

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, 2022

☐ 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**

(State or other jurisdiction of  
incorporation or organization)

**04-3321804**

(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: 9,385,272 shares of common stock, \$0.00001 par value per share, as of October 31, 2022.

CELLECTAR BIOSCIENCES, INC.

FORM 10-Q INDEX

<a href="#">Forward-Looking Statements</a>	3
<b><a href="#">PART I. FINANCIAL INFORMATION</a></b>	<b>5</b>
<a href="#">Item 1. Financial Statements</a>	5
<a href="#">Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	18
<a href="#">Item 4. Controls and Procedures</a>	27
<b><a href="#">PART II. OTHER INFORMATION</a></b>	<b>28</b>
<a href="#">Item 1. Legal Proceedings</a>	28
<a href="#">Item 1A. Risk Factors</a>	28
<a href="#">Item 6. Exhibits</a>	29

---

## FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q of Collectar Biosciences, Inc. (the “Company”, “Collectar”, “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 to recruit 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 for iopofosine I 131 (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)<sup>TM</sup>;
- our ability to maintain orphan drug designation in the U.S. for iopofosine as a therapeutic for the treatment of multiple myeloma, neuroblastoma, osteosarcoma, rhabdomyosarcoma, Ewing’s sarcoma and lymphoplasmacytic lymphoma, and the expected benefits of orphan drug status;
- any disruptions at our sole supplier of iopofosine;
- our ability to 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 such as the COVID-19 pandemic, cyber-attacks and general instability;
- the future impacts of legislative and regulatory developments in the United States on the pricing and reimbursement of our product candidates;
- our ability to meet the continued listing standards of Nasdaq;
- assumptions underlying any of the foregoing; and
- any other statements that address events or developments that we intend or believe will or may occur in the future.

[Table of Contents](#)

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

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

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

# PART I. FINANCIAL INFORMATION

## Item 1. Financial Statements

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

	September 30, 2022	December 31, 2021
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 17,785,322	\$ 35,703,975
Prepaid expenses and other current assets	975,936	867,485
Total current assets	18,761,258	36,571,460
Fixed assets, net	338,944	344,491
Right-of-use asset, net	138,097	204,644
Long-term and other assets	81,214	81,214
<b>TOTAL ASSETS</b>	<b>\$ 19,319,513</b>	<b>\$ 37,201,809</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 6,367,035	\$ 3,854,914
Lease liability	148,200	135,449
Total current liabilities	6,515,235	3,990,363
Long-term lease liability, net of current portion	53,769	166,292
<b>TOTAL LIABILITIES</b>	<b>6,569,004</b>	<b>4,156,655</b>
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized; Series D preferred stock: 111 shares issued and outstanding	1,382,023	1,382,023
Common stock, \$0.00001 par value; 160,000,000 shares authorized; 6,110,119 and 6,110,125 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	61	61
Additional paid-in capital	183,652,376	182,560,859
Accumulated deficit	(172,283,951)	(150,897,789)
Total stockholders' equity	12,750,509	33,045,154
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 19,319,513</b>	<b>\$ 37,201,809</b>

*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,	
	2022	2021	2022	2021
<b>COSTS AND EXPENSES:</b>				
Research and development	\$ 5,380,190	\$ 3,937,464	\$ 13,765,846	\$ 13,198,294
General and administrative	2,435,296	1,882,190	7,625,391	5,009,581
Total costs and expenses	7,815,486	5,819,654	21,391,237	18,207,875
<b>LOSS FROM OPERATIONS</b>	<b>(7,815,486)</b>	<b>(5,819,654)</b>	<b>(21,391,237)</b>	<b>(18,207,875)</b>
<b>OTHER INCOME:</b>				
Interest income, net	4,164	590	5,075	3,611
Total other income	4,164	590	5,075	3,611
<b>NET LOSS</b>	<b>\$ (7,811,322)</b>	<b>\$ (5,819,064)</b>	<b>\$ (21,386,162)</b>	<b>\$ (18,204,264)</b>
<b>BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE</b>	<b>\$ (1.28)</b>	<b>\$ (0.97)</b>	<b>\$ (3.50)</b>	<b>\$ (3.39)</b>
<b>SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE</b>	<b>6,110,119</b>	<b>5,986,837</b>	<b>6,110,123</b>	<b>5,363,342</b>

