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, 2021

☐ 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: 61,101,264 shares of common stock, $0.00001 par value per share, as of November 5, 2021.

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 future impacts of the COVID-19 pandemic on our business, employees, operating results, ability torecruit patients for clinical studies, ability to obtain additional funding, product development programs, research and development programs, suppliers and third-party manufacturers;
- 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 foriopofosine 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. foriopofosine 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 ofiopofosine;
- our ability to pursue strategic alternatives;
- 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, including 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;
- 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" 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. We qualify all of the information presented in this report, and particularly our forward-looking statements, by these cautionary statements.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 40,344,727	$ 57,165,377
Prepaid expenses and other current assets	1,048,082	774,432
Total current assets	41,392,809	57,939,809
Fixed assets, net	254,041	355,982
Right-of-use asset, net	225,205	282,365
Long-term assets	75,000	75,000
Other assets	6,214	6,214
TOTAL ASSETS	$ 41,953,269	$ 58,659,370
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 3,034,489	$ 3,443,197
Lease liability	131,406	119,904
Total current liabilities	3,165,895	3,563,101
Long-term lease liability	201,970	301,740
TOTAL LIABILITIES	3,367,865	3,864,841
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.00001 par value; 7,000 shares authorized; Series C preferred stock: 0 and 215 issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	—	1,148,204
Series D preferred stock: 111 and 1,519 issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	1,382,023	18,887,645
Common stock, $0.00001 par value; 160,000,000 and 80,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 61,101,264 and 45,442,729 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	611	454
Additional paid-in capital	182,182,461	161,533,653
Accumulated deficit	(144,979,691)	(126,775,427)
Total stockholders' equity	38,585,404	54,794,529
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 41,953,269	$ 58,659,370

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,	
	2021	**2020**	**2021**	**2020**
COSTS AND EXPENSES:				
Research and development	$ 3,937,464	$ 2,683,944	$ 13,198,294	$ 7,765,673
General and administrative	1,882,190	1,225,993	5,009,581	3,725,153
Total costs and expenses	5,819,654	3,909,937	18,207,875	11,490,826
LOSS FROM OPERATIONS	(5,819,654)	(3,909,937)	(18,207,875)	(11,490,826)
OTHER INCOME:				
Interest income, net	590	374	3,611	11,730
Total other income	590	374	3,611	11,730
NET LOSS	$ (5,819,064)	$ (3,909,563)	$ (18,204,264)	$ (11,479,096)
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	$ (0.10)	$ (0.15)	$ (0.34)	$ (0.69)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	59,868,374	26,326,782	53,633,421	16,539,183

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

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(UNAUDITED)

	Preferred Stock		Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Par Amount	Paid-In Capital	Deficit	Equity
BALANCE AT DECEMBER 31, 2019	215	$ 1,148,204	9,386,689	$ 94	$ 119,592,366	$ (111,681,255)	$ 9,059,409
Stock-based compensation	—	—	—	—	144,146	—	144,146
Vested restricted stock	—	—	9,334	—	—	—	—
Retired shares	—	—	(8)	—	—	—	—
Net loss	—	—	—	—	—	(3,957,608)	(3,957,608)
BALANCE AT MARCH 31, 2020	215	$ 1,148,204	9,396,015	$ 94	$ 119,736,512	$ (115,638,863)	$ 5,245,947
Issuance of common stock and warrants, net of issuance costs	—	—	14,601,628	146	18,258,435	—	18,258,581
Stock-based compensation	—	—	—	—	92,643	—	92,643
Conversion of warrants for common shares	—	—	1,474,740	14	—	—	14
Net loss	—	—	—	—	—	(3,611,925)	(3,611,925)
BALANCE AT JUNE 30, 2020	215	$ 1,148,204	25,472,383	$ 254	$ 138,087,590	$ (119,250,788)	$ 19,985,260
Stock-based compensation	—	—	—	—	116,292	—	116,292
Conversion of warrants for common shares	—	—	1,341,210	14	31,697	—	31,711
Net loss	—	—	—	—	—	(3,909,563)	(3,909,563)
BALANCE AT SEPTEMBER 30, 2020	215	$ 1,148,204	26,813,593	$ 268	$ 138,235,579	$ (123,160,351)	$ 16,223,700
BALANCE AT DECEMBER 31, 2020	1,734	$ 20,035,849	45,442,729	$ 454	$ 161,533,653	$ (126,775,427)	$ 54,794,529
Stock-based compensation	—	—	—	—	124,564	—	124,564
Conversion of preferred shares for common shares	(789)	(8,288,652)	6,278,236	63	8,288,589	—	—
Exercise of warrants for common shares	—	—	1,005,320	10	1,213,914	—	1,213,924
Retired shares	—	—	(7)	—	—	—	—
Net loss	—	—	—	—	—	(6,357,170)	(6,357,170)
BALANCE AT MARCH 31, 2021	945	$ 11,747,197	52,726,278	$ 527	$ 171,160,720	$ (133,132,597)	$ 49,775,847
Stock-based compensation	—	—	—	—	200,617	—	200,617
Conversion of preferred shares for common shares	(250)	(3,109,552)	2,500,000	25	3,109,527	—	—
Issuance of common stock, net of issuance costs	—	—	41,692	1	34,872	—	34,873
Retired shares	—	—	(39)	—	—	—	—
Net loss	—	—	—	—	—	(6,028,030)	(6,028,030)
BALANCE AT JUNE 30, 2021	695	$ 8,637,645	55,267,931	$ 553	$ 174,505,736	$ (139,160,627)	$ 43,983,307
Stock-based compensation	—	—	—	—	421,161	—	421,161
Conversion of preferred shares for common shares	(584)	(7,255,622)	5,833,333	58	7,255,564	—	—
Net loss	—	—	—	—	—	(5,819,064)	(5,819,064)
BALANCE AT SEPTEMBER 30, 2021	111	1,382,023	61,101,264	$ 611	$ 182,182,461	$ (144,979,691)	$ 38,585,404

