

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, 2020

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
Warrant to purchase common stock, expiring April 20, 2021	CLRBZ	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: 26,813,593 shares of common stock, \$0.00001 par value per share, as of November 4, 2020.

CELLECTAR BIOSCIENCES, INC.

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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 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 CLR 131, CLR 1800 series, CLR 1900 series, CLR 2000 series, CLR 2100 series, CLR 2200 series and CLR 12120;
- our ability to continue development plans for our Phospholipid Drug Conjugates (PDC)[™];
- our ability to maintain orphan drug designation in the U.S. for CLR 131 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 CLR 131;
- our ability to pursue strategic alternatives;
- our ability to advance our technologies into product candidates;
- our enhancement and consumption of current resources along with ability to obtain additional funding;
- our current view regarding general economic and market conditions, including our competitive strengths;
- uncertainty and economic instability resulting from conflicts, military actions, terrorist attacks, natural disasters, public health crises, including the occurrence of a contagious disease or illness, including the COVID-19 pandemic, cyber-attacks and general instability;
- assumptions underlying any of the foregoing; and
- any other statements that address events or developments that we intend or believe will or may occur in the future.

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

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

PART I. FINANCIAL INFORMATION

Item 1. *Financial Statements*

**CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS**

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 18,841,944	\$ 10,614,722
Prepaid expenses and other current assets	960,906	770,951
Total current assets	19,802,850	11,385,673
Fixed assets, net	374,697	435,083
Right-of-use asset, net	299,982	348,841
Long-term assets	219,121	75,000
Other assets	—	6,214
TOTAL ASSETS	\$ 20,696,650	\$ 12,250,811
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 3,839,318	\$ 2,663,873
Lease liability	116,257	105,885
Total current liabilities	3,955,575	2,769,758
LONG-TERM LIABILITIES:		
Lease liability	333,375	421,644
Loan payable	184,000	—
Total long-term liabilities	517,375	421,644
TOTAL LIABILITIES	4,472,950	3,191,402
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized; Series C preferred stock: 215 issued and outstanding as of September 30, 2020 and December 31, 2019	1,148,204	1,148,204
Common stock, \$0.00001 par value; 80,000,000 shares authorized; 26,813,593 and 9,386,689 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	268	94
Additional paid-in capital	138,235,579	119,592,366
Accumulated deficit	(123,160,351)	(111,681,255)
Total stockholders' equity	16,223,700	9,059,409
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 20,696,650	\$ 12,250,811

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,	
	2020	2019	2020	2019
COSTS AND EXPENSES:				
Research and development	\$ 2,683,944	\$ 2,703,831	\$ 7,765,673	\$ 6,821,775
General and administrative	1,225,993	1,260,048	3,725,153	3,972,275
Total costs and expenses	<u>3,909,937</u>	<u>3,963,879</u>	<u>11,490,826</u>	<u>10,794,050</u>
LOSS FROM OPERATIONS	<u>(3,909,937)</u>	<u>(3,963,879)</u>	<u>(11,490,826)</u>	<u>(10,794,050)</u>
OTHER INCOME:				
Gain on revaluation of derivative warrants	—	46,000	—	43,000
Interest income, net	374	14,072	11,730	38,041
Total other income	<u>374</u>	<u>60,072</u>	<u>11,730</u>	<u>81,041</u>
NET LOSS	<u>\$ (3,909,563)</u>	<u>\$ (3,903,807)</u>	<u>\$ (11,479,096)</u>	<u>\$ (10,713,009)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (0.15)</u>	<u>\$ (0.42)</u>	<u>\$ (0.69)</u>	<u>\$ (1.51)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>26,326,782</u>	<u>9,386,703</u>	<u>16,539,183</u>	<u>7,098,285</u>

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 Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Par Amount			
BALANCE AT DECEMBER 31, 2018	473	\$ 2,526,049	4,732,387	\$ 47	\$ 108,323,208	\$ (97,588,343)	\$ 13,260,961
Stock-based compensation	—	—	—	—	207,654	—	207,654
Vested restricted stock	—	—	9,334	—	—	—	—
Retired shares	—	—	(12)	—	—	—	—
Conversion of preferred shares into common shares	(138)	(736,987)	345,000	4	736,983	—	—
Net loss	—	—	—	—	—	(3,621,641)	(3,621,641)
BALANCE AT MARCH 31, 2019	<u>335</u>	<u>\$ 1,789,062</u>	<u>5,086,709</u>	<u>\$ 51</u>	<u>\$ 109,267,845</u>	<u>\$ (101,209,984)</u>	<u>\$ 9,846,974</u>
Issuance of common stock and warrants, net of issuance costs	—	—	4,000,000	40	9,024,529	—	9,024,569
Stock-based compensation	—	—	—	—	301,471	—	301,471
Retired shares	—	—	(6)	—	—	—	—
Conversion of preferred shares into common shares	(120)	(640,858)	300,000	3	640,855	—	—
Net loss	—	—	—	—	—	(3,187,561)	(3,187,561)
BALANCE AT JUNE 30, 2019	<u>215</u>	<u>\$ 1,148,204</u>	<u>9,386,703</u>	<u>\$ 94</u>	<u>\$ 119,234,700</u>	<u>\$ (104,397,545)</u>	<u>\$ 15,985,453</u>
Stock-based compensation	—	—	—	—	149,774	—	149,774
Net loss	—	—	—	—	—	(3,903,807)	(3,903,807)
BALANCE AT SEPTEMBER 30, 2019	<u>215</u>	<u>\$ 1,148,204</u>	<u>9,386,703</u>	<u>\$ 94</u>	<u>\$ 119,384,474</u>	<u>\$ (108,301,352)</u>	<u>\$ 12,231,420</u>
BALANCE AT DECEMBER 31, 2019	<u>215</u>	<u>\$ 1,148,204</u>	<u>9,386,689</u>	<u>\$ 94</u>	<u>\$ 119,592,366</u>	<u>\$ (111,681,255)</u>	<u>\$ 9,059,409</u>
Stock-based compensation	—	—	—	—	144,146	—	144,146
Vested restricted stock	—	—	9,334	—	—	—	—
Retired shares	—	—	(8)	—	—	—	—
Net loss	—	—	—	—	—	(3,957,608)	(3,957,608)
BALANCE AT MARCH 31, 2020	<u>215</u>	<u>\$ 1,148,204</u>	<u>9,396,015</u>	<u>\$ 94</u>	<u>\$ 119,736,512</u>	<u>\$ (115,638,863)</u>	<u>\$ 5,245,947</u>
Issuance of common stock and warrants, net of issuance costs	—	—	14,601,628	146	18,258,435	—	18,258,581
Stock-based compensation	—	—	—	—	92,643	—	92,643
Conversion of warrants into common shares	—	—	1,474,740	14	—	—	14
Net loss	—	—	—	—	—	(3,611,925)	(3,611,925)
BALANCE AT JUNE 30, 2020	<u>215</u>	<u>\$ 1,148,204</u>	<u>25,472,383</u>	<u>\$ 254</u>	<u>\$ 138,087,590</u>	<u>\$ (119,250,788)</u>	<u>\$ 19,985,260</u>
Stock-based compensation	—	—	—	—	116,292	—	116,292
Conversion of warrants into common shares	—	—	1,341,210	14	31,697	—	31,711
Net loss	—	—	—	—	—	(3,909,563)	(3,909,563)
BALANCE AT SEPTEMBER 30, 2020	<u>215</u>	<u>\$ 1,148,204</u>	<u>26,813,593</u>	<u>\$ 268</u>	<u>\$ 138,235,579</u>	<u>\$ (123,160,351)</u>	<u>\$ 16,223,700</u>