*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
	Shares	Amount	Shares	Par Amount	Paid-In Capital	Deficit	Stockholders' Equity
BALANCE AT DECEMBER 31, 2020	1,734	\$ 20,035,849	4,544,272	\$ 45	\$ 161,534,062	\$ (126,775,427)	\$ 54,794,529
Stock-based compensation	—	—	—	—	124,564	—	124,564
Conversion of preferred shares for common shares	(789)	(8,288,652)	627,823	6	8,288,646	—	—
Exercise of warrants for common shares	—	—	100,532	1	1,213,923	—	1,213,924
Net loss	—	—	—	—	—	(6,357,170)	(6,357,170)
BALANCE AT MARCH 31, 2021	945	\$ 11,747,197	5,272,627	\$ 52	\$ 171,161,195	\$ (133,132,597)	\$ 49,775,847
Stock-based compensation	—	—	—	—	200,617	—	200,617
Conversion of preferred shares for common shares	(250)	(3,109,552)	250,000	3	3,109,549	—	—
Issuance of common stock, net of issuance costs	—	—	4,169	—	34,873	—	34,873
Retired shares	—	—	(3)	—	—	—	—
Net loss	—	—	—	—	—	(6,028,030)	(6,028,030)
BALANCE AT JUNE 30, 2021	695	\$ 8,637,645	5,526,793	\$ 55	\$ 174,506,234	\$ (139,160,627)	\$ 43,983,307
Stock-based compensation	—	—	—	—	421,161	—	421,161
Conversion of preferred shares for common shares	(584)	(7,255,622)	583,333	6	7,255,616	—	—
Net loss	—	—	—	—	—	(5,819,064)	(5,819,064)
BALANCE AT SEPTEMBER 30, 2021	111	\$ 1,382,023	6,110,126	\$ 61	\$ 182,183,011	\$ (144,979,691)	\$ 38,585,404
BALANCE AT DECEMBER 31, 2021	111	\$ 1,382,023	6,110,126	\$ 61	\$ 182,560,859	\$ (150,897,789)	\$ 33,045,154
Stock-based compensation	—	—	—	—	303,805	—	303,805
Retired shares	—	—	(1)	—	—	—	—
Net loss	—	—	—	—	—	(6,139,797)	(6,139,797)
BALANCE AT MARCH 31, 2022	111	\$ 1,382,023	6,110,125	\$ 61	\$ 182,864,664	\$ (157,037,586)	\$ 27,209,162
Stock-based compensation	—	—	—	—	419,953	—	419,953
Retired shares	—	—	(2)	—	—	—	—
Net loss	—	—	—	—	—	(7,435,043)	(7,435,043)
BALANCE AT JUNE 30, 2022	111	\$ 1,382,023	6,110,123	\$ 61	\$ 183,284,617	\$ (164,472,629)	\$ 20,194,072
Stock-based compensation	—	—	—	—	367,759	—	367,759
Retired shares	—	—	(4)	—	—	—	—
Net loss	—	—	—	—	—	(7,811,322)	(7,811,322)
BALANCE AT SEPTEMBER 30, 2022	111	\$ 1,382,023	6,110,119	\$ 61	\$ 183,652,376	\$ (172,283,951)	\$ 12,750,509

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

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

	<b>Nine Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (21,386,162)	\$ (18,204,264)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	110,276	110,624
Stock-based compensation expense	1,091,517	746,342
Noncash lease expense	66,547	57,160
Loss on disposal of fixed assets	3,386	2,938
Changes in:		
Prepaid expenses and other current assets	(108,451)	(273,650)
Lease liability	(99,772)	(88,268)
Accounts payable and accrued liabilities	2,512,121	(408,708)
Cash used in operating activities	(17,810,538)	(18,057,826)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(108,115)	(11,622)
Cash used in investing activities	(108,115)	(11,622)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock, net of issuance costs	—	34,874
Proceeds from exercise of warrants	—	1,213,924
Cash provided by financing activities	—	1,248,798
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(17,918,653)</b>	<b>(16,820,650)</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>35,703,975</b>	<b>57,165,377</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 17,785,322</b>	<b>\$ 40,344,727</b>
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION</b>		
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 designed to specifically target cancer cells and to 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 \$172,284,000 as of September 30, 2022. During the nine months ended September 30, 2022, the Company generated a net loss of approximately \$21,386,000 and expects that it will continue to generate operating losses for the foreseeable future. The Company believes that its cash balance as of September 30, 2022 is adequate to fund its basic budgeted operations into the fourth quarter of 2023.

After the third quarter ended, in October 2022, the Company completed a registered direct offering and concurrent private placement of shares of the Company’s common stock, prefunded warrants and common warrants. The offering and private placements resulted in total gross proceeds of approximately \$10.7 million with net proceeds to the Company of approximately \$9.7 million after deducting estimated offering expenses (see Note 8). 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 other source of capital. The Company plans to continue actively pursuing financing alternatives, however, there can be no assurance that it will obtain the necessary funding, raising substantial doubt about the Company’s ability to continue as a going concern within one year of the date these financial statements are issued. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The accompanying Condensed Consolidated Balance Sheet as of December 31, 2021 has been derived from our audited financial statements. The accompanying unaudited Condensed Consolidated Balance Sheet as of September 30, 2022, and the Condensed Consolidated Statements of Operations, the Condensed Statements of Stockholders’ Equity for the three and nine months ended September 30, 2022 and 2021, the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2022 and 2021, 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 U.S. 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, 2022 and the consolidated results of its operations and stockholders’ equity for the three and nine months ended September 30, 2022 and 2021, and cash flows for the nine months ended September 30, 2022 and 2021. The results for the three and nine months ended September 30, 2022 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, 2021, which was filed with the SEC on March 21, 2022.

**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, 2022.

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

**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 stock option grants issued in 2022 and 2021 ranged from one year to three years.