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,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (18,204,264)	$ (11,479,096)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	110,624	105,529
Stock-based compensation expense	746,342	353,081
Noncash lease expense	57,160	48,859
Loss on disposal of fixed assets	2,938	—
Changes in:		
Prepaid expenses and other current assets	(273,650)	(189,955)
Lease liability	(88,268)	(77,897)
Accounts payable and accrued liabilities	(408,708)	1,175,445
Cash used in operating activities	(18,057,826)	(10,064,034)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(11,622)	(45,143)
Cash used in investing activities	(11,622)	(45,143)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of underwriting issuance costs	34,874	18,258,581
Deferred issuance costs	—	(137,907)
Proceeds from long-term obligations	—	184,000
Issuance of common stock in connection with exercise of pre-funded warrants	—	28
Proceeds from exercise of warrants	1,213,924	31,697
Cash provided by financing activities	1,248,798	18,336,399
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(16,820,650)	8,227,222
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	57,165,377	10,614,722
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 40,344,727	$ 18,841,944
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest expense	$ —	$ 1,584
Conversion of preferred stock to common stock	$ 18,653,826	$ —

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 and development of drugs for the treatment of cancer leveraging our proprietary phospholipid drug conjugate™ (PDC™) delivery platform that specifically targets cancer cells and deliver improved efficacy and better safety as a result of fewer off-target effects.

The Company has incurred losses since inception in devoting substantially all of its efforts toward research and development and has an accumulated deficit of approximately $144,979,691 at September 30, 2021. During the nine months ended September 30, 2021, the Company generated a net loss of approximately $18,204,264 and expects that it will continue to generate operating losses for the foreseeable future. However, the Company believes that its cash balance at September 30, 2021 is adequate to fund our basic budgeted operations for at least 12 months from the filing of these financial statements.The Company's ability to execute its current operating plan depends on its ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. The Company plans to continue to actively pursue financing alternatives , but there can be no assurance that it will obtain the necessary funding.

The accompanying Condensed Consolidated Balance Sheet as of December 31, 2020 has been derived from our audited financial statements. The accompanying unaudited Condensed Consolidated Balance Sheet as of September 30, 2021, and the Condensed Consolidated Statements of Operations, the Condensed Statements of Stockholders' Equity for the three and nine months ended September 30, 2021 and 2020, the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2021 and 2020, 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 at September 30, 2021 and consolidated results of its operations and stockholders' equity for the three and nine months ended September 30, 2021 and 2020 and cash flows for the nine months ended September 30, 2021 and 2020. The results for the three and nine months ended September 30, 2021 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 for the fiscal year ended December 31, 2020, which was filed with the SEC on March 2, 2021.

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

Fixed Assets — Property and equipment are stated at cost. Depreciation on property and equipment is provided using the straight-line method over the estimated useful lives of the assets (3 to 10 years). Because of the significant value of leasehold improvements purchased, leasehold improvements are depreciated over 64 months (their estimated useful life), which represents the full term of the lease. Our only long-lived assets are property and equipment. The Company periodically evaluates long-lived assets for potential impairment. Whenever events or circumstances change, an assessment is made as to whether there has been impairment to the value of long-lived assets by determining whether projected undiscounted cash flows generated by the applicable asset exceed its net book value as of the assessment date. There were no long-lived fixed asset impairment charges recorded during the nine months ended September 30, 2021 or year ended December 31, 2020.

Right-of-Use (ROU) Asset and Lease Liabilities -On January 1, 2019, the Company implemented FASB Accounting Standards Codification ("ASC") Topic 842 using the modified retrospective method for all material leases that existed at or commenced after January 1, 2019. ROU Assets are amortized over their estimated useful life, which represents the full term of the lease.

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 for awards that are not performance-based is recognized on a straight-line basis over the service period of the award, which for grants issued in 2021 and 2020 ranged from one year to three years for stock options.

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 in the Consolidated Statements of Operations 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 Consolidated Statements of Operations. The Company records government grants receivable in the Consolidated Balance Sheets in accounts receivable.

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 were no uncertain tax positions that require accrual to or disclosure in the financial statements as of September 30, 2021 and December 31, 2020.

Fair Value of Financial Instruments — The guidance under FASB 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 long-term obligations. The carrying amount of cash equivalents and accounts payable approximate their fair value as a result of their short-term nature. (See Note 2)

Concentration of Credit Risk — Financial instruments that subject the Company to credit risk consist of cash and equivalents on deposit with financial institutions. The Company's excess cash as of September 30, 2021 and December 31, 2020 is on deposit in interest-bearing transaction accounts with well-established financial institutions. At times, such amounts may exceed the FDIC insurance limits. As of September 30, 2021, and December 31, 2020, uninsured cash balances totaled approximately $39,800,000 and $56,700,000, respectively.

Recently Adopted Accounting Pronouncements - For the fiscal year beginning January 1, 2021, management early adopted Accounting Standards Update ("ASU") 2020-06 using the modified retrospective method. ASU 2020-06 simplifies entities' accounting for convertible instruments by eliminating the cash conversion and beneficial conversion feature ("BCF") models outlined in ASC 470-20 *Debt-Debt with Conversion and Other Options.* Under ASU 2020-06, convertible instruments that would have previously been subject to the BCF or cash conversion guidance no longer require separate accounting for the conversion feature. Entities may elect to early adopt ASU 2020-06 for fiscal years beginning after December 15, 2020. Since the Company early adopted ASU 2020-06 beginning January 1, 2021, the Company would no longer be required to recognize a BCF even when shareholder approval is received. In December 2020, the Company completed a private placement where we issued Series D convertible preferred stock. The preferred shares are convertible into shares of common stock upon receipt of stockholder approval of the issuance of the underlying shares of common stock as required by Nasdaq Marketplace Rule 5635(d) at a special stockholder meeting. The shareholders approved this conversion on February 25, 2021. As such, management will continue to account for the Series D preferred stock in equity without any separate accounting for the conversion options.

2. FAIR VALUE

In accordance with the Fair Value Measurements and Disclosures Topic of the FASB 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 on the Consolidated Balance sheets for other current financial assets and liabilities approximate fair value because of their short-term nature.

3. STOCKHOLDERS' EQUITY

Authorized Share Increase

At a special meeting held on February 25, 2021, the Company's stockholders approved the amendment of the Company's Second Amended and Restated Certificate of Incorporation, as amended, to increase the authorized common stock from 80,000,000 shares to 160,000,000 shares.