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

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

	Nine Months Ended September 30,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (11,479,096)	\$ (10,713,009)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	105,529	100,216
Stock-based compensation expense	353,081	658,899
Noncash lease expense	48,859	41,542
Gain on revaluation of derivative warrants	—	(43,000)
Changes in:		
Prepaid expenses and other current assets	(189,955)	(331,451)
Other assets	—	—
Lease liability	(77,897)	(57,263)
Accounts payable and accrued liabilities	1,175,445	1,331,523
Cash used in operating activities	<u>(10,064,034)</u>	<u>(9,012,543)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(45,143)	(18,817)
Cash used in investing activities	<u>(45,143)</u>	<u>(18,817)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants, net of underwriting issuance costs	18,258,581	9,024,569
Deferred issuance costs	(137,907)	—
Proceeds from long-term obligations	184,000	—
Proceeds from issuance of warrants	31,697	—
Issuance of common stock in connection with exercise of warrants	28	—
Payments on capital lease obligations	—	(2,213)
Cash provided by financing activities	<u>18,336,399</u>	<u>9,022,356</u>
NET INCREASE IN CASH AND CASH EQUIVALENTS	8,227,222	(9,004)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	10,614,722	13,310,616
CASH AND CASH EQUIVALENTS AT END OF PERIOD	<u>\$ 18,841,944</u>	<u>\$ 13,301,612</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest expense	\$ 1,584	\$ 1,936
Obtaining a right-of-use asset in exchange for a lease liability	\$ —	\$ 405,000
Lease liability established through right-of-use asset	\$ —	\$ 609,000

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, ORGANIZATION AND GOING CONCERN

Collectar Biosciences, Inc. (the Company) is a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer leveraging our proprietary phospholipid drug conjugate™ (PDCs™) delivery platform that are designed to specifically target cancer cells and deliver improved efficacy and better safety as a result of fewer off-target effects. The COVID-19 pandemic 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 at this time. The Company has not yet experienced any significant impacts as a result of the pandemic and have continued to enroll patients in our clinical studies. However, COVID-19 may impact our future ability to recruit patients for clinical studies, obtain adequate supply of CLR 131 and obtain additional financing.

The accompanying financial statements have been prepared on a basis that assumes that the Company will continue as a going concern and that contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. 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 \$123,160,351 at September 30, 2020. The Company has devoted substantially all its efforts toward research and development and has, during the nine months ended September 30, 2020, generated an operating loss of approximately \$11,491,000. The Company expects that it will continue to generate operating losses for the foreseeable future.

The Company believes that it has sufficient liquidity to fund operations for at least 12 months from the filing of these financial statements, therefore, the accompanying financial statements have been prepared on a basis that assumes the Company will continue as a going concern and that contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company's ability to execute its operating plan beyond that time depends on its ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. The Company plans to continue to actively pursue financing alternatives as there can be no assurance that the Company will obtain the necessary funding.

The accompanying Condensed Consolidated Balance Sheet as of December 31, 2019 has been derived from audited financial statements. The accompanying unaudited Condensed Consolidated Balance Sheet as of September 30, 2020, the Condensed Consolidated Statements of Operations, the Condensed Statements of Stockholders' Equity for the three and nine months ended September 30, 2020 and 2019, the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2020 and 2019 and the related interim information contained within the notes to the Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions, rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all the information and the notes required by U.S. GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all adjustments which are of a nature necessary for the fair presentation of the Company's consolidated financial position at September 30, 2020 and consolidated results of its operations, stockholders' equity and cash flows for the nine months ended September 30, 2020 and 2019. The results for the three or nine months ended September 30, 2020 are not necessarily indicative of future results.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and related notes thereto included in the Company's Form 10-K for the fiscal year ended December 31, 2019, which was filed with the SEC on March 9, 2020.

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. The Company's 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, 2020 or year ended December 31, 2019.

Right-of-Use Asset and Lease Liabilities — In February 2016, the Financial Accounting Standard Board ("FASB") issued Accounting Standard Update ("ASU") 2016-02, Leases (ASC 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 required lessees to recognize Right-Of-Use ("ROU") Asset and Lease Liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). On January 1, 2019, the Company adopted FASB Accounting Standards Codification ("ASC") Topic 842 using the modified retrospective method for all material leases that existed at or commenced after January 1, 2019. ROU Assets are amortized over their estimated useful life, which represents the full term of the lease.

