosine in r/r MM were presented. The trial was designed to evaluate the safety and potential initial efficacy of iopofosine administered in an up to 30-minute I.V. infusion either as a single bolus dose or as a fractionated dose in heavily pretreated MM patients. The study enrolled a total of 26 evaluable patients at three trial sites. For the trial, which used a modified three-plus-three dose escalation design, 15 evaluable patients were dosed in single bolus doses from 12.5mCi/m2 up to 31.25mCi/m2 (TBD 20.35-59.17 mCi) and 11 evaluable patients were dosed in fractionated dosing cohorts of 31.25mCi/m2 to 40mCi/m2 (TBD 54.915-89.107 mCi). An iDMC did not identify dose-limiting toxicities in any cohort. Of the 26 evaluable patients in the trial, a partial response was observed in 4 of 26 patients (15.4%) and stable disease or minimal response in 22 of 26 patients (84.6%), for a disease control rate of 100%. A significant decrease in M-protein and free light chain (FLC) was also observed.

Iopofosine in combination with dexamethasone was under investigation in adult patients with r/r MM. MM is an incurable cancer of the plasma cells and is the second most common form of hematologic cancer. Patients had to be refractory to or relapsed from at least one proteasome inhibitor and at least one immunomodulatory agent. The clinical study was a standard three-plus-three dose escalation safety study to determine the maximum tolerable dose. We use the International Myeloma Working Group (IMWG) definitions of response, which involve monitoring the surrogate markers of efficacy, M protein and FLC. The IMWG defines a PR as a 50% or greater decrease in M protein or to 50% or greater decrease in FLC levels (for patients in whom M protein is unmeasurable). Secondary objectives included the evaluation of therapeutic activity by assessing surrogate efficacy markers, which include M protein, FLC, PFS and OS. All patients were heavily pretreated with an average of five prior lines of therapy. An iDMC assessed the safety of iopofosine up to its planned maximum single, bolus dose of 31.25 mCi/m^2 or a TBD of ~63 mCi. The four single dose cohorts examined were: 12.5 mCi/m^2 (~25mCi TBD), 18.75 mCi/m^2 (~37.5mCi TBD), 25 mCi/m^2(~50mCi TBD), and 31.25 mCi/m^2(~62.5mCi TBD), all in combination with low dose dexamethasone (40 mg weekly). Of the five patients in the first cohort, four were assessed as achieving stable disease and one patient progressed at Day 15 after administration and was taken off the study. Of the five patients admitted to the second cohort, all five were assessed as achieving stable disease; however, one patient progressed at Day 41 after administration and was taken off the study. Four patients were enrolled to the third cohort, and all were assessed as achieving stable disease. In September 2017, we announced safety and tolerability data for cohort 4, in which patients were treated with a single infusion up to 30-minutes of 31.25mCi/m^2 of iopofosine, which was tolerated by the three patients in the cohort. Additionally, all three patients experienced CBR with one patient achieving a partial response (PR). The patient experiencing a PR had an 82% reduction in FLC. This patient did not produce M protein, had received seven prior lines of treatment including radiation, stem cell transplantation and multiple triple combination treatments including one with daratumumab that was not tolerated. One patient experiencing stable disease attained a 44% reduction in M protein. In January 2019, we announced that the pooled mOS data from the first four cohorts was 22.0 months. In late 2018, we modified this study to evaluate a fractionated dosing strategy to potentially increase efficacy and decrease adverse events.

Cohorts five and six received fractionated dosing of 31.25 mCi/m^2(~62.5mCi TBD) and 37.5 mCi/m^2 (~75mCi TBD), each administered on day 1 and day 8. Following the determination that all prior dosing cohorts were tolerated, we initiated a cohort seven utilizing a 40mCi/m2 (~95mCi TBD) fractionated dose administered 20mCi/m2 (~40mCi TBD) on days 1 and day 8. Cohort seven was the highest pre-planned dose cohort and subjects have completed the evaluation period. The study completed enrollment and the final clinical study report is expected in the first half of 2022. Adverse events occurring in at least 25% of subjects were fatigue (26%) and cytopenias, specifically, thrombocytopenia (90%), anemia (65%), neutropenia (55%), leukopenia (61%), and lymphopenia (58%). Serious adverse events occurring in greater than two subjects were restricted to febrile neutropenia n=3 (9.7%).