Equity Distribution Agreement

On August 11, 2020, the Company entered into an equity distribution agreement (the "Sales Agreement") with Oppenheimer & Co. Inc. (the "Sales Agent"). Pursuant to the Sales Agreement, the Company may offer and sell from time to time through the Sales Agent, up to $14.5 million of shares of the Company's common stock, par value $0.00001 per share (the "ATM Shares"). The Sales Agent will receive from the Company a commission of3.0% of the gross proceeds from the sales of the ATM Shares pursuant to the terms of the Sales Agreement. The offering of the ATM Shares pursuant to the Sales Agreement will terminate upon the earliest of (i) the sale of all ATM Shares subject to the Sales Agreement, and (ii) the termination of the Sales Agreement by the Company or the Sales Agent. Net proceeds from the sale of the ATM Shares will be used for general corporate purposes, including working capital.

The ATM Shares issued under the Sales Agreement are offered pursuant to a registration statement on Form S-3, which was declared effective by the SEC on August 20, 2020.

In June 2021, the Company issued and sold an aggregate of41,692 ATM Shares pursuant to the Sales Agreement and received gross proceeds of approximately $69,000 and net proceeds of $35,000 after deducting commissions to the Sales Agent and other offering expenses.

December 2020 Public Offering and Private Placement

On December 23, 2020, the Company issued and sold18,148,136 shares of common stock, par value $0.00001 per share, at a public offering price of $1.35 per share of common stock, prior to deducting underwriting discounts and commissions and estimated offering expenses.

In a concurrent private placement, the Company issued and sold 1,518.5180 shares of Series D convertible preferred stock. The preferred shares are convertible into a number of shares of common stock equal to $13,500 divided by $1.35 (or 10,000 shares of common stock for each share of Series D preferred stock converted) and were issued at a price of $13,500 per share of Series D preferred stock. The preferred shares will only be convertible into common stock upon receipt of stockholder approval of the issuance of the underlying shares of common stock as required by Nasdaq Marketplace Rule 5635(d) at a special stockholder meeting to be called for that purpose. At a special meeting of stockholders held on February 25, 2021, the stockholders approved, in accordance with Nasdaq Listing Rule 5635(d), the issuance of shares of the Company's common stock upon the conversion of the Series D preferred stock. During the three months ended March 31, 2021, 574.0736 shares of our Series D convertible preferred stock were converted into 5,740,736 Common Stock at a rate of 1 to 10,000 shares. During the three months ended June 30, 2021, 250 shares of our Series D convertible preferred stock were converted into 2,500,000 Common Stock at a rate of 1 to 10,000 shares. During the three months ended September 30, 2021, 583.33 shares of our Series D convertible preferred stock were converted into 5,833,333 Common Stock at a rate of 1 to 10,000 shares. For the nine months ended September 30, 2021 the total Series D convertible preferred stock converted into 14,074,069 Common Stock at a rate of 1 to 10,000 shares.

The net proceeds of the offerings to the Company, after deducting the underwriting discounts and commissions, placement agency fees and estimated offering expenses payable by the Company were approximately $41.4 million.

The common stock issued in the public offering was offered by the Company pursuant to a registration statement on Form S-3, which was declared effective by the SEC on August 20, 2020.

The common stock issuable upon conversion of the Series D preferred stock in the private placement was offered by the Company pursuant to a registration statement on Form S-3, which was declared effective by the SEC on February 1, 2021.

In accordance with the concept of ASC 820 regarding the December 2020 public offering, the Company allocated the value of the proceeds to the common stock and preferred stock utilizing a relative fair value basis. Using the Nasdaq closing trading price for our stock on December 28, 2020, the Company computed the fair value of the shares sold. The fair value of the preferred stock was estimated on a relative fair value basis. This valuation did not impact total Stockholders' Equity of $45.0 million, but is an internal proportionate calculation allocating the gross proceeds of approximately $24.5 million to common stock and $20.5 million to preferred stock.

June 2020 Public Offering

On June 5, 2020, the Company issued and sold 14,601,628 shares of common stock, 2,789,700 pre-funded warrants exercisable for one share of our common stock at an exercise price of $0.00001 per share and 8,695,664 Series H warrants to purchase 8,695,664 shares of common stock. The public offering price of a share of common stock together with one-half of a Series H warrant to purchase one share of common stock was $1.15. The public offering price of a pre-funded warrant together with one-half of a Series H Warrant was $1.1499. The Series H warrants have an exercise price of $1.2075 per share and are exercisable for five years from the date of issuance. As of September 30, 2021, all 2,789,700 pre-funded warrants have been exercised. As of September 30, 2021, a total of 1,487,695 Series H warrants have been exercised.

In accordance with the concept of ASC 820 regarding the June 2020 public offering, the Company allocated value of the proceeds to the common stock and warrants utilizing a relative fair value basis. Using the Nasdaq closing trading price for our stock on June 5, 2020, the Company computed the fair value of the shares sold. The fair value of the warrants was estimated using the Black-Scholes option-pricing model at that same date. This valuation did not impact total Stockholders' Equity of $20.0 million, but is an internal proportionate calculation allocating the gross proceeds of approximately $12.1 million to common stock and $7.9 million to warrants.

Gross offering proceeds to the Company were $20.0 million, with net proceeds to the Company of approximately $18.3 million after deducting placement agent fees and related offering expenses. The Company intends to use the net proceeds from the offering for research and development, funding clinical studies, working capital and general corporate purposes.

The common stock, pre-funded warrants and Series H warrants were offered by the Company pursuant to a registration statement on Form S-1 , which was declared effective by the SEC on June 2, 2020 and an additional registration statement filed on June 2, 2020 pursuant to Rule 462(b) under the Act.

Common Stock Warrants

The following table summarizes information with regard to outstanding warrants to purchase common stock as of September 30, 2021.