Stock-Based Compensation — The Company uses the Black-Scholes option-pricing model to calculate the grant-date fair value of stock option awards. The resulting compensation expense, net of expected forfeitures, for awards that are not performance-based is recognized on a straight-line basis over the service period of the award, which for grants issued in 2020 and 2019 ranged from one year to three years for stock options. For stock options with performance-based vesting provisions, recognition of compensation expense, net of expected forfeitures, commences if and when the achievement of the performance criteria is deemed probable. The compensation expense, net of expected forfeitures, for performance-based stock options is recognized over the relevant performance period. Non-employee stock-based compensation is accounted for in accordance with the guidance of FASB ASC Topic 505, *Equity*. As such, the Company recognizes expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered and deemed completed by such non-employees.

Research and Development — Research and development costs are expensed as incurred. To the extent that such costs are reimbursed by the federal government on a fixed price, best efforts basis and the federal government is the sole customer for such research and development, the funding is recognized as a reduction of research and development expenses.

Income Taxes — Income taxes are accounted for using the liability method of accounting. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement basis and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some portion of the deferred tax assets will not be realized. Management has provided a full valuation allowance against the Company's gross deferred tax asset. Tax positions taken or expected to be taken in the course of preparing tax returns are required to be evaluated to determine whether the tax positions are "more likely than not" to be sustained by the applicable tax authority. Tax positions deemed not to meet a more-likely-than-not threshold would be recorded as tax expense in the current year. There were no uncertain tax positions that require accrual to or disclosure in the financial statements as of September 30, 2020 and December 31, 2019.

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. The carrying value of long-term obligations, including the current portion, approximates fair value because the fixed interest rate approximates current market rates of interest available in the market.

Derivative Instruments — The Company generally does not use derivative instruments to hedge exposures to cash flow or market risks; however, certain warrants to purchase common stock that do not meet the requirements for classification as equity, in accordance with the Derivatives and Hedging Topic of the FASB ASC, are classified as liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. These warrants are considered derivative instruments because the agreements contain a certain type of cash settlement feature, contain “down-round” provisions whereby the number of shares for which the warrants are exercisable, and/or the exercise price of the warrants are subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. The number of shares issuable under such warrants was 49,425 at June 30, 2019. The primary underlying risk exposures pertaining to the warrants and their related fair value is the change in fair value of the underlying common stock, the market price of traded warrants, and estimated timing and probability of future financings. Such financial instruments are initially recorded at fair value with subsequent changes in fair value recorded as a component of gain or loss on derivatives on the consolidated statements of operations in each reporting period. If these instruments subsequently meet the requirements for equity classification, the Company reclassifies the fair value to equity. At June 30, 2019, these warrants represented the only outstanding derivative instruments issued or held by the Company and expired on August 20, 2019.

Concentration of Credit Risk — Financial instruments that subject the Company to credit risk consist of cash and equivalents on deposit with financial institutions. The Company’s excess cash as of September 30, 2020 and December 31, 2019 is on deposit in interest-bearing transaction accounts with well-established financial institutions. At times, such amounts may exceed the FDIC insurance limits. As of September 30, 2020, and December 31, 2019, uninsured cash balances totaled approximately \$18,600,000 and \$10,100,000, respectively.

Leases — In February 2016, the FASB issued ASU 2016-02, Leases (ASC 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 required lessees to recognize Right-Of-Use Asset and Lease Liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). Lessor accounting remains largely unchanged except for changes in the definition and classification of leases. Because of the immaterial financial impact, the Company will not apply ASC 842 to leases that individually have total lease payments of less than \$100,000 over their life of service to the Company.

2. FAIR VALUE

In accordance with 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.

3. STOCKHOLDERS' EQUITY

June 2020 Public Offering

On June 5, 2020, the Company issued and sold 14,601,628 shares of common stock, 2,789,700 pre-funded warrants exercisable for one share of our common stock at an exercise price of \$0.00001 per share and 8,695,664 Series H warrants to purchase 8,695,664 shares of common stock. The public offering price of a share of common stock together with one-half of a Series H warrant to purchase one share of common stock was \$1.15. The public offering price of a pre-funded warrant together with one-half of a Series H Warrant was \$1.1499. The Series H warrants have an exercise price of \$1.2075 per share and are exercisable for five years from the date of issuance. As of September 30, 2020, all 2,789,700 pre-funded warrants and 26,250 Series H warrants have been exercised.

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

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

The common stock, pre-funded warrants and Series H warrants were offered by the Company pursuant to a registration statement on Form S-1 filed on May 8, 2020 with the SEC under the Securities Act of 1933, as amended (the "Act") and an additional registration statement filed on June 2, 2020 pursuant to Rule 462(b) under the Act.

May 2019 Public Offering

On May 20, 2019, the Company issued and sold 1,982,000 shares of common stock at an offering price of \$2.50 per share. In a concurrent private placement, the Company issued to the purchasers of our common stock, Series F warrants to purchase an aggregate of 1,982,000 shares of common stock. The Series F warrants were immediately exercisable, expire five years after the date of issuance, and have an exercise price of \$2.40.

In a separate concurrent private placement transaction, the Company sold 2,018,000 shares of common stock together with Series G warrants to purchase an aggregate of up to 2,018,000 shares of common stock. The shares of common stock and Series G warrants were priced at \$2.50 per fixed combination. The warrants sold in the private placement were immediately exercisable, expire five years after the date of issuance, and have an exercise price of \$2.40.

In accordance with the concept of ASC 820 regarding the May 2019 public offering, the Company allocated value to the proceeds to the common stock and warrants utilizing a relative fair value basis. Using the Nasdaq closing trading price for our stock on May 20, 2019, the Company computed the fair value of the shares sold. The fair value of the warrants was estimated using the Black-Scholes option-pricing model at that same date. This valuation did not impact total Stockholders' Equity of \$10.0 million, but is an internal proportionate calculation allocating the gross proceeds of approximately \$6 million to common stock and \$4.0 million to warrants.

Gross offering proceeds to the Company were \$10.0 million, with net proceeds to the Company of approximately \$9.0 million after deducting placement agent fees and related offering expenses. The Company used the net proceeds from the offering for research and development, funding clinical studies, working capital and general corporate purposes.