In May 2019, we announced that the FDA granted Fast Track Designation for iopofosine in fourth line or later r/r MM. Iopofosine is currently being evaluated in our ongoing CLOVER-1 Phase 2 clinical study in patients with r/r MM and other select B-cell lymphomas. Patients in the study received up to four, approximately 20-minute, IV infusions of iopofosine over 3 months, with doses given 14 days apart in each cycle and a maximum of two cycles. Low dose dexamethasone 40 mg weekly (20mg in patients ≥ 75), was provided for up to 12 weeks. The planned study enrollment was up to 80 patients. Its primary endpoint was clinical benefit rate (CBR), with additional endpoints of ORR, PFS, median overall survival (OS) and other markers of efficacy. Over the course of the study the dosing regimen of iopofosine advanced from a single bolus dose to two cycles of fractionated administrations of 15 mCi/m2 per dose on days 1, 15 (cycle 1), and days 57, 71 (cycle 2). Following treatment with iopofosine, approximately 91% of patients experience a reduction in tumor marker with approximately 73% experiencing greater than 37% reduction.

CLOVER 2: Phase 1 Study in r/r Pediatric Patients with select Solid tumors, Lymphomas and Malignant Brain Tumors

In December 2017, the Division of Oncology at the FDA accepted our IND and study design for the Phase 1 study of iopofosine in children and adolescents with select rare and orphan designated cancers. This study was initiated during the first quarter of 2019. In December 2017, we submitted an IND application for r/r pediatric patients with select solid tumors, lymphomas and malignant brain tumors. The Phase 1 clinical study of iopofosine is an open-label, sequential-group, dose-escalation study evaluating the safety and tolerability of intravenous administration of iopofosine in children and adolescents with relapsed or refractory malignant solid tumors (neuroblastoma, Ewing's sarcoma, osteosarcoma, rhabdomyosarcoma) and lymphoma or recurrent or refractory malignant brain tumors for which there are no standard treatments. Secondary objectives of the study are to identify the recommended efficacious dose of iopofosine and to determine preliminary antitumor activity (treatment response) of iopofosine in children and adolescents.

In August 2020, based on data on four dose levels from 15mCi/m^2 up to 60mCi/m2, the iDMC permitted the beginning of the evaluation of the next higher dose cohort, at 75mCi/m2. The iDMC advised, based upon the initial data, to enrich the 60 mCi/m2 dose level for patients over the age of 10 with HGG and Ewing sarcoma. Changes in various tumor parameters appeared to demonstrate initial response and tumor uptake. This includes patients with relapsed HGGs with over five months of PFS. In November 2020, we announced clinical data providing that iopofosine had been measured in pediatric brain tumors, confirming that systemic administration of iopofosine crosses the blood brain barrier and is delivered into tumors and that the data show disease control in heavily pretreated patients with ependymomas. In November 2021, we announced favorable data on changes in various tumor parameters in a Phase 1 study in children and adolescents with relapsed and refractory high-grade gliomas (HGGs) and soft tissue sarcomas. Pediatric HGGs are a collection of aggressive brain and central nervous system tumor subtypes (i.e. diffuse intrinsic pontine gliomas, glioblastomas, astrocytomas, ependymomas, etc.) with about 400 new pediatric cases diagnosed annually in the U.S. Children with these tumors have a poor prognosis and limited 5-year survival. Adverse events occurring in at least 25% of subjects were fatigue, headache, nausea and vomiting (28% respectively), and cytopenias, specifically, thrombocytopenia (67%), anemia (67%), neutropenia (61%), leukopenia (56%), and lymphopenia (33%). There were no serious adverse events occurring in more than 2 subjects. The Part A portion of this Phase 1 study has concluded, and part B has initiated to determine the appropriate dosing regimen in pediatric patients with r/r HGG. In 2022, the NCI awarded Cellectar a $1,900,000 SBIR Phase 2 grant to explore iopofosine in pediatric HGG.