Offering	Number of Shares Issuable Upon Exercise of Outstanding Warrants	Exercise Price	Expiration Date
June 2020 Series H Warrants	7,207,969	$ 1.2075	June 5, 2025
May 2019 Series F Warrants	1,957,000	$ 2.40	May 20, 2024
May 2019 Series G Warrants	2,018,000	$ 2.40	May 20, 2024
July 2018 Series E Warrants	4,140,000	$ 4.00	July 31, 2023
October 2017 Series D Warrants	310,856	$ 17.80	October 14, 2024
November 2016 Public Offering Series C	415,785	$ 15.00	November 29, 2021
October 2015 Incremental Series A	30,006	$ 21.30	October 20,2021
Total	16,079,616		

4. STOCK-BASED COMPENSATION

Accounting for Stock-Based Compensation

2021 Stock Incentive Plan The 2021 Stock Incentive Plan (the "2021 Plan") was adopted on June 23, 2021 authorizing an aggregate of 6,000,000 shares of common stock for grants of incentive or nonqualified stock options, rights to purchase restricted and unrestricted shares of common stock, stock appreciation rights and performance share grants. The Compensation Committee determines exercise prices, vesting periods and any performance requirements on the date of grant, subject to the provisions of the 2021 Plan. Options are granted at or above the fair market value of the common stock at the grant date and expire on the tenth anniversary of the grant date. Vesting periods are generally between one and four years. Options granted pursuant to the 2021 Plan generally will become fully vested upon a termination event occurring within one year following a change in control, as defined. A termination event is defined as either termination of employment or services other than for cause or constructive termination of employees or consultants resulting from a significant reduction in either the nature or scope of duties and responsibilities, a reduction in compensation or a required relocation. All outstanding awards under the 2015 Stock Incentive Plan (the "2015 Plan") remained in effect according to the terms of the 2015 Plan and the respective agreements relating to such awards. In addition, any shares that are currently available under the 2015 Plan and any shares underlying awards under the 2015 Plan which are forfeited, cancelled, reacquired by the Company or otherwise terminated will be added to the number of shares available for grant under the 2021 Plan. As of September 30, 2021, there are an aggregate of 3,184,363 shares available for future grants under the 2021 Plan.

During the nine-month periods ended September 30, 2021 and 2020, options granted were3,537,500 and 653,750, respectively. 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,	
	2021	2020	2021	2020
Employee and director stock option grants:				
Research and development	$ 62,655	$ 22,858	$ 133,450	$ 50,071
General and administrative	358,506	93,435	612,892	303,010
Total stock-based compensation	$ 421,161	$ 116,292	$ 746,342	$ 353,081

On March 4, 2021, we granted 2,810,000 contingent non-statutory stock option awards at an exercise price of $1.74 per share to our employees. Each of these grants was contingent on approval of the 2021 Plan that was voted on and approved by the stockholders at the Annual Meeting of Stockholders held on June 23, 2021. In accordance with the timing of the stockholder approval, the Company recognized the compensation expense of the contingent non-statutory stock option awards issued in March 2021 beginning in June 2021 and continuing through vesting period.

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. The Company 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, 2021 were equal to the market value of the Company's common stock on the date of grant.

Stock Option Activity

A summary of stock option activity is as follows:

	Number of Shares Issuable Upon Exercise of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2020	1,184,464	$ 4.34		$ 316,688
Granted	208,500	$ 1.78		
Outstanding at March 31, 2021	1,392,964	$ 3.96	8.56	$ 122,700
Granted	3,309,000	$ 1.66		
Expired	(177)	$ 2,800.00		
Outstanding at June 30, 2021	4,701,787	$ 2.23	9.31	$ —
Granted	20,000	$ 1.06		
Forfeited	(46,001)	$ 2.01		
Outstanding at September 30, 2021	4,675,786	$ 2.23	9.05	$ —
Exercisable, September 30, 2021	810,100	$ 4.87	7.45	$ —
Unvested, September 30, 2021	3,865,686	$ 1.68	9.38	$ —

The aggregate intrinsic value of options outstanding is calculated based on the positive difference between the estimated per-share fair value of common stock at the end of the respective period and the exercise price of the underlying options. There have been no option exercises to date. Shares of common stock issued upon the exercise of options are from authorized but unissued shares.

As of September 30, 2021, there was approximately $3,005,000 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, the Company expects to recognize approximately $413,000, $1,396,000, $1,020,000, and $176,000 during 2021, 2022, 2023, and 2024 respectively. The Company's expense estimates are based upon the expectation that all unvested options will vest in the future. The weighted-average grant-date fair value of vested and unvested options outstanding at September 30, 2021 was $3.86 and $0.90, respectively.

*Restricted Stock Grant*s. During 2017, the Company issued 46,000 shares under the 2015 Plan of restricted common stock with a weighted average grant date fair value of $20.96. The shares vested annually over a three year period. The following table summarizes the restricted stock grants:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share	Total Grant Date Fair Value
Outstanding at December 31, 2019	9,334	$ 21.00	$ 196,000
Vested	(9,334)	$ 21.00	$ (196,000)
Outstanding at December 31, 2020	—	$ —	$ —

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, 2021 or 2020 because the Company has experienced losses on a tax basis since inception. Because of the limited operating history, continuing losses and uncertainty associated with the utilization of the NOLs in the future, management has provided a full allowance against the value of its gross deferred tax assets.

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 income (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted net income (loss) per share for the three and nine months ended September 30, 2021 and September 30, 2020 is computed by dividing net income (loss) 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, non-vested restricted stock, preferred shares convertible into common stock and, pre-funded warrants. Since there is a net loss attributable to common stockholders for the three and nine months ended September 30, 2021 and September 30, 2020, the inclusion of common stock equivalents in the computation for that period would be antidilutive.

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

	Nine Months Ended September 30,	
	2021	**2020**
Warrants	16,079,616	17,937,766
Preferred shares as convertible into common stock	1,111,111	537,500
Stock options	4,675,786	1,184,464
Total potentially dilutive shares	21,866,513	19,659,730

7. COMMITMENTS AND CONTINGENCIES

Real Property Leases

Florham Park, New Jersey

On June 4, 2018, the Company entered in an Agreement of Lease for3,893 square feet for its corporate headquarters in Borough of Florham Park, New Jersey (the "HQ Lease"). The HQ Lease commencement date was October 2018 and terminates in February 2024. The Company has an option to extend the term of the HQ Lease for one additional 60-month period.