**Research and Development** — Research and development costs are expensed as incurred. The Company recognizes revenue and cost reimbursements from government grants when it is probable that the Company will comply with the conditions attached to the grant arrangement and the grant proceeds will be received. Government grants are recognized in the Condensed 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 Condensed Consolidated Statements of Operations. The Company records government grants receivable in the Condensed 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 are no uncertain tax positions that require accrual to or disclosure in the financial statements as of September 30, 2022 and December 31, 2021.

**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 cash equivalents on deposit with financial institutions. The Company's excess cash as of September 30, 2022 and December 31, 2021 is on deposit in interest-bearing accounts with well-established financial institutions. At times, such amounts may exceed the FDIC insurance limits. As of September 30, 2022 and December 31, 2021, uninsured cash balances totaled approximately \$17,300,000 and \$35,200,000, respectively.

**Recently Adopted Accounting Pronouncements** — Beginning January 1, 2021, management adopted FASB 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. 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.

**New Accounting Pronouncements – Issued but Not Yet Adopted** — In December 2021, the FASB issued ASU No. 2021-10, Government Assistance (Topic 832), which aims to provide increased transparency by requiring business entities to disclose information about certain type of government assistance they receive in the notes to the financial statements. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

## 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 in the Condensed Consolidated Balance sheets for other current financial assets and liabilities approximate fair value because of their short-term nature.

## 3. STOCKHOLDERS' EQUITY

### *2022 Reverse Stock Split*

At the annual stockholders' meeting held on June 24, 2022, the Company's stockholders approved an amendment to the Company's certificate of incorporation to effect a reverse split of the Company's common stock at a ratio between 1-for-5 to 1-for-10 in order to satisfy requirements for the continued listing of the Company's common stock on Nasdaq. The board of directors authorized the 1-for-10 ratio of the reverse split on June 27, 2022, and effective at the close of business on July 21, 2022, the Company's certificate of incorporation was amended to effect a 1-for-10 reverse split of the Company's common stock (the "Reverse Stock Split"). The accompanying condensed consolidated financial statements and notes to condensed consolidated financial statements give retroactive effect to the Reverse Stock Split for all periods presented.

### *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. The Reverse Stock Split did not change the amount of authorized common stock.

### *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 of 3.0% 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, or (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 (see Note 8).

In June 2021, the Company issued and sold an aggregate of 4,169 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 sold 1,814,813 shares of common stock, par value \$0.00001 per share, at a public offering price of \$13.50 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 1,518,518 shares of Series D convertible preferred stock. These preferred shares are convertible into a number of shares of common stock equal to \$13,500 divided by \$13.50 (or 1,000 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 were only 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, 574,073 shares of our Series D convertible preferred stock were converted into 574,073 shares of common stock at the established conversion rate. During the three months ended June 30, 2021, 250 shares of our Series D convertible preferred stock were converted into 250,000 of common stock. During the three months ended September 30, 2021, 583.33 shares of our Series D convertible preferred stock were converted into 583,333 shares of common stock. There were no preferred stock conversions in the three months ended December 31, 2021, or the nine months ended September 30, 2022.

The net proceeds of the December public offering and private placement to the Company, after deducting 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 the total increase to Stockholders' Equity of \$45.0 million, but is an internal, proportionate calculation allocating gross proceeds of approximately \$24.5 million to common stock and \$20.5 million to preferred stock.

### Common Stock Warrants

The following table summarizes information regarding outstanding warrants to purchase common stock as of September 30, 2022:

Offering	Number of Shares Issuable Upon Exercise of Outstanding Warrants	Exercise Price	Expiration Date
June 2020 Series H Warrants	720,796	\$ 12.075	June 5, 2025
May 2019 Series F Warrants	195,700	\$ 24.00	May 20, 2024
May 2019 Series G Warrants	201,800	\$ 24.00	May 20, 2024
July 2018 Series E Warrants	414,000	\$ 40.00	July 31, 2023
October 2017 Series D Warrants	31,085	\$ 178.00	October 14, 2024
Total	<u>1,563,381</u>		

## 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, with an initial authorization of an aggregate of 600,000 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 three 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.

At the 2022 annual meeting of stockholders held on June 24, 2022, the Company’s stockholders approved an increase in the number of shares of common stock available for issuance under our 2021 Stock Incentive Plan by 500,000 shares.

As of September 30, 2022, there are an aggregate of 612,742 shares available for future grants under the 2021 Plan.