The registered direct offering described above was made pursuant to a registration statement on Form S-3 previously filed with and subsequently declared effective by the SEC. The unregistered common shares and warrants were offered pursuant to the exemption from registration afforded by Section 4(a)(2) under the Act, and Regulation D promulgated thereunder. The offerings' unregistered common shares and warrants were ultimately registered through our May 31, 2019 filing of Form S-1 and acceptance of this Registration Statement by the SEC.

Common Stock Warrants

The following table summarizes information with regard to outstanding warrants to purchase common stock as of September 30, 2020.

Offering	Number of Shares Issuable Upon Exercise of Outstanding Warrants	Exercise Price	Expiration Date
June 2020 Series H Warrants	8,669,414	\$ 1.21	June 5, 2025
May 2019 Series F Warrants	1,982,000	\$ 2.40	May 20, 2024
May 2019 Series G Warrants	2,018,000	\$ 2.40	May 20, 2024
July 2018 Series E Warrants	4,140,000	\$ 4.00	July 31, 2023
October 2017 Series D Warrants	310,856	\$ 17.80	October 14, 2024
November 2016 Public Offering Series C	415,785	\$ 15.00	November 29, 2021
April 2016 Underwritten Registered Series A	362,694	\$ 30.40	April 20, 2021
October 2015 Incremental Series A	30,006	\$ 21.30	October 20, 2021
October 2015 Private Placement Series A	8,636	\$ 21.30	April 1, 2021
October 2015 Offering – Placement Agent	375	\$ 283.00	October 1, 2020
Total	<u>17,937,766</u>		

4. STOCK-BASED COMPENSATION

Accounting for Stock-Based Compensation

During the nine-month periods ended September 30, 2020 and 2019 options granted were 653,750 and 411,930, respectively. The following table summarizes amounts charged to expense for stock-based compensation related to employee and director stock option grants and recorded in connection with stock options granted to non-employee consultants:

	Nine Months Ended September 30,	
	2020	2019
Employee and director stock option grants:		
Research and development	\$ 50,071	\$ 47,825
General and administrative	303,010	611,074
Total stock-based compensation	<u>\$ 353,081</u>	<u>\$ 658,899</u>

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 has been 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 applied 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. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates. An annual forfeiture rate of 2% was applied to all unvested options for employees and directors, respectively, for the nine months ended September 30, 2020 and for the year ended December 31, 2019. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest.

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, 2020 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, 2019	610,714	\$ 6.78	8.83	\$ 34,750
Granted	653,750	\$ 1.84		
Forfeited	(80,000)	\$ 2.46		
Outstanding at September 30, 2020	<u>1,184,464</u>	<u>\$ 4.34</u>	<u>8.82</u>	<u>\$ —</u>
Exercisable, September 30, 2020	<u>432,096</u>	<u>\$ 8.62</u>	<u>7.94</u>	<u>\$ —</u>
Unvested, September 30, 2020	<u>752,368</u>	<u>\$ 1.88</u>	<u>9.33</u>	<u>\$ —</u>

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, 2020, there was approximately \$904,000 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, the Company expects to recognize approximately \$114,000, \$425,000, \$292,000, and \$73,000 during 2020, 2021, 2022, and 2023 respectively. The Company’s expense estimates are based upon the expectation that all unvested options will vest in the future, less the forfeiture rate discussed above. The weighted-average grant-date fair value of vested and unvested options outstanding at September 30, 2020 was \$6.91 and \$1.45, respectively.

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

	Number of Shares	Weighted Average Grant Date Fair Value Per Share	Total Grant Date Fair Value
Outstanding at December 31, 2019	9,334	\$ 21.00	\$ 196,000
Vested	(9,334)	\$ 21.00	\$ (196,000)
Outstanding at September 30, 2020	<u>—</u>	<u>\$ —</u>	<u>\$ —</u>

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, 2020 or 2019 because the Company has experienced losses on a tax basis since inception. Because of the limited operating history, continuing losses and uncertainty associated with the utilization of the NOLs in the future, management has provided a full allowance against the value of its gross deferred tax assets.

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

6. NET LOSS PER SHARE

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted net income (loss) per share for the three and nine months ended September 30, 2020 and September 30, 2019 is computed by dividing net income (loss) by the sum of the weighted average number of shares of common stock and the dilutive potential common stock equivalents then outstanding. Potential common stock equivalents consist of stock options, non-vested restricted stock, preferred shares convertible into common stock and, pre-funded warrants. Since there is a net loss attributable to common stockholders for the three and nine months ended September 30, 2020 and September 30, 2019, the inclusion of common stock equivalents in the computation for that period would be antidilutive.

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

	Nine Months Ended September 30,	
	2020	2019
Warrants	17,937,766	9,268,352
Preferred shares as convertible into common stock	537,500	537,500
Stock options	1,184,464	610,714
Non-vested restricted stock	—	9,334
Total potentially dilutive shares	<u>19,659,730</u>	<u>10,425,900</u>

7. COMMITMENTS AND CONTINGENCIES

Real Property Leases

Florham Park, New Jersey

On June 4, 2018, the Company entered in an Agreement of Lease for 3,893 square feet for its new corporate headquarters in Florham Park, New Jersey. The lease commencement date was October 2018 and terminates in February 2024. The Company has an option to extend the term of the lease for one additional 60-month period.

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

Madison, Wisconsin

The Company presently rents office space in Madison and is rented for approximately \$3,000 per month under an agreement that expires on August 31, 2021.

Legal

From time to time, the Company may become engaged in litigation or other legal proceedings as part of our ordinary course of business but are not currently party to any litigation or legal proceedings that, in the opinion of management, are likely to have a material adverse effect on its business.

8. LEASES

Operating Lease Liability

In June 2018, the Company executed an agreement for office space in the Borough of Florham Park, Morris County, New Jersey to be used as its headquarters ("HQ Lease"). The HQ Lease commenced upon completion of certain improvements in October 2018 and terminates in February 2024 with an option to extend the term of the lease for one additional 60-month period. During 2018, the landlord made certain improvements to the facility. As of December 31, 2018, the Company recorded a deferred lease liability of approximately \$176,000 for the improvements funded by the landlord in deferred rent current and deferred rent, long-term on the consolidated balance sheet. The Company amortized the deferred liability as a reduction to rent expense in the consolidated statement of operations over the term of the lease.