In 2018, the FDA granted ODD and RPDD for iopofosine for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. If iopofosine should be approved for any of these pediatric indications, the first approved RPDD would enable us to receive a priority review voucher. Priority review vouchers can be used by the sponsor to receive priority review for a future New Drug Application (NDA) or Biologic License Application (BLA) submission, which would reduce the FDA review time from 12 months to six months. Currently, these vouchers can also be transferred or sold to another entity. In December 2020, the FDA extended the Priority Review Voucher Program through September 2026 for rare pediatric diseases.

Phase 1 Study in r/r Head and Neck Cancer

In August 2016, the University of Wisconsin Carbone Cancer Center (UWCCC) was awarded a five-year Specialized Programs of Research Excellence (SPORE) grant of $12,000,000 from the NCI and the National Institute of Dental and Craniofacial Research to improve treatments and outcomes for head and neck cancer (HNC) patients. HNC is the sixth most common cancer across the world with approximately 56,000 new patients diagnosed every year in the U.S. As a key component of this grant, the UWCCC researchers completed testing of iopofosine in various animal HNC models and initiated the first human clinical study enrolling up to 30 patients combining iopofosine and external beam radiation treatment (EBRT) with recurrent HNC in the fourth quarter of 2019. UWCCC has completed the part A portion of a safety and tolerability study of iopofosine in combination with EBRT and preliminary data suggest safety and tolerability in relapsed or refractory HNC. The reduction in the amount or fractions (doses) of EBRT has the potential to diminish the (number and severity of) adverse events associated with EBRT. Patients with HNC typically receive approximately 60-70 Grays (Gy) of EBRT given as 2 – 3 Gy daily doses over a six-week timeframe. Patients can experience long-term tumor control following re-irradiation in this setting; however, this approach can cause severe injury to normal tissue structures, significant adverse events and diminished quality of life. Part B of the study was to assess the safety and potential benefits of iopofosine in combination with EBRT in a cohort of up to 24 patients. This portion of the study has fully enrolled, and data were reported at the ASTRO 2024 conference on March 2, 2024. Complete remission was achieved in 64% of patients, with an ORR of 73% (n=11). Prior to treatment with iopofosine I 131, six patients had multiple recurrence and one had metastatic disease, both of which are indicative of poor outcomes. Additionally, the study demonstrated durability of tumor control with an overall survival of 67% and progression free survival of 42% at 12 months. Eleven patients (92%) experienced a treatment-related adverse event. Treatment-related adverse events of grade 3 or higher occurring in 20% or more patients were thrombocytopenia (75%), lymphopenia (75%), leukopenia (75%), neutropenia (67%), and anemia (42%). Observed adverse events were consistent with the known toxicity profile of iopofosine I 131, with cytopenias being the most common. All patients recovered. We believe that these data support the notion of enhanced patient outcomes when combining the use of iopofosine I 131 in combination with external beam radiation for a treatment of solid tumors.

Preclinical Pipeline

We believe our PDC platform has potential to provide targeted delivery of a diverse range of oncologic payloads, as exemplified by the product candidates listed below, that may result in improvements upon current standard of care (SOC) for the treatment of a broad range of human cancers:

- CLR 12120 Series is an alpha emitting radio-conjugate program. The company has validated the *in vivo* potential of alpha emitting phospholipid radioconjugates and their potential to treat highly refractory and difficult to treat solid tumors. Cellectar is currently progressing with a lead molecule using actinium-225 as the alpha emitting payload.

- The company has developed a series of proprietary small molecule phospholipid drug conjugates. These programs employ either novel payload or novel linkers. Many of these molecules have demonstrated efficacy and tolerability in preclinical mouse models. The collaboration with IntoCell Inc. successfully met its agreed upon endpoint. The collaboration provided significant data which has led Cellectar to select a series of highly potent cytotoxic small molecule payloads for further development.

- In collaboration with other parties, Cellectar has also validated that the PLE is capable of delivering peptide payloads and oligonucleotide (siRNA, mRNA, etc.) payloads to the tumors when delivered systemically. These molecules have also been shown to demonstrate activity and safety in multiple preclinical mouse models. Based upon these collaborations and the data, the company has initiated internal proprietary programs with each of these treatment modalities.