[Table of Contents](#)

During the nine-month periods ended September 30, 2022 and 2021, options granted were 340,250 and 353,750, respectively. The following table summarizes amounts charged to expense for stock-based compensation related to employee and director stock option grants:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
Employee and director stock option grants:				
Research and development	\$ 37,211	\$ 62,655	\$ 123,638	\$ 133,450
General and administrative	330,548	358,506	967,879	612,892
Total stock-based compensation	<u>\$ 367,759</u>	<u>\$ 421,161</u>	<u>\$ 1,091,517</u>	<u>\$ 746,342</u>

On March 4, 2021, the Company granted 281,000 contingent non-statutory stock option awards at an exercise price of \$17.40 per share to its 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 the remaining 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, 2022 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, 2021	423,820	\$ 22.70		\$ —
Granted	277,850	\$ 5.47		
Forfeited	(95,200)	\$ 12.78		
Outstanding at March 31, 2022	606,470	\$ 16.37	9.03	\$ —
Granted	62,400	\$ 4.69		
Forfeited	(11,543)	\$ 9.09		
Outstanding at June 30, 2022	657,327	\$ 15.39	8.84	\$ —
Granted	—			
Forfeited	(3,064)	\$ 36.04		
Outstanding at September 30, 2022	654,263	\$ 15.29	8.63	\$ —
Exercisable, September 30, 2022	202,398	\$ 28.00	7.73	\$ —
Unvested, September 30, 2022	451,865	\$ 9.59	9.04	\$ —

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, 2022, there was approximately \$2,144,000 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, the Company expects to recognize approximately \$366,000, \$1,244,900, \$501,100, and \$32,000 during 2022, 2023, 2024, and 2025, 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 as of September 30, 2022 was \$20.41 and \$6.14, respectively. As of September 30, 2021, the weighted-average grant-date fair value of vested and unvested options was \$42.40 and \$9.20, respectively.

## 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, 2022 or 2021, 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 loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing net 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, preferred shares convertible into common stock and, pre-funded warrants. Since there is a net loss attributable to common stockholders for all periods presented, the inclusion of common stock equivalents in the computation for each period would be antidilutive.

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

	As of September 30,	
	2022	2021
Warrants	1,563,381	1,607,961
Preferred shares as convertible into common stock	111,111	694,444
Stock options	654,263	470,178
Total potentially dilutive shares	2,328,755	2,772,583

## 7. COMMITMENTS AND CONTINGENCIES

### Real Property Leases

#### *Florham Park, New Jersey*

On June 4, 2018, the Company entered into an Agreement of Lease for 3,893 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 until the termination date.

#### *Madison, Wisconsin*

The Company presently rents office space in Madison for approximately \$3,000 per month under an agreement that expires on October 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 a fixed rent amount monthly based on an 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 \$138,000 and (\$202,000), respectively, as of September 30, 2022 and rental expense for the nine months ended September 30, 2022 was 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 considered 10% per annum as reasonable to use as the incremental borrowing rate for purposes of the calculation of lease liabilities at their inception.

**Maturity Analysis of Short-Term and Operating Leases**

The following table approximates the Company's undiscounted payments for its short-term leases and operating lease liabilities as of September 30, 2022:

Years ending December 31,	
Remainder of 2022	\$ 40,000
2023	161,000
2024	14,000
Total undiscounted lease payments	215,000
Less: Imputed interest	(13,000)
Present value of lease liabilities	\$ 202,000

**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. SUBSEQUENT EVENT**

On October 25, 2022, we completed a registered direct offering of 3,275,153 shares of the Company's common stock at \$2.085 per share and warrants to purchase up to an aggregate of 3,275,153 shares of common stock in a concurrent private placement priced at-the-market under Nasdaq rules. In a separate concurrent private placement transaction, the Company offered and sold pre-funded warrants to purchase an aggregate of 1,875,945 shares of common stock and warrants to purchase an aggregate of 1,875,945 shares of common stock. The warrants are immediately exercisable at an exercise price of \$1.96 per share and will expire on the fifth anniversary of the closing date. Each pre-funded warrant had a purchase price of \$2.08499, is immediately exercisable at an exercise price of \$0.00001 per share and will not expire until exercised in full. The registered direct offering and private placements resulted in total gross proceeds of approximately \$10.7 million with net proceeds to the Company of approximately \$9.7 million after deducting estimated offering expenses.

In conjunction with this offering, the Company filed a prospectus supplement suspending the ATM program discussed in Note 3. The Company will not make any sales of its common stock pursuant to the Equity Distribution Agreement unless and until a new prospectus supplement is filed with the SEC; however, the Equity Distribution Agreement remains in full force and effect.

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

### **Overview**

*You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited financial information and notes thereto included in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, include forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section in our Annual Report on Form 10-K for the year ended December 31, 2021, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

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

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 Waldenström's macroglobulinemia (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 resulting from concerns among patients about participating in clinical studies while COVID-19 continues to be a significant concern. 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 U.S., 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 U.S., 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 patients' and their caregivers' access to high quality care and innovative treatments for their cancer.

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

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

Our PDC platform is designed to provide selective delivery of a diverse range of oncologic payloads to cancerous cells, whether a hematologic cancer or solid tumor, a primary tumor, or a metastatic tumor and cancer stem cells. The PDC platform's mechanism of entry is designed not to rely upon 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 are designed to bind to these regions and directly enter the intracellular compartment. This mechanism allows the PDC molecules to accumulate in tumor cells over time, which we believe can enhance drug efficacy, 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, we were granted Small and Medium-Sized Enterprise (SME) status by the the European Medicines Agency's (EMA) 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 (PRiority MEdicines) 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.