For fiscal year 2018, rent expense was recognized on a straight-line basis and accordingly the difference between the recorded rent expense and the actual cash payments had been recorded as deferred rent current and deferred rent, long-term of each balance sheet date on the consolidated balance sheet. As of December 31, 2018, the Lease Liability was measured at the present value of the lease payments to be made over the lease term. Lease payments comprise of fixed and variable payments to be made by the Company to the Lessor during the lease term minus any incentives or rebates or abatements receivable by the Company from the Lessor or owner. Payments for non-lease components did not form part of lease payments. The lease term calculation included renewal options only in the case if these options are specified in the lease agreement and if failure to exercise the renewal option imposes a significant economic penalty. As there are no such significant economic penalties in the HQ Lease and renewal cannot be reasonably assured, the valuation of the HQ Lease does not include any renewal options. The Company has not entered into any leases with related parties.

Under the HQ Lease, the Company will pay monthly fixed rent based on approximate rate per rentable square foot which ranges between approximately \$12,400 to \$13,600 over the lease period. In addition, the Company received certain rent abatements and lease incentives subject to the limitations in the HQ Lease. The HQ Lease's net ROU asset and ROU lease liability are approximately \$300,000 and (\$450,000), respectively, as of September 30, 2020 and rental expense for the nine months ended September 30, 2020 is approximately \$85,000.

On January 1, 2019, the Company adopted ASC 842 using the modified retrospective method for all material leases that existed at or commenced after January 1, 2019 and elected to apply the practical expedients in ASC 842-10-65-1 (f) and (gg) to the HQ Lease. The Company accounts for short-term leases (i.e., lease term of 12 months or less) by making the short-term lease policy election and will not apply the recognition and measurement requirements of ASC 842. As a result of the immaterial financial impact, the Company will not apply ASC 842's extensive calculation and reporting requirement against the leases that individually have total lease payments of less than \$100,000 over their life of service to the Company. The adoption of ASC 842 did not have a material net impact on the Company's Condensed Consolidated Statements of Operations as of the effective date. See **Note 1** for additional details.

Discount Rate

The Company has determined the interest rate implicit in the lease considering factors such as Company's credit rating, borrowing terms offered by the U.S. Small Business Administration, amount of lease payments, quality of collateral and alignment of the borrowing term and lease term. The Company considers 10% per annum as reasonable to use as the incremental borrowing rate for purposes of the calculation of lease liabilities.

Maturity Analysis of Short-Term and Operating Leases

The following table approximates the dollar maturity of the Company's undiscounted payments for its short-term leases and operating lease liabilities as of September 30, 2020:

Remainder of 2020	\$	39,000
Years ending December 31,		
2021		155,000
2022		158,000
2023		161,000
2024		14,000
Total undiscounted lease payments		527,000
Less: Imputed interest		(77,000)
Present value of lease liabilities	\$	<u>450,000</u>

9. LOAN PAYABLE

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

The unforgiven portion of the PPP loan is payable over two years at an interest rate of 1%, with a deferral of payments for the first six months. The Company intends to use the proceeds for purposes consistent with the PPP requirements. While the Company currently believes that its use of the loan proceeds will meet the conditions for forgiveness of the loan, the Company cannot assure you that it will not take actions that could cause the Company to be ineligible for forgiveness of the loan, in whole or in part.

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

Overview

We are a late-stage clinical biopharmaceutical company focused on the discovery, 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. 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 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 at this time. We have not yet experienced any significant impacts as a result of the pandemic and have continued to enroll patients in our clinical studies. However, COVID-19 may impact our future ability to recruit patients for clinical studies, obtain adequate supply of CLR 131 and obtain additional financing.

Our lead PDC therapeutic, CLR 131 is a small-molecule PDC designed to provide targeted delivery of iodine-131 directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates CLR 131 from many traditional on-market treatment options. CLR 131 is the company's lead product candidate and is currently being evaluated in two clinical studies: the CLOVER-1 Phase 2 Adult B-Cell Malignancy study and the CLOVER-2 Phase 1 pediatric safety study.

The CLOVER-1 study met the primary efficacy endpoints from the Part A dose-finding portion, conducted in relapsed/refractory (r/r) B-cell malignancies, and is now enrolling in expansion cohorts to evaluate triple class refractory multiple myeloma (MM) and BTK inhibitor failed Waldenström's macroglobulinemia (WM) patients. The dosing regimen is designed to provide the optimal dose identified in Part A of $\geq 60\text{mCi}$ total body dose.

The CLOVER-2 Phase 1 pediatric study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of CLR 131 in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). The study is being conducted internationally at seven leading pediatric cancer centers.

The U.S. Food and Drug Administration ("FDA") granted CLR 131 Fast Track Designation for both r/r MM and r/r diffuse large B-cell lymphoma (DLBCL) and Orphan Drug Designation (ODD) of MM, WM, neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. CLR 131 was also granted Rare Pediatric Disease Designation (RPDD) for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Earlier this year, the European Commission granted an ODD for r/r MM and most recently, the FDA granted Fast Track Designation for CLR 131 in WM patients having received two prior treatment regimens or more.

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

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

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

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

We employ a drug discovery and development approach that allows us to efficiently design, research and advance drug candidates. Our iterative process allows us to rapidly and systematically produce multiple generations of incrementally improved targeted drug candidates.

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

A description of our PDC product candidates follows:

Clinical Pipeline

Our lead PDC therapeutic, CLR 131 is a small-molecule, PDC designed to provide targeted delivery of iodine-131 directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates CLR 131 from many traditional on-market treatments and treatments in development. CLR 131 is currently being evaluated in two clinical studies: the CLOVER-1 Phase 2 adult B-cell malignancy study and the CLOVER-2 Phase 1 pediatric safety study.