Results of Operations

Research and development expenses. Research and development expenses consist of costs incurred in identifying, developing and testing, and manufacturing product candidates, which primarily include salaries and related expenses for personnel, cost of manufacturing materials and contract manufacturing fees paid to contract manufacturers and contract research organizations, fees paid to medical institutions for clinical studies, and costs to secure intellectual property. The Company analyzes its research and development expenses based on four categories as follows: clinical project costs, preclinical project costs, manufacturing and related costs, and general research and development costs that are not allocated to the functional project costs, including personnel costs, facility costs, related overhead costs and patent costs.

General and administrative expenses. General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance and administrative functions. Other costs include insurance, costs for public company activities, investor relations, directors' fees and professional fees for legal and accounting services.

Other income (expense), net. Other income (expense), net, consists primarily of the impacts related to issuing and revaluing equity securities, and interest income.

Three Months Ended September 30, 2024 and 2023

Research and Development. Research and development expenses for the three months ended September 30, 2024, were approximately $5,493,000, compared to approximately $7,035,000 for the three months ended September 30, 2023.

The following table is a summary comparison of approximate research and development costs for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		
	2024	**2023**	**Variance**
Clinical project costs	$ 1,510,000	$ 3,412,000	$ (1,902,000)
Manufacturing and related costs	2,469,000	2,832,000	(363,000)
Pre-clinical project costs	49,000	206,000	(157,000)
General research and development costs	1,465,000	585,000	880,000
	$ 5,493,000	$ 7,035,000	$ (1,542,000)

The overall decrease in research and development expense of approximately $1,542,000, or 22%, was primarily a result of decreased clinical project costs of approximately $1,902,000, driven by the conclusion of patient enrollment in our WM pivotal study having occurred earlier in the year, partially offset by increased activity in our ongoing pediatric trial and an increase in personnel.

General and administrative. General and administrative expense for the three months ended September 30, 2024, was approximately $7,834,000, compared to approximately $2,379,00 for the same period in 2023. The overall increase in general and administrative expense of approximately $5,455,000, or 229%, was driven by costs associated with the development of infrastructure necessary to support commercialization upon anticipated NDA approval, including the related market preparation and personnel cost.

Other income (expense), net. Other income (expense), net, for the three months ended September 30, 2024, was an expense of approximately $1,337,000, as compared to approximately $8,107,000 of expense in the same period of 2023, resulting almost exclusively from changes in warrant valuation. Fluctuations in the Company's common stock price are the primary aspect of warrant valuation changes. Interest income increased year-over-year to approximately $318,000 in 2024 as compared to approximately $51,000 in 2023. The Company's cash on hand and increased interest rates drove the improved return.

Nine Months Ended September 30, 2024 and 2023

Research and Development. Research and development expense for the nine months ended September 30, 2024, was approximately $19,927,000, compared to approximately $19,529,000 for the nine months ended September 30, 2023.

The following table is a summary comparison of approximate research and development costs for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		
	2024	2023	Variance
Clinical project costs	$ 8,154,000	$ 10,235,000	$ (2,081,000)
Manufacturing and related costs	8,410,000	7,007,000	1,403,000
Pre-clinical project costs	101,000	422,000	(321,000)
General research and development costs	3,262,000	1,865,000	1,397,000
	$ 19,927,000	$ 19,529,000	$ 398,000

The overall increase in research and development expenses of approximately $398,000, or 2%, was primarily a result of increased manufacturing and related costs of approximately $1,403,000 related to production sourcing and an increase in general research and development costs related to an increase in personnel. These increases were largely offset by a reduction in clinical project costs of approximately $2,081,000, resulting from the timing of the patient enrollment related to our pivotal WM trial.

General and administrative. General and administrative expense for the nine months ended September 30, 2024, was approximately $19,106,000, compared to approximately $6,884,000 for the same period in 2023. The overall increase in general and administrative expense of $12,222,000, or 178%, was primarily driven by costs associated with the development of infrastructure necessary to support commercialization upon anticipated NDA approval, including the related market preparation and personnel costs.