### **Clinical Pipeline**

Our lead PDC therapeutic, iopofosine I 131 ("iopofosine"), is a small-molecule PDC designed to provide targeted delivery of iodine-131 directly to cancer cells, while limiting exposure to healthy cells. We believe this profile and its unique mechanism of action 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 r/r CNS lymphomas and the CLOVER-2 Phase 1 study for a variety of pediatric cancers. As with all clinical trials, adverse events, serious adverse events or fatalities may arise during a clinical trial due to medical problems that may not be related to clinical trial treatments. Adverse events across all studies include fatigue (39%) and cytopenias, specifically, thrombocytopenia (75%), anemia (61%), neutropenia (54%), leukopenia (56%), and lymphopenia (34%). Patients in our clinical trials have developed infections (<4%) and in at least one instance led to a fatality possibly attributed to iopofosine.

The CLOVER-WaM pivotal Phase 2b study is enrolling 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 an 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, and to determine maximum tolerated dose (MTD), and was initiated in April 2015. The study completed enrollment and the final clinical study report was completed during the third quarter 2022. 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-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-1 Phase 2b study, where iopofosine remains under further evaluation in late treatment line highly refractory MM patients, is ongoing.

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 ODD from the European Union for MM. In December 2019, the FDA and the European Union each granted ODD for iopofosine for the treatment of LPL/MM. The FDA granted Fast Track designation for iopofosine for the treatment of r/r LPL and MM in May 2020.

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

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

In January 2021, we announced that a Type C guidance meeting with the FDA was conducted in September 2020. The results of that guidance meeting provided Cellectar with an agreed upon path for conducting the CLOVER-WaM study; a single arm, pivotal study in MM patients that have received standard of care first line therapy and either failed or had a suboptimal response to BTKi therapy. We believe this design is in alignment with the feedback received from the FDA during the guidance meeting held in September 2020. The FDA agreed with our choice of 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 and requested that we submit a revised protocol. Based upon this agreement, a revised protocol was submitted and the pivotal study was initiated. MM 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.

This Phase 2 pivotal portion of the study is expected to include 40 to 50 global sites and enroll 50 WM patients who have received at least two prior lines of therapy, failed both lines of therapy including having failed or had a suboptimal response to a BTKi (i.e. ibrutinib). Patients in the trial will receive up to 4-doses of iopofosine over two cycles (cycle one: days 1, 15, and cycle two: days 57, 71) with each dose administered as a 15mCi/m<sup>2</sup> infusion. The primary endpoint of the trial is major response rate (MRR) as defined as a partial response (a minimum of a 50% reduction in IgM) or better in patients that receive a minimum total body dose (TBD) of 60 mCi with secondary endpoints of treatment free survival (treatment free remission), duration of response and progression free survival. In April 2022, we announced that an independent data monitoring committee (DMC) performed an interim safety and futility evaluation on the first 10 patients enrolled and unanimously recommended continuation of the trial as planned.

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

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 partially supported the Phase 2 CLOVER-1 study which was initiated in March 2017 as an open-label study designed to determine the efficacy and safety of CLR 131 in select B-cell malignancies (multiple myeloma (MM), indolent chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), lymphoplasmacytic lymphoma (LPL)/Waldenstrom's macroglobulinemia (WM), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), DLBCL, and central nervous system lymphoma (CNSL) who have been previously treated with standard therapy for their underlying malignancy. As of March 2022, the study arms for CLL/SLL, LPL, MZL, MCL, and DLBCL are closed. Dosing of patients varied by disease state cohort and was measured in terms of TBD.

This Phase 2a portion of the study was conducted in approximately 10 U.S. cancer centers in patients with orphan-designated relapse or refractory hematologic cancers. The planned study enrollment was up to 80 patients.

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

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

Patients in the r/r WM cohort all received TBD of  $\geq 60$  mCi (25 mCi/m<sup>2</sup> single bolus, 31.25 mCi/m<sup>2</sup> fractionated, 37.5 mCi/m<sup>2</sup> fractionated, or two cycles of mCi/m<sup>2</sup> fractionated) either as a bolus dose or fractionated. Current data from our Phase 2a CLOVER-1 clinical study show a 100% ORR in 6 WM patients and an 83.3% major response rate with one patient achieving a complete response (CR), which continues at nearly 37 months post-last treatment. While median treatment free survival (TFS), also known as treatment free remission (TFR), and DOR have not been reached, the average treatment TFS/TFR is currently at 330 days. We believe this may represent an important improvement in the treatment of r/r WM as we believe no approved or late-stage development treatments for second- and third-line patients have reported a CR to date. Based on study results to date, patients continue to tolerate iopofosine well, with the most common adverse events being cytopenias and fatigue.