Under the terms of the HQ Lease, the Company paid a security deposit of $75,000 and the aggregate rent due over the term of the HQ Lease is approximately $828,000, which will be reduced to approximately $783,000 after certain rent abatements. The Company is required to pay its proportionate share of certain operating expenses and real estate taxes applicable to the leased premises. After certain rent abatements the rent is approximately $12,500 per month for the first year and then escalates thereafter by 2% per year for the duration of the term.

Madison, Wisconsin

The Company presently rents office space in Madison and is rented for approximately $3,000 per month under an agreement that expires on August 31, 2022.

Operating Lease Liability

In June 2018, the Company entered into the HQ Lease. The HQ Lease commenced upon completion of certain improvements by the landlord in October 2018 and terminates in February 2024 with an option to extend the term of the lease for one additional 60-month period. As of December 31, 2018, the Company recorded a deferred lease liability of approximately $176,000 for the improvements funded by the landlord on the consolidated balance sheet. The Company amortizes the deferred liability as a reduction to rent expense in the consolidated statement of operations over the term of the lease.

Under the HQ Lease, the Company will pay monthly fixed rent based on approximate rate per rentable square foot which ranges between approximately $12,400 to $13,600 over the lease period. In addition, the Company received certain rent abatements and lease incentives subject to the limitations in the HQ Lease. The HQ Lease's net ROU asset and lease liability are approximately $225,000 and ($333,000), respectively, as of September 30, 2021 and rental expense for the nine months ended September 30, 2021 is approximately $85,000.

Discount Rate

The Company has determined the interest rate implicit in the lease considering factors such as 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 10% per annum as reasonable to use as the incremental borrowing rate for purposes of the calculation of lease liabilities.

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, 2021:

Years ending December 31,		
Remainder of 2021	$	39,000
2022		158,000
2023		161,000
2024		14,000
Total undiscounted lease payments		372,000
Less: Imputed interest		(39,000)
Present value of lease liabilities	$	333,000

Legal

The Company may be involved in legal matters and disputes in the ordinary course of business. We do not anticipate that the outcome of such matters and disputes will materially affect the Company's financial statements.

8. LOAN PAYABLE

On April 21, 2020, the Company received loan proceeds in the amount of approximately $184,000 under the Paycheck Protection Program ("PPP"). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loans and accrued interest are forgivable after 24 weeks as long as the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels. The amount of loan forgiveness will be reduced if the borrower terminates employees or reduces salaries during the 24-week period.

The unforgiven portion of the PPP loan is payable over two years at an interest rate of 1%, with a deferral of payments for the first six months. The Company intends to use the proceeds for purposes consistent with the PPP requirements. On December 30, 2020, the principal loan amount of $184,000 and accrued interest of $1,280 were forgiven and recognized as a gain on extinguishment of debt in the fourth quarter of 2020.

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

Overview

We are a late-stage clinical biopharmaceutical company focused on the discovery and development of drugs for the treatment of cancer. Our core objective is to leverage our proprietary 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. 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.

The COVID-19 pandemic, including variants thereof, has created uncertainties in the expected timelines for clinical stage biopharmaceutical companies such as us, and because of such uncertainties, it is difficult for us to accurately predict expected outcomes. While we have commenced dosing in our CLOVER-WaM pivotal clinical study of iopofosine in WM, we have experienced material delays in patient recruitment and enrollment as a result of continued resourcing issues related to COVID-19 at study sites and potentially due to concerns among patients about participating in clinical studies during a public health emergency. The COVID-19 pandemic is also affecting the operations of third parties upon whom we rely. We are unable to predict how the COVID-19 pandemic may affect our ability to successfully progress our CLOVER-WaM pivotal clinical study or any other clinical programs in the future. Moreover, there remains uncertainty relating to the trajectory of the pandemic and whether it may cause further delays in patient study recruitment. The impact of related responses and disruptions caused by the COVID-19 pandemic may result in difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing studies and the incurrence of unforeseen costs as a result of disruptions in clinical supply of iopofosine or preclinical study or clinical study delays and our ability to obtain additional financing. The continued impact of COVID-19 on results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease or variants thereof, the duration of the pandemic, vaccination rates, travel restrictions and social distancing in the United States, Canada and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the United States, Canada and other countries to contain and treat the disease. In October 2021, we announced that we are collaborating with BBK Worldwide to provide new concierge services for patients participating in our clinical studies. These services are designed to improve patient's and their caregivers access to high quality care and innovative treatments for their cancer.

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. Iopofosine is currently being evaluated in the CLOVER-WaM Phase 2 pivotal study in patients with relapsed/refractory (r/r) Waldenstrom's macroglobulinemia (WM), a Phase 2B study in r/r multiple myeloma (MM) patients and the CLOVER-2 Phase 1 study for a variety of pediatric cancers.

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. The CLOVER-WaM Study is a pivotal registration study currently evaluating iopofosine in Bruton tyrosine kinase inhibitor (BTKi) failed or suboptimal response in WM. The CLOVER-1 Phase 2B study is ongoing where iopofosine remains under further evaluation in highly refractory MM patients.

The CLOVER-2 Phase 1 pediatric study is 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 study is being conducted internationally at seven leading pediatric cancer centers.

The U.S. Food and Drug Administration ("FDA") granted iopofosine Fast Track Designation for 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 WM, MM, neuroblastoma, 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 an ODDs for r/r MM and WM.

Our product pipeline also includes one preclinical PDC chemotherapeutic program (CLR 1900) and several partnered PDC assets. The CLR 1900 Series is being targeted for solid tumors with a payload that inhibits mitosis (cell division) a validated pathway for treating cancers.

We have leveraged our PDC platform to establish four 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 provides 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 does not rely upon specific cell surface epitopes or antigens as are required by other targeted delivery platforms. Our PDC platform takes advantage of a metabolic pathway utilized by all tumor cell types in all stages of the tumor cycle. Tumor cells modify specific regions on the cell surface as a result of the utilization of this metabolic pathway. Our PDCs bind to these regions and directly enter the intracellular compartment. This mechanism allows the PDC molecules to accumulate in tumor cells over time, which can enhance drug efficacy, and to avoid the specialized highly acidic cellular compartment known as lysosomes, which allows a PDC to deliver molecules that previously could not be delivered. Additionally, molecules targeting specific cell surface epitopes face challenges in completely eliminating a tumor because the targeted antigens are limited in the total number on the cell surface, have longer cycling time from internalization to being present on the cell surface again and available for binding and are not present on all of the tumor cells in any cancer. This means a subpopulation of tumor cells always exist that cannot be targeted by therapies targeting specific surface epitopes. In addition to the benefits provided by the mechanism of entry, PDCs offer the ability to conjugate payload molecules in numerous ways, thereby increasing the types of molecules selectively delivered via the PDC.