The CLOVER-1 study met the primary efficacy endpoints from the Part A dose-finding portion, conducted in r/r B-cell malignancies, and is now enrolling in expansion cohorts to evaluate triple class refractory MM and BTK inhibitor failed WM patients. The dosing regimen is designed to provide the optimal dose of $\geq 60\text{mCi}$ total body dose (TBD) identified in Part A. The initial Investigational New Drug (IND) application was accepted by the FDA in March 2014 with multiple INDs submitted since that time. 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. In the expansion portion of the study the goal is to confirm the efficacy of the $\geq 60\text{mCi}$ TBD in triple class refractory MM and BTK inhibitor failed WM patients. The Phase 1 study was designed to assess the compound's safety and tolerability in patients with r/r MM (to determine maximum tolerated dose (MTD)) and was initiated in April 2015. The study completed enrollment and the final clinical study report is expected in the first half of 2021.

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 CLR 131 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 CLR 131 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 CLR 131 for the treatment of MM. In 2018, the FDA granted ODD and RPDD for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. In May 2019, the FDA granted Fast Track designation for CLR 131 for the treatment of MM and in July 2019 for the treatment of DLBCL, in September 2019 CLR 131 received Orphan Drug Designation from the European Union for Multiple Myeloma, and in January 2020, the FDA granted Orphan Drug Designation for CLR 131 Waldenström's macroglobulinemia. The FDA granted Fast Track designation for CLR 131 for the treatment of WM in May 2020.

The FDA may award priority review vouchers to sponsors of a RPDD that meet its specified criteria. The key criteria to receiving a priority review voucher (PRV) is that the disease being treated is life-threatening and that it primarily affects individuals under the age of 18. Under this program, a sponsor who receives an approval for a drug or biologic for a rare pediatric disease can receive a PRV that can be redeemed to receive a priority review of a subsequent marketing application for a different product. Additionally, the PRV's can be exchanged or sold to other companies so that the receiving company may use the voucher.

Phase 2 Study in Patients with r/r select B-cell Malignancies

In February 2020, we announced positive data from our Phase 2 CLOVER-1 study in patients with relapsed/refractory B-cell lymphomas. Relapsed/Refractory MM and non-Hodgkin lymphoma (NHL) patients were treated with three different doses (<50mCi, ~50mCi and ≥60mCi total body dose (TBD)). The <50mCi total body dose was a deliberately planned sub-therapeutic dose. CLR 131 achieved the primary endpoint for the study. Patients with r/r MM who received the ≥60mCi TBD of CLR 131 showed a 42.8% overall response rate (ORR). Those who received ~50mCi TBD had a 26.3% ORR with a combined rate of 34.5% ORR (n=33) while maintaining a well-tolerated safety profile. Patients in the studies were elderly with a median age of 70, and heavily pre-treated, with a median of five prior lines of treatment (range: 3 to 17), which included immunomodulatory drugs, proteasome inhibitors and CD38 antibodies for the majority of patients. Additionally, a majority of the patients (53%) were quad refractory or greater and 44% of all treated multiple myeloma patients were triple class refractory. 100% of all evaluable patients (n=43) achieved clinical benefit (primary outcome measure) as defined by having stable disease or better. 85.7% of multiple myeloma patients receiving the higher total body dose levels of CLR 131 experienced tumor reduction. The ≥60mCi TBD demonstrated positive activity in both high-risk patients and triple class refractory patients with a 50% and 33% ORR, respectively.

Patients with r/r NHL who received <60mCi TBD and the ≥60mCi TBD had a 42% and 43% ORR, respectively and a combined rate of 42%. These patients were also heavily pre-treated, having a median of three prior lines of treatment (range, 1 to 9) with the majority of patients being refractory to rituximab and/or ibrutinib. The patients had a median age of 70 with a range of 51 to 86. All patients had bone marrow involvement with an average of 23%. In addition to these findings, subtype assessments were completed in the r/r B-cell NHL patients. Patients with DLBCL demonstrated a 30% ORR with one patient achieving a complete response (CR), which continues at nearly 24 months post-treatment. The ORR for CLL/SLL/MZL patients was 33%. Current data from our Phase 2 CLOVER-1 clinical study show that four LPL/WM patients demonstrated 100% ORR with one patient achieving a CR which continues at nearly 35 months post-treatment. This may represent an important improvement in the treatment of relapsed/refractory LPL/WM as we believe no approved or late-stage development treatments for second- and third-line patients have reported a CR. LPL/WM is a rare, indolent and incurable form of NHL that is composed of a patient population in need of new and better treatment options.

Based upon the dose response observed in Part A patients receiving total body doses of 60mCi or greater, we determined that patient dosing of CLR 131 would be ≥60mCi TBD. Therefore, patients are now grouped as receiving <60mCi or ≥60mCi TBD. In September 2020, we announced that a clinically meaningful 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 ≥60mCi TBD. All MM patients enrolled in the expansion cohort are required to be triple class refractory. The additional six patients were heavily pre-treated with an average of nine prior multi-drug regimens. Three patients received a total body dose of ≥ 60 mCi and three received less than 60 mCi. Consistent with the data released in February 2020, patients receiving ≥ 60 mCi typically exhibit greater responses. Based on study results to date, patients continue to tolerate CLR 131 well, with the most common and almost exclusive treatment emergent adverse events being cytopenias.

We recently held FDA Type B guidance meeting to define the registrational pathway for our priority adult hematology oncology indications and planned initiation of the pivotal study for our lead indication in the fourth quarter

The most frequently reported adverse events in r/r MM patients were cytopenias, which followed a predictable course and timeline. The frequency of adverse events have not increased as doses were increased and the profile of cytopenias remains consistent. Importantly, these cytopenias have had a predictable pattern to initiation, nadir and recovery and are treatable. The most common grade ≥3 events at the highest dose (75mCi TBD) were hematologic toxicities including thrombocytopenia (65%), neutropenia (41%), leukopenia (30%), anemia (24%) and lymphopenia (35%). No patients experienced cardiotoxicities, neurological toxicities, infusion site reactions, peripheral neuropathy, allergic reactions, cytokine release syndrome, keratopathy, renal toxicities, or changes in liver enzymes. The safety and tolerability profile in patients with r/r NHL was similar to r/r MM patients except for fewer cytopenias of any grade. Based upon CLR 131 being well tolerated across all dose groups and the observed response rate, especially in difficult to treat patients such as high risk and triple class refractory or penta-refractory, and corroborating data showing the potential to further improve upon current ORRs and durability of those responses, the study has been expanded to test a two-cycle dosing optimization regimen with a target total body dose ≥60 mCi/m² of CLR 131.