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

In September 2020, we announced that a 40% ORR was observed in the subset of refractory multiple myeloma patients deemed triple class refractory who received 60 mCi or greater TBD. Triple class refractory is defined as patients that are refractory to immunomodulatory, proteasome inhibitors and anti-CD38 antibody drug classes. The 40% ORR (6/15 patients) represents triple class refractory patients enrolled in Part A of Cellectar's CLOVER-1 study and additional patients enrolled in Part B from March through May 2020 and received  $\geq 60$  mCi TBD (25 mCi/m<sup>2</sup> single bolus, 31.25 mCi/m<sup>2</sup> fractionated, 37.5 mCi/m<sup>2</sup> fractionated, or two cycles of mCi/m<sup>2</sup> fractionated) either as a bolus dose or fractionated. Patients with MM received 40 mg of dexamethasone concurrently beginning within 24 hours of the first CLR 131 infusion. All MM patients enrolled in the expansion cohort are required to be triple class refractory. The additional six patients enrolled in 2020 were heavily pre-treated with an average of nine prior multi-drug regimens. Three patients received a TBD of  $\geq 60$  mCi and three received less than 60 mCi. Consistent with the data released in February 2020, patients receiving  $\geq 60$  mCi typically exhibit greater responses. Based on study results to date, patients continue to tolerate iopofosine well, with the most common and almost exclusive treatment-emergent adverse events are cytopenias, such as thrombocytopenia, neutropenia, and anemia.

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

Based upon the dose response observed in the Phase 2a study for patients receiving TBDs of 60 mCi or greater, we determined that patient dosing of iopofosine in the pivotal study for WM would be  $>60$  mCi. Therefore, previously dosed patients are now grouped as receiving  $<60$  mCi or  $>60$  mCi, and the study is designed to have all patients who are evaluated for efficacy receive  $>60$  mCi in the future.

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

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 indicate that iopofosine was tolerated up to a TBD of approximately 95 mCi 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 MM patients in this study received single cycle doses ranging from approximately 20 mCi to 95 mCi TBD. An independent DMC assessed the safety of all doses used with patients and deemed them to be well tolerated.

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. 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. Multiple myeloma is an incurable cancer of the plasma cells and is the second most common form of hematologic cancer. 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. An independent DMC assessed the safety of iopofosine up to its planned maximum single, bolus dose of 31.25 mCi/m<sup>2</sup> or a TBD of ~63 mCi. The four single dose cohorts examined were: 12.5 mCi/m<sup>2</sup> (~25mCi TBD), 18.75 mCi/m<sup>2</sup> (~37.5mCi TBD), 25 mCi/m<sup>2</sup> (~50mCi TBD), and 31.25 mCi/m<sup>2</sup> (~62.5mCi TBD), all in combination with low dose dexamethasone (40 mg weekly). Of the five patients in the first cohort, four were assessed as achieving stable disease and one patient progressed at Day 15 after administration and was taken off the study. Of the five patients admitted to the second cohort, all five were assessed as achieving stable disease; however, one patient progressed at Day 41 after administration and was taken off the study. Four patients were enrolled to the third cohort, and all were assessed as achieving stable disease. In September 2017, we announced safety and tolerability data for cohort 4, in which patients were treated with a single infusion up to 30-minutes of 31.25mCi/m<sup>2</sup> of iopofosine, which was tolerated by the three patients in the cohort. Additionally, all three patients experienced CBR with one patient achieving a partial response (PR). The patient experiencing a PR had an 82% reduction in FLC. This patient did not produce M protein, had received seven prior lines of treatment including radiation, stem cell transplantation and multiple triple combination treatments including one with daratumumab that was not tolerated. One patient experiencing stable disease attained a 44% reduction in M protein. In January 2019, we announced that the pooled mOS data from the first four cohorts was 22.0 months. In late 2018, we modified this study to evaluate a fractionated dosing strategy to potentially increase efficacy and decrease adverse events.

Cohort 5 and cohort 6 received fractionated dosing of 31.25 mCi/m<sup>2</sup> (~62.5mCi TBD) and 37.5 mCi/m<sup>2</sup> (~75mCi TBD), each administered on day 1 and on day 8. Following the determination that all prior dosing cohorts were tolerated, we initiated a cohort 7 utilizing a 40mCi/m<sup>2</sup> (~95mCi TBD) fractionated dose administered 20mCi/m<sup>2</sup> (~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 second half of 2022. Adverse events occurring in at least 25% of subjects were fatigue (26%) and cytopenias, specifically, thrombocytopenia (90%), anemia (65%), neutropenia (55%), leukopenia (61%), and lymphopenia (58%). Serious adverse events occurring in greater than 2 subjects were restricted to febrile neutropenia n=3 (9.7%).

In May 2019, we announced that the FDA granted Fast Track Designation for iopofosine in fourth line or later r/r MM. Iopofosine is currently being evaluated in our ongoing CLOVER-1 Phase 2 clinical study in patients with r/r MM and other select B-cell lymphomas. Patients in the study received up to 4, approximately 20-minute IV infusions of iopofosine over 3 months, with doses given 14 days apart in each cycle and a maximum of 2 cycles. Low dose dexamethasone 40 mg weekly (20mg in patients  $\geq$  75), was provided for up to 12 weeks. The planned study enrollment was up to 80 patients. Its primary endpoint was clinical benefit rate (CBR), with additional endpoints of ORR, PFS, median overall survival (OS) and other markers of efficacy. Over the course of the study the dosing regimen of iopofosine advanced from a single bolus dose to two cycles of fractionated administrations of 15 mCi/m<sup>2</sup> per dose on days 1, 15 (cycle 1), and days 57, 71 (cycle 2). Following treatment with iopofosine, approximately 91% of patients experience a reduction in tumor marker with approximately 73% experiencing greater than 37% reduction.