The PDC platform features include the capacity to link with almost any molecule, provide a significant increase in targeted oncologic payload delivery and the ability to target all types of tumor cells. As a result, we believe that we can generate 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.

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.

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 is currently being evaluated in the CLOVER-WaM Phase 2 pivotal study in patients with r/r WM, a Phase 2B study in r/r MM patients and the CLOVER-2 Phase 1 study for a variety of pediatric cancers.

Iopofosine is currently being evaluated in a pivotal study, CLOVER-WaM, in Waldenstrom's macroglobulinemia (WM) patients that have failed or had a suboptimal response to a BTKi therapy after receiving first line standard of care. 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 a MM expansion cohort (Phase 2B). The Phase 2B study will evaluate highly refractory MM patients including triple, quad and penta class refractory 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 (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 second half of 2021. 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 1 pediatric study is being conducted internationally at seven leading pediatric cancer centers. The study is 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 FDA previously accepted our IND application for a Phase 1 open-label, dose escalating study to evaluate the safety and tolerability of a single intravenous administration of iopofosine in up to 30 children and adolescents with cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. This study was initiated during the first quarter of 2019. 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 Orphan Drug Designation from the European Union for Multiple Myeloma, in January 2020, the FDA granted Orphan Drug Designation for iopofosine Waldenstrom's macroglobulinemia and the European Union granted Orphan Drug Designation for iopofosine Waldenstrom's macroglobulinemia. The FDA granted Fast Track designation for iopofosine for the treatment of 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 RPDD that meet its specified criteria. The key criteria to receiving a priority review voucher is that the disease being treated is life-threatening and that it primarily effects individuals under the age of 18. 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.

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

In January 2021, we announced that a Type C guidance meeting with the FDA was conducted in September of 2020. The results of that guidance meeting provided Cellectar with an agreed upon path for conducting the CLOVER-WaM study; single arm, pivotal study in Waldenstrom's macroglobulinemia patients that have received at least two prior lines of therapy and either failed or had a suboptimal response to BTKi therapy. The FDA agreed with 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 50 patients. Based upon this agreement the pivotal study was initiated. 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.

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

Current data from our Phase 2A CLOVER-1 clinical study show that six WM patients demonstrated 100% overall response rate (ORR) and an 83.3% major response rate with one patient achieving a complete response (CR), which continues at nearly 27 months post- last treatment. While median treatment free survival ((TRS) also known as treatment free remission (TFR)) and duration of response (DOR) has not been reached, the average treatment TFS/TFR is currently at 330 days. This may represent an important improvement in the treatment of relapsed/refractory WM as we believe no approved or late-stage development treatments for second- and third-line patients have reported a CR to date.

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 multiple myeloma patients deemed triple class refractory who received 60 mCi or greater total body dose (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. 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 total body dose 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 being cytopenias.

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 relapsed/refractory non-Hodgkin lymphoma (NHL) patients were treated with three different doses (<50mCi, ~50mCi and ≥60mCi TBD. 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 chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) and marginal zone lymphoma (MZL) patients was 33%.

Based upon the dose response observed in the Phase 2A for patients receiving total body doses of 60mCi or greater, we determined that patient dosing of iopofosine 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 have not increased as doses were increased and the profile of cytopenias remains consistent. Importantly, 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 and the observed response rate, 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 total body dose ≥60 mCi/m^2 of iopofosine.

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 Chronic Lymphocytic Leukemia, Small Lymphocytic Lymphoma, Marginal Zone Lymphoma, Lymphoplasmacytic Lymphoma/WM and DLBCL. The study is being conducted in approximately 10 U.S. cancer centers in patients with orphan-designated relapse or refractory hematologic cancers. The study's primary endpoint is clinical benefit response (CBR), with secondary endpoints of ORR, progression free survival (PFS,) median Overall Survival (mOS) 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.

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

Phase 1 Study in Patients with r/r Multiple Myeloma

In February 2020, we announced the successful completion of our Phase 1 dose escalation study. Data from the study demonstrated that iopofosine was safe and tolerated up to a total body dose of approximately 95mCi in r/r MM. The Phase 1 multicenter, open-label, dose-escalation study was designed to evaluate the safety and tolerability of iopofosine administered in an up to 30-minute I.V. infusion, either as a single bolus dose or as fractionated doses. The r/r multiple myeloma patients in this study received single cycle doses ranging from approximately 20mCi to 95mCi total body dose. An independent Data Monitoring Committee determined that all doses used were safe and well-tolerated by patients.

Iopofosine in combination with dexamethasone was under investigation in adult patients with r/r MM. 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. Multiple myeloma is an incurable cancer of the plasma cells and is the second most common form of hematologic cancers. Secondary objectives included the evaluation of therapeutic activity by assessing surrogate efficacy markers, which include M protein, free light chain (FLC), PFS and OS. All patients were heavily pretreated with an average of five prior lines of therapy. Iopofosine was deemed by an Independent Data Monitoring Committee (IDMC) to be safe and tolerable up to its planned maximum single, bolus dose of 31.25 mCi/m^2 or a total body dose 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 achieved 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 achieved 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 achieved stable disease. In September 2017, we announced results for cohort 4, showing that a single infusion up to 30-minutes of 31.25mCi/m^2 of iopofosine was safe and tolerated by the three patients in the cohort. Additionally, all three patients experienced CBR with one patient achieving a partial response (PR). 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 greater than or equal to 50% decrease in FLC levels (for patients in whom M protein is unmeasurable) or 50% or greater decrease in M protein. 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.

Cohort 5 and 6 were fractionated cohorts of 31.25 mCi/m^2(~62.5mCi TBD) and 37.5 mCi/m^2(~75mCi TBD), each administered on day 1 and on day 8. Following the determination that all prior dosing cohorts were safe and tolerated, we initiated a cohort 7 utilizing a 40mCi/m2 (~95mCi TBD) fractionated dose administered 20mCi/m2 (~40mCi TBD) on days 1 and day 8. Cohort 7 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 2021.