Other income (expense), net. Other income (expense), net, for the first nine months of 2024 was an expense of approximately $3,193,000, while the expense for the same period in 2023 was approximately $8,477,000. A significant portion of the expense comes from changes in the valuation of the Company's outstanding warrants. Warrant valuation consists of a number of aspects, but the most significant driver is the value at which the Comapany's common stock is trading at the end of each reporting period. Interest income was approximately $967,000 year-to-date in 2024, and approximately $248,000 in 2023. The Company's improved return on cash equivalents is a product of higher average cash balance and a higher interest rate environment.

Liquidity and Capital Resources

We have incurred losses since inception in devoting substantially all of our efforts toward research and development of drug candidates for which we are seeking FDA approval. During the nine months ended September 30, 2024, we generated a net loss of approximately $42.2 million and used approximately $36.7 million in cash for operations. We expect that we will continue to generate operating losses for the foreseeable future. As of September 30, 2024, our consolidated cash balance was approximately $34.3 million. As of the date the accompanying consolidated financial statements were issued (the "issuance date"), the Company's available liquidity to fund the Company's operations over the next twelve months beyond the issuance date was limited to approximately $28.6 million of unrestricted cash and cash equivalents. Absent further action taken by management to increase its liquidity, the Company may be unable to fund its operations under normal course beyond the second quarter of 2025. To improve the Company's liquidity, management plans to secure additional outside capital via the sale of equity and/or debt securities or execute a strategic transaction. Management also plans to preserve liquidity, as needed, by implementing temporary cost saving measures. While management believes their plans will be successful, no assurance can be provided such plans will be effectively implemented over the next twelve months beyond the issuance date. In the event management's plans are not effectively implemented, the Company will be required to seek other alternatives which may include, among others, the sale of assets, discontinuance of certain operations, and/or filing for bankruptcy protection.

These uncertainties raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on the basis that the Company will continue to operate as a going concern, which contemplates it will be able to realize assets and settle liabilities and commitments in the normal course of business for the foreseeable future. Accordingly, the accompanying consolidated financial statements do not include any adjustments that may result from the outcome of these uncertainties.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision, and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), in connection with the period ending March 31, 2024. Based on that evaluation, management has concluded that as of the respective period, our disclosure controls and procedures were not effective due to the material weaknesses in internal control over financial reporting described below.

Notwithstanding the material weaknesses in our internal control over financial reporting, management has concluded that the audited consolidated financial statements included in this Form 10-Q/A fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States of America.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act for the Company. Management assessed the effectiveness of internal control over financial reporting as of the year ended December 31, 2023. In making this assessment, our management used the criteria set forth in the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO Framework"). Based on this evaluation, our management concluded that our internal control over financial reporting was not effective as of December 31, 2023, continuing through September 30, 2024, because of the material weaknesses described below.

Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or interim consolidated financial statements would not be prevented or detected on a timely basis.

Management concluded that material weaknesses existed as of the year ended December 31, 2023. Specifically, management identified deficiencies in the principles associated with the control environment, risk assessment, control activities, information and communication and monitoring components of internal control, based on the criteria established by the COSO Framework, that constitute material weaknesses, either individually or in the aggregate.

- Control Environment: The Company lacked appropriate policies and resources to develop and operate effective internal control over financial reporting, which contributed to the Company's inability to properly analyze, record and disclose accounting matters accurately and timely. This was further impacted by the limited number of staff in the Company's accounting and finance function. This material weakness contributed to additional material weaknesses further described below.

- Risk Assessment: The Company does not have a formal process to identify, update, and assess risks, including risks around the accounting for complex transactions, that could significantly impact the design and operation of the Company's control activities.