In December 2021, we presented data from 11 MM patients from our ongoing Phase 2 CLOVER-1 study in a poster at the American Society of Hematology (ASH) Annual Meeting and Exposition. The MM patients were at least triple class refractory (defined as refractory to an immunomodulatory agent, proteasome inhibitor and monoclonal antibody) with data current as of the end of May 2021. Patients had a median of greater than 7 prior therapies with 50% classified as high risk. Initial results in these patients showed an ORR of 45.5%, a CBR of 72.7% and a disease control rate (DCR) of 100%. Median PFS was 3.4 months. In a subset of 5 quad/penta drug refractory patients, efficacy increased, demonstrating an ORR of 80% and CBR of 100% in this highly treatment refractory group. The most commonly observed treatment emergent adverse events were cytopenias that included Grade 3 or 4 thrombocytopenia (62.5%), anemia (62.5%), neutropenia (62.5%) and decreased white blood cell count (50%). Treatment emergent adverse events were mostly limited to bone marrow suppression in line with prior observations. No patients experienced a treatment emergent adverse event of neuropathy, arrhythmia, cardiovascular event, bleeding, ocular toxicities, renal function, alterations in liver enzymes, or infusion-site reactions or adverse events.



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

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

In 2018, the FDA granted ODD and RPDD for iopofosine for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. If iopofosine should be approved for any of these pediatric indications, the first approved RPDD would enable us to receive a priority review voucher. Priority review vouchers can be used by the sponsor to receive priority review for a future New Drug Application (NDA) or Biologic License Application (BLA) submission, which would reduce the FDA review time from 12 months to nine 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.

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

In September 2022, we were awarded \$1.98 million in additional grant funding to expand our ongoing Phase 1 study of iopofosine I 131 in children and adolescents with inoperable relapsed or refractory high grade gliomas (HGGs). The grant was awarded by the NCI based upon the initial signals of efficacy in the Phase 1 study, which is an international, open-label, dose escalation, safety study. The funding allows for an expansion from Part 1a into the Part 1b portion of our ongoing Phase 1 pediatric study.

### **Phase 1 Study in r/r Head and Neck Cancer**

In August 2016, the University of Wisconsin Carbone Cancer Center (UWCCC) was awarded a five-year Specialized Programs of Research Excellence (SPORE) grant of \$12,000,000 from the NCI and the National Institute of Dental and Craniofacial Research to improve treatments and outcomes for head and neck cancer (HNC) patients. HNC is the sixth most common cancer across the world with approximately 56,000 new patients diagnosed every year in the U.S. As a key component of this grant, the UWCCC researchers completed testing of iopofosine in various animal HNC models and initiated the first human clinical study enrolling up to 30 patients combining iopofosine and external beam radiation treatment (EBRT) with recurrent HNC in the fourth quarter of 2019. UWCCC has completed the part A portion of a safety and tolerability study of iopofosine in combination with EBRT and preliminary data suggest safety and tolerability in relapsed or refractory HNC. The reduction in the amount or fractions (doses) of EBRT has the potential to diminish the (number and severity of) adverse events associated with EBRT. Patients with HNC typically receive approximately 60-70 Grays (Gy) of EBRT given as 2 – 3 Gy daily doses over a 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. Adverse events occurring in at least 25% of subjects were fatigue (46%) and cytopenias, specifically, thrombocytopenia (69%), anemia (77%), neutropenia (54%), leukopenia (69%), and lymphopenia (62%). There were no serious adverse events occurring in more than 2 subjects.



## 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 an alpha emitting radio-conjugate program. We have initiated efforts to validate the potential of this class of PDC radio-conjugates and for the potential development of novel PDCs utilizing alpha emitters such as lead 212 conjugated to our phospholipid ether. The evaluation of these new PDCs focused on three oncology indications. The in vivo animal data demonstrated that the PDC combined with an alpha emitting radioisotope resulted in significant reduction in tumor volumes in all animal models tested.
- 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, 2022 and 2021

**Research and Development.** Research and development expense for the three months ended September 30, 2022 was approximately \$5,380,000, compared to approximately \$3,937,000 for the three months ended September 30, 2021. The following table is a summary comparison of research and development costs.

	Three Months Ended September 30,		Variance
	2022	2021*	
Clinical project costs	\$ 3,720,000	\$ 2,909,000	\$ 811,000
Manufacturing and related costs	1,049,000	506,000	543,000
Pre-clinical project costs	89,000	4,000	85,000
General research and development costs	522,000	518,000	4,000
	<u>\$ 5,380,000</u>	<u>\$ 3,937,000</u>	<u>\$ 1,443,000</u>

\* Prior period amounts have been reclassified to conform with current period presentation.