In May 2019, we announced that the FDA granted Fast Track Designation for iopofosine in fourth line or later r/r MM. Iopofosine is our small molecule radiotherapeutic PDC designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. It is currently being evaluated in our ongoing CLOVER-1 Phase 2 clinical study in patients with relapsed or refractory multiple myeloma and other select B-cell lymphomas.

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 filed 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 cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. 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, it was announced that four dose levels 15mCi/m^2 up to 60mCi/m^2 were deemed safe and tolerable by an independent Data Monitoring Committee and evaluation of the next higher dose cohort, 75mCi/m^2 was initiated. In November 2020, we announced that iopofosine had been measured in tumors, confirming that systemic administration of iopofosine crosses the blood brain barrier and is delivered into tumors and that disease control has been exhibited in heavily pretreated patients with ependymomas. In 2018, the FDA granted ODD and RPDD for iopofosine for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Should iopofosine 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 National Cancer Institute 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 (EBRT) with recurrent HNC in Q4 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 head and neck cancer. 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 head and neck cancer typically receive approximately 60-70 Grays (Gy) of EBRT given as 2 – 3 Gy daily doses over a 6-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 will further assess the safety and potential benefits of iopofosine in combination with EBRT in a cohort of up to 24 patients.

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 1900 Series is an internally developed proprietary PDC program leveraging a novel small molecule cytotoxic compound as the payload. The payload inhibits mitosis (cell division) and targets a key pathway required to inhibit rapidly dividing cells that results in apoptosis. We believe that this program could produce a product candidate targeted to select solid tumors. Currently, the program is in early preclinical development and if we elect to progress any molecules further, we will select preferred candidates.

- CLR 2000 Series is a collaborative PDC program with Avicenna Oncology, or Avicenna, that we entered into in July 2017. Avicenna is a developer of antibody drug conjugates ("ADCs"). The objective of the research collaboration is to design and develop a series of PDCs utilizing Avicenna's proprietary cytotoxic payload. Although Avicenna is a developer of ADCs, this collaboration was sought as a means to overcome many of the challenges associated with ADCs, including those associated with the targeting of specific cell surface epitopes. The CLR 2000 Series has demonstrated improved safety, efficacy and tissue distribution with the cytotoxic payload in animal models. A candidate molecule and a back-up have been selected for further advancement at a future time.

- CLR 12120 Series is a collaborative PDC program with Orano Med for the development of novel PDCs utilizing Orano Med's unique alpha emitter, lead 212 conjugated to our phospholipid ether; the companies intend to evaluate the new PDCs in up to three oncology indications.

- Expanded ongoing collaboration with biotechnology company IntoCell Inc., combining their novel linker chemistry with our validated targeting platform to create novel next generation phospholipid drug conjugate therapeutics.

- Co-development and commercialization collaboration with LegoChemBio, a clinical stage biotechnology company to utilize their proprietary drug conjugate linker-toxin platform to further enhance our portfolio of next generation PDC therapeutics.

Results of Operations

Research and development expense. Research and development expense 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 expense. General and administrative expense consists 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.

Three Months Ended September 30, 2021 and 2020

Research and Development. Research and development expense for the three months ended September 30, 2021 was approximately $3,937,000 compared to approximately $2,684,000 for the three months ended September 30, 2020.

The following table is an approximate comparison summary of research and development costs for the three months ended September 30, 2021 and September 30, 2020:

	Three Months Ended September 30,		
	2021	**2020**	**Variance**
Clinical project costs	$ 2,242,000	$ 1,184,000	$ 1,058,000
Manufacturing and related costs	506,000	655,000	(149,000)
Pre-clinical project costs	4,000	36,000	(32,000)
General research and development costs	1,185,000	809,000	376,000
	$ 3,937,000	$ 2,684,000	$ 1,253,000

The overall increase in research and development expense of $1,253,000, or 47%, was primarily a result of an increase related to clinical project costs of approximately $1,058,000. General research and development costs increased due to an increase in personnel slightly offset by a decrease in manufacturing and related costs and pre-clinical project costs.

General and administrative. General and administrative expense for the three months ended September 30, 2021 was approximately $1,882,000, compared to approximately $1,226,000. The overall increase in general and administrative expense of $656,000, or 54% was primarily a result of an increase in professional fees and stock-based compensation expense.

Nine Months Ended September 30, 2021 and 2020

Research and Development. Research and development expense for the nine months ended September 30, 2021 was approximately $13,198,000 compared to approximately $7,766,000 for the nine months ended September 30, 2020.

The following table is an approximate comparison summary of research and development costs for the nine months ended September 30, 2021 and September 30, 2020:

	Nine Months Ended September 30,		
	2021	2020	Variance
Clinical project costs	$ 8,237,000	$ 3,066,000	$ 5,171,000
Manufacturing and related costs	1,664,000	1,918,000	(254,000)
Pre-clinical project costs	9,000	193,000	(184,000)
General research and development costs	3,288,000	2,589,000	699,000
	$ 13,198,000	$ 7,766,000	$ 5,432,000

The overall increase in research and development expense of $5,432,000, or 70%, was primarily a result of an increase related to start-up costs for our WM pivotal study and clinical project costs of approximately $5,171,000 and general research and development costs of approximately $699,000 offset by a decrease in manufacturing and related costs.

General and administrative. General and administrative expense for the nine months ended September 30, 2021 was approximately $5,010,000, compared to approximately $3,725,000. The overall increase in general and administrative expense of $1,285,000, or 34%, was primarily a result of an increase in professional fees and insurance, personnel costs and stock-based compensation expense.

Liquidity and Capital Resources

As of September 30, 2021, we had cash and cash equivalents of approximately $40,345,000 compared to $57,165,000 as of December 31, 2020. This decrease was due primarily a result of research and development expense and general and administrative expenses. Net cash used in operating activities during the nine months ended September 30, 2021 was approximately $18,058,000.

Our cash requirements have historically been for our research and development activities, finance and administrative costs, capital expenditures and overall working capital. We have experienced negative operating cash flows since inception and have funded our operations primarily from sales of common stock and other securities. As of September 30, 2021, we had an accumulated deficit of approximately $144,980,000.