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 CLR 131. The funds are supporting the Phase 2 study initiated in March 2017 to define the clinical benefits of CLR 131 in r/r MM and other niche hematologic malignancies with unmet clinical need. These niche hematologic malignancies include Chronic Lymphocytic Leukemia, Small Lymphocytic Lymphoma, Marginal Zone Lymphoma, Lymphoplasmacytic Lymphoma/WM and DLBCL. The study is being conducted in approximately 10 U.S. cancer centers in patients with orphan-designated relapse or refractory hematologic cancers. The study's primary endpoint is clinical benefit response (CBR), with secondary endpoints of ORR, progression free survival (PFS,) median Overall Survival (mOS) and other markers of efficacy following patients receiving one of three TBDs of CLR 131 (<50mCi, ~50mCi and ≥60mCi), with the option for a second cycle approximately 75-180 days later. Dosages were provided either as single bolus or fractionated (the assigned dose level split into two doses) given day 1 and day 15.

In May 2020, we announced that the FDA granted Fast Track Designation for CLR 131 in WM in patients having received two prior treatment regimens or more.

Phase 1 Study in Patients with r/r Multiple Myeloma

In February 2020, we announced the successful completion of our Phase 1 dose escalation study. Data from the study demonstrated that CLR 131 was safe and tolerated at total body dose of approximately 90mCi in r/r MM. The Phase 1 multicenter, open-label, dose-escalation study was designed to evaluate the safety and tolerability of CLR 131 administered as a 30-minute I.V. infusion, either as a single bolus dose or as fractionated doses. The r/r multiple myeloma patients in this study received single cycle doses ranging from approximately 20mCi to 90mCi total body dose. An independent Data Monitoring Committee determined that all doses have been safe and well-tolerated by patients.

CLR 131 in combination with dexamethasone is currently under investigation in adult patients with r/r MM. Patients must have been refractory to or relapsed from at least one proteasome inhibitor and at least one immunomodulatory agent. The clinical study is a standard three-plus-three dose escalation safety study to determine the maximum tolerable dose. Multiple myeloma is an incurable cancer of the plasma cells and is the second most common form of hematologic cancers. Secondary objectives include the evaluation of therapeutic activity by assessing surrogate efficacy markers, which include M protein, free light chain (FLC), PFS and OS. All patients have been heavily pretreated with an average of five prior lines of therapy. CLR 131 was deemed by an Independent Data Monitoring Committee (IDMC) to be safe and tolerable up to its planned maximum single, bolus dose of 31.25 mCi/m². The four single dose cohorts examined were: 12.5 mCi/m² (~25mCi TBD), 18.75 mCi/m² (~37.5mCi TBD), 25 mCi/m² (~50mCi TBD), and 31.25 mCi/m² (~62.5mCi TBD), all in combination with low dose dexamethasone (40 mg weekly). Of the five patients in the first cohort, four achieved stable disease and one patient progressed at Day 15 after administration and was taken off the study. Of the five patients admitted to the second cohort, all five achieved stable disease however one patient progressed at Day 41 after administration and was taken off the study. Four patients were enrolled to the third cohort and all achieved stable disease. In September 2017, we announced results for cohort 4, showing that a single infusion up to 30-minutes of 31.25mCi/m² of CLR 131 was safe and tolerated by the three patients in the cohort. Additionally, all three patients experienced CBR with one patient achieving a partial response (PR). We use the International Myeloma Working Group (IMWG) definitions of response, which involve monitoring the surrogate markers of efficacy, M protein and FLC. The IMWG defines a PR as a greater than or equal to 50% decrease in FLC levels (for patients in whom M protein is unmeasurable) or 50% or greater decrease in M protein. The patient experiencing a PR had an 82% reduction in FLC. This patient did not produce M protein, had received seven prior lines of treatment including radiation, stem cell transplantation and multiple triple combination treatments including one with daratumumab that was not tolerated. One patient experiencing stable disease attained a 44% reduction in M protein. In January 2019, we announced that the pooled mOS data from the first four cohorts was 22.0 months. In late 2018, we modified this study to evaluate a fractionated dosing strategy to potentially increase efficacy and decrease adverse events.

Cohort 5 and 6 were fractionated cohorts of 31.25 mCi/m² (~62.5mCi TBD) and 37.5 mCi/m² (~75mCi TBD), each administered on day 1 and on day 8. Following the determination that all prior dosing cohorts were safe and tolerated, we initiated a cohort 7 utilizing a 40mCi/m² (~80mCi TBD) fractionated dose administered 20mCi/m² (~40mCi TBD) on days 1 and day 8. Cohort 7 was the highest pre-planned dose cohort and subjects have completed the evaluation period. The study completed enrollment and the final clinical study report is expected in the first half of 2021.

In May 2019, we announced that the FDA granted Fast Track Designation for CLR 131 in fourth line or later r/r MM. CLR 131 is our small molecule radiotherapeutic PDC designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. It is currently being evaluated in our ongoing CLOVER-1 Phase 2 clinical study in patients with relapsed or refractory multiple myeloma and other select B-cell lymphomas.