- Control Activities: Management did not design and implement effective control activities and identified the following material weaknesses:
    - Management failed to design and implement adequate internal controls over financial reporting which resulted in the inaccurate accounting of preferred equity and warrants
    - Management failed to design and implement adequate internal controls over the recording of stock-based compensation expense related to the restricted stock awards granted in December 2023.
    - Management failed to design and implement adequate internal controls over financial reporting as it relates to the proper fair value methodologies and assumptions used to value financial instruments, specific to the assumptions utilized in the valuation of the preferred warrants.
- Information and Communication: As noted above, the Company had a limited number of staff in its finance and accounting function, and therefore was unable to design and maintain appropriate segregation of duties in the initiation, recording, and approval of transactions within its financial systems. This, coupled with management having not designed and maintained user access controls that adequately restrict user and privileged access to financial applications, and the absence of sufficient other mitigating controls, created a segregation of duties deficiencies.
- Monitoring Activities: Management did not appropriately select, develop, and perform ongoing evaluations to ascertain whether the components of internal controls are present and functioning

  These material weaknesses resulted in errors that required the restatement of the Company's consolidated financial statements as of and for the fiscal years ended December 31, 2023 and December 31, 2022, as well as the restatement of the Company's condensed consolidated financial statements as of and for the interim periods ended September 30, 2023, June 30, 2023, March 31, 2023, September 30, 2022, June 30, 2022, and March 31, 2022. Additionally, these material weaknesses could result in a misstatement of the account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or timely detected.

Management's Plan to Remediate the Material Weaknesses

The process of designing and maintaining effective internal control over financial reporting is a continuous effort that requires management to anticipate and react to changes in our business, economic and regulatory environments and to expend significant resources. In early 2024, the Company began recruiting and hired qualified accounting and financial reporting personnel to supplement our level of knowledge and experience with internal control over financial reporting in order to begin to design and implement a formal control environment and risk assessment process. Such process includes identification of risks, the level of detail in our risk assessment, and the clarity of the linkage between risks and internal controls. The results of this effort are expected to enable us to effectively identify, develop, evolve and implement controls and procedures to address risks. Additionally, the Company has also initiated the implementation of an ERP system, which will provide a system-based control structure for all financial transactions.

As our remediation efforts are still on-going, we will continue to consider the need for additional resources and implement further enhancements to our policies and procedures as necessary to further improve our internal control over financial reporting. As we work to improve our internal control over financial reporting, we may modify our remediation plan and may implement measures as we continue to review, optimize and enhance our financial reporting controls and procedures in the ordinary course. The material weaknesses will not be considered remediated until the remediated controls have been operating for a sufficient period of time and can be evidenced through testing that these are operating effectively.

Changes in Internal Control over Financial Reporting

Except for the identification of the material weaknesses described above, there has been no change in our internal control over financial reporting during the period ended September 30, 2024, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We may be a party to proceedings in the ordinary course of business, however, we do not anticipate that the outcome of such matters and disputes will materially affect our financial statements.

Item 1A. Risk Factors

Other factors that could materially adversely affect our business and our equity securities are described in the Risk Factors previously disclosed in Form 10-K/A, our Annual Report filed with the SEC on October 28, 2024, pursuant to Section 13 or 15(d) of the Exchange Act. That information should be considered carefully, together with other information in this report and other reports and materials we file with the SEC.

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

None.

Item 3. Default Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Description	Filed with this Form 10-Q	Incorporation by Reference		
			Form	Filing Date	Exhibit No.
10.1	Cellectar Biosciences, Inc. 2021 Stock Incentive Plan, as Amended		8-K	June 29, 2023	10.1
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
101	Interactive Data Files	X			
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit).	X			

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CELLECTAR BIOSCIENCES, INC.

Date: November 18, 2024

By: */s/ James V. Caruso*
James V. Caruso
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 18, 2024

By: */s/ Chad J. Kolean*
Chad J. Kolean
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

I, JAMES V. CARUSO, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cellectar Biosciences, Inc., a Delaware Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 18, 2024

/s/ James V. Caruso
James V. Caruso
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

I, CHAD J. KOLEAN, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cellectar Biosciences, Inc., a Delaware Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 18, 2024

/s/ Chad J. Kolean
Chad J. Kolean
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. § 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Cellectar Biosciences, Inc. (the "Company") for the quarter ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, James V. Caruso, President and Chief Executive Officer of the Company, and Chad J. Kolean, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to our knowledge, that:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James V. Caruso
James V. Caruso
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 18, 2024

/s/ Chad J. Kolean
Chad J. Kolean
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: November 18, 2024