We believe that the cash balance is adequate to fund our basic budgeted operations for at least 12 months from the filing of these financial statements. However, our future results of operations involve significant risks and uncertainties. Our ability to execute our operating plan beyond that time depends on our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. We plan to actively pursue all available financing alternatives; however, there can be no assurance that we will obtain the necessary funding. Other than the uncertainties regarding our ability to obtain additional funding, there are currently no known trends, demands, commitments, events or uncertainties that are likely to materially affect our liquidity.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Based on our management's evaluation (with the participation of our principal executive officer and principal financial officer), as of September 30, 2021, our management has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Changes in internal control over financial reporting. Based on our management's evaluation (with the participation of our principal executive officer and principal financial officer), as of September 30, 2021, our management has concluded that there have not been any significant changes in the Company's internal control over financial reporting.

The Chief Executive Officer and the Audit Committee perform significant roles in ensuring the accuracy and completeness of our financial reporting and the effectiveness of our disclosure controls and procedures. We have not identified any changes that occurred

during the Company's fiscal quarter ended September 30, 2021 that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Important Considerations. Any system of controls, however well designed and operated, can provide only reasonable, and not absolute assurance that the objectives of the system are met. In addition, the design of any control system is based in part on certain assumptions about the likelihood of future events. The effectiveness of our disclosure controls and procedures is subject to various inherent limitations, including cost limitations, judgments used in decision making, assumptions about the likelihood of future events, the soundness of our systems, the possibility of human error, and the risk of fraud. Because of these and other inherent limitations of control systems, there can be no assurance that any system of disclosure controls and procedures will be successful in achieving its stated goals, including but not limited to preventing all errors or fraud or in making all material information known in a timely manner to the appropriate levels of management, under all potential future conditions, regardless of how remote.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On October 15, 2021, the Company filed a lawsuit against Dr. Jamey Weichert, a former director and executive officer of the Company ("Dr. Weichert") and Dr. Anatoly Pinchuk, a former employee and consultant of the Company ("Dr. Pinchuk") in the U.S. District Court for the Western District of Wisconsin. The Company is alleging, among other claims, that Dr. Weichert and Dr. Pinchuk breached their contractual and fiduciary duties to the Company by diverting intellectual property that rightfully belonged to the Company to a company controlled by Dr. Weichert. Although the disputed intellectual property does not directly affect the clinical studies of iopofosine or other compounds in the Company's clinical pipeline, the disputed intellectual property may potentially enhance future areas of research, development and commercialization. The Company is seeking monetary damages, injunctive relief, and reasonable attorneys' fees and expenses in conjunction with this lawsuit.

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, our Annual Report filed with the SEC on March 2, 2021 pursuant to Section 13 or 15(d) of the Exchange Act (the "2020 10-K"). This information should be considered carefully, together with other information in this report and other reports and materials we file with the SEC. In addition, the following risk factor included substantive changes from those disclosed in the 2020 10-K:

If we are unable to adequately protect or enforce our rights to intellectual property or to secure rights to third-party patents, we may lose valuable rights, experience reduced market share, assuming any, or incur costly litigation to protect our intellectual property rights.

Our ability to obtain licenses to patents, maintain trade-secret protection, and operate without infringing the proprietary rights of others will be important to commercializing any products under development. Therefore, any disruption in access to the technology could substantially delay the development of our technology.

We require our employees and consultants to execute appropriate confidentiality and assignment-of-inventions agreements. However, such employees and consultants may not always comply with these agreements and enforcing them can be expensive and uncertain. For example, on October 15, 2021, we filed a lawsuit against Dr. Jamey Weichert, a former director and executive officer of the Company and Dr. Anatoly Pinchuk, a former employee and consultant of the Company, alleging breach of their contractual and fiduciary duties by diverting intellectual property that rightfully belongs to the Company. If our employees and consultants fail to comply with their obligations, we may be unable to meaningfully protect our rights in our patentable technology.

The patent positions of biotechnology and pharmaceutical companies, such as ours, for products that involve licensing agreements are frequently uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued or in subsequent legal proceedings. Consequently, our patent applications and any issued and licensed patents may not provide protection against competitive technologies or may be held invalid if challenged or circumvented. To the extent we license patents from third parties, the early termination of any such license agreement would result in the loss of our rights to use the covered patents, which could severely delay, inhibit or eliminate our ability to develop and commercialize compounds based on the licensed patents. Our competitors may also independently develop products similar to ours or

design around or otherwise circumvent patents issued or licensed to us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

We also rely on trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. Although we generally require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other nonpatented technology.

Enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and may affect the prices we may set.

In the United States, particularly over the past few years, a number of legislative and regulatory proposals have been introduced in an attempt to lower drug prices. These include proposals that would allow the U.S. government to negotiate prices for drugs covered under Medicare and to limit drug reimbursement in Medicare and/or the commercial market based on reference prices. For example, in late 2019, a drug-pricing bill, H.R. 3, passed the House of Representatives, which would, among other things, enable direct price negotiations by the federal government on certain drugs (with the maximum price paid by Medicare capped by prices derived from an international index), includes a penalty for failing to reach agreement with the government and requires that manufacturers offer these negotiated prices to other payers. On November 2, 2021, Congress announced a framework for drug pricing reform that includes inflation penalties, Medicare negotiation for select drugs paid for under Parts B and D, and a Medicare Part D redesign. As of the date of this filing, this framework remains in discussion with policymakers in Congress and the Administration. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Item 6. Exhibits

			Incorporation by Reference		
Exhibit No.	**Description**	**Filed with this Form 10-Q**	**Form**	**Filing Date**	**Exhibit No.**
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			

* Filed herewith.

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 8, 2021

By: */s/ James V. Caruso*
James V. Caruso
President and Chief Executive 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 8, 2021

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

EXHIBIT 31.2

I, DOV ELEFANT, 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 8, 2021

/s/ Dov Elefant
Dov Elefant
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, 2021, 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 Dov Elefant, 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 8, 2021

/s/ Dov Elefant
Dov Elefant
Chief Financial Officer (Principal Financial and Accounting Officer)

Date: November 8, 2021