The overall increase in research and development expense of approximately \$1,443,000, or 37%, was primarily a result of increased clinical project costs of approximately \$811,000, driven by the timing of the activities related to our pivotal trial, and an increase in manufacturing and related costs related to production sourcing of approximately \$543,000.

**General and administrative.** General and administrative expense for the three months ended September 30, 2022 was approximately \$2,435,000, compared to approximately \$1,882,000 for the same period in 2021. The overall increase in general and administrative expense of \$553,000, or 29%, was primarily driven by increased professional fees and public company costs.

### Nine months Ended September 30, 2022 and 2021

**Research and Development.** Research and development expense for the nine months ended September 30, 2022 was approximately \$13,776,000, compared to approximately \$13,198,000 for the nine months ended September 30, 2021. The following table is a summary comparison of research and development costs for the nine months.

	Nine Months Ended September 30,		Variance
	2022	2021*	
Clinical project costs	\$ 9,715,000	\$ 10,200,000	\$ (485,000)
Manufacturing and related costs	3,011,000	1,663,000	1,348,000
Pre-clinical project costs	191,000	23,000	168,000
General research and development costs	849,000	1,312,000	(463,000)
	<u>\$ 13,766,000</u>	<u>\$ 13,198,000</u>	<u>\$ 568,000</u>

\* Prior period amounts have been reclassified to conform with current period presentation.

The overall increase in research and development expense of approximately \$568,000, or 4%, was primarily a result of an increase in manufacturing and related costs related to production sourcing and pre-clinical project costs. This increase was partially offset by reduced clinical project costs of approximately \$485,000, driven by the timing of the activities related to our pivotal trial and a reduction in general research and development costs of approximately \$463,000.

**General and administrative.** General and administrative expense for the nine months ended September 30, 2022 was approximately \$7,625,000, compared to approximately \$5,010,000 for the same period in 2021. The overall increase in general and administrative expense of \$2,615,000, or 52%, was primarily driven by increased professional fees, travel and personnel costs.

## **Liquidity and Capital Resources**

As of September 30, 2022, we had cash and cash equivalents of approximately \$17,785,000, compared to approximately \$35,704,000 as of December 31, 2021. This decrease was due to our ongoing investment in clinical trials and pre-clinical research and development, and general and administrative expenses. Net cash used in operating activities during the nine months ended September 30, 2022 was approximately \$17,811,000.

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, 2022, we had an accumulated deficit of approximately \$172,284,000.

As discussed in Note 8 to the financial statements, in October 2022 we completed a registered direct offering and concurrent private placement. The offering and private placements resulted in total gross proceeds of approximately \$10.7 million with net proceeds to the Company of approximately \$9.7 million after deducting estimated offering expenses.

We believe that our cash balance, as supplemented by the October 2022 financing, is adequate to fund our basic budgeted operations into the fourth quarter of 2023. 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 3. Quantitative and Qualitative Disclosures about Market Risk***

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

### ***Item 4. Controls and Procedures***

*Evaluation of Disclosure Controls and Procedures.* Based on management's evaluation (with the participation of our principal executive officer and principal financial officer), as of September 30, 2022, 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 management's evaluation (with the participation of our principal executive officer and principal financial officer), as of September 30, 2022, 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, 2022 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 alleged, 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. Wisconsin Alumni Research Foundation, the putative owner of the disputed intellectual property that licensed the intellectual property to Dr. Weichert’s new company, moved to intervene in litigation. 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.

In October 2022, Collectar Biosciences, Inc., Wisconsin Alumni Research Foundation, and Drs. Weichert and Pinchuk resolved the dispute. As a result of the settlement, Collectar Biosciences, Inc. has secured non-exclusive license to the patents at issue in the 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 21, 2022 pursuant to Section 13 or 15(d) of the Exchange Act (the “2021 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.

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

None.

### ***Item 3. Default Upon Senior Securities***

None.

### ***Item 4. Mine Safety Disclosures***

Not applicable.

### ***Item 5. Other Information***

None.

**Item 6. Exhibits**

Exhibit No.	Description	Filed with this Form 10-Q	Incorporation by Reference		
			Form	Filing Date	Exhibit No.
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>	X			
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>	X			
32.1	<a href="#">Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>	X			
101	Interactive Data Files	X			
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit).	X			

**SIGNATURES**

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

**CELLECTAR BIOSCIENCES, INC.**

Date: November 3, 2022

By: /s/ James V. Caruso

James V. Caruso  
President and Chief Executive Officer

I, JAMES V. CARUSO, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Collectar 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 3, 2022

/s/ James V. Caruso

James V. Caruso

President and Chief Executive Officer

(Principal Executive Officer)

---

I, CHAD J. KOLEAN, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cellestar 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 3, 2022

/s/ Chad J. Kolean

Chad J. Kolean

Chief Financial Officer

(Principal Financial and Accounting Officer)

---



**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 Collectar Biosciences, Inc. (the "Company") for the quarter ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, James V. Caruso, President and Chief Executive Officer of the Company, and Chad J. Kolean, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to our knowledge, that:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James V. Caruso

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

Date: November 3, 2022

/s/ Chad J. Kolean

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

Date: November 3, 2022

---