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

In December 2017 the Division of Oncology at the FDA accepted our IND and study design for the Phase 1 study of CLR 131 in children and adolescents with select rare and orphan designated cancers. This study was initiated during the first quarter of 2019. In December 2017, we filed an IND application for r/r pediatric patients with select solid tumors, lymphomas and malignant brain tumors. The Phase 1 clinical study of CLR 131 is an open-label, sequential-group, dose-escalation study evaluating the safety and tolerability of intravenous administration of CLR 131 in children and adolescents with cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. Secondary objectives of the study are to identify the recommended efficacious dose of CLR 131 and to determine preliminary antitumor activity (treatment response) of CLR 131 in children and adolescents. In August 2020, it was announced that four dose levels 15mCi/m² up to 60mCi/m² were deemed safe and tolerable by an independent Data Monitoring Committee and evaluation of the next higher dose cohort, 75mCi/m² was to initiate. In 2018, the FDA granted OD and RPDD for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Should any of these indications reach approval, the RPDD would enable us to receive a priority review voucher. Priority review vouchers can be used by the sponsor to receive priority review for a future New Drug Application ("NDA") or Biologic License Application ("BLA") submission, which would reduce the FDA review time from 12 months to six months. Currently, these vouchers can also be transferred or sold to another entity. This Priority Review Voucher Program is currently under evaluation for renewal.

Phase 1 Study in r/r Head and Neck Cancer

In August 2016, the University of Wisconsin Carbone Cancer Center (“UWCCC”) was awarded a five-year Specialized Programs of Research Excellence (“SPORE”) grant of \$12,000,000 from the National Cancer Institute and the National Institute of Dental and Craniofacial Research to improve treatments and outcomes for head and neck cancer, HNC, patients. HNC is the sixth most common cancer across the world with approximately 56,000 new patients diagnosed every year in the U.S. As a key component of this grant, the UWCCC researchers completed testing of CLR 131 in various animal HNC models and initiated the first human clinical study enrolling up to 30 patients combining CLR 131 and external beam radiation with recurrent HNC in Q4 2019. This clinical study was suspended due to the COVID-19 pandemic but has now been reopened for enrollment.

Preclinical Pipeline

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

- CLR 1900 Series is an internally developed proprietary PDC program leveraging a novel small molecule cytotoxic compound as the payload. The payload inhibits mitosis (cell division) and targets a key pathway required to inhibit rapidly dividing cells that results in apoptosis. We believe that this program could produce a product candidate targeted to select solid tumors. Currently, the program is in early preclinical development and if we elect to progress any molecules further, we will select preferred candidates.
- CLR 2000 Series is a collaborative PDC program with Avicenna Oncology, or Avicenna, that we entered into in July 2017. Avicenna is a developer of antibody drug conjugates (“ADCs”). The objective of the research collaboration is to design and develop a series of PDCs utilizing Avicenna’s proprietary cytotoxic payload. Although Avicenna is a developer of ADCs, this collaboration was sought as a means to overcome many of the challenges associated with ADCs, including those associated with the targeting of specific cell surface epitopes. The CLR 2000 Series has demonstrated improved safety, efficacy and tissue distribution with the cytotoxic payload in animal models. A candidate molecule and a back-up have been selected for further advancement at a future time.

CLR 12120 Series is a collaborative PDC program with Orano Med for the development of novel PDCs utilizing Orano Med's unique alpha emitter, lead 212 conjugated to our phospholipid ether; the companies intend to evaluate the new PDCs in up to three oncology indications. Currently this series has shown efficacy in the first two animal models tested.

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. We analyze our research and development expenses based on four categories as follows: clinical study costs, preclinical study costs, manufacturing and related costs, and general research and development costs that are not allocated to the functional study 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, 2020 and 2019

Research and Development. Research and development expense for the three months ended September 30, 2020 was approximately \$2,684,000 compared to approximately \$2,704,000 for the three months ended September 30, 2019.

The following table is an approximate comparison summary of research and development costs for the three months ended September 30, 2020 and September 30, 2019:

	Three Months Ended September 30,		Variance
	2020	2019	
Clinical study costs	\$ 1,184,000	\$ 1,377,000	\$ (193,000)
Manufacturing and related costs	655,000	677,000	(22,000)
Pre-clinical study costs	36,000	39,000	(3,000)
General research and development costs	809,000	611,000	198,000
	<u>\$ 2,684,000</u>	<u>\$ 2,704,000</u>	<u>\$ (20,000)</u>

The overall decrease in research and development expense of \$20,000, or 1%, was primarily a result of a decrease in clinical study costs offset by an increase in general research and development costs resulting from increased personnel. Manufacturing and related costs decreased due to a reduction in materials production processes and related costs. Pre-clinical study costs were relatively consistent.

General and administrative. General and administrative expense for the three months ended September 30, 2020 was approximately \$1,226,000, compared to approximately \$1,260,000 in the three months ended September 30, 2019 and remained relatively consistent.

Nine Months Ended September 30, 2020 and 2019

Research and Development. Research and development expense for the nine months ended September 30, 2020 was approximately \$7,766,000 compared to approximately \$6,822,000 for the nine months ended September 30, 2019.

The following table is a comparison summary of research and development costs for the nine months ended September 30, 2020 and September 30, 2019:

	Nine Months Ended September 30,		Variance
	2020	2019	
Clinical study costs	\$ 3,066,000	\$ 2,690,000	\$ 376,000
Manufacturing and related costs	1,918,000	2,321,000	(403,000)
Pre-clinical study costs	193,000	285,000	(92,000)
General research and development costs	2,589,000	1,526,000	1,063,000
	<u>\$ 7,766,000</u>	<u>\$ 6,822,000</u>	<u>\$ 944,000</u>

The overall increase in research and development expense of approximately \$944,000, or 12%, was primarily a result of higher general research and development costs resulting from increased personnel related costs and clinical study costs. Manufacturing and related costs decreased because of a reduction in materials production processes and related costs.

General and Administrative. General and administrative expense for the nine months ended September 30, 2020 was approximately \$3,725,000, compared to approximately \$3,972,000 in the nine months ended September 30, 2019. The decrease of approximately \$247,000, or 6%, was primarily a result of lower stock-based compensation expense.

Liquidity and Capital Resources

As of September 30, 2020, we had cash and cash equivalents of approximately \$18,842,000 compared to \$10,615,000 as of December 31, 2019. This increase was due primarily to the approximately \$18,300,000 of net proceeds received in connection with the June 5, 2020 public offering. Net cash used in operating activities during the nine months ended September 30, 2020 was approximately \$10,064,000.

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, 2020, we had an accumulated deficit of approximately \$123,160,000.

We believe that the cash balance is adequate to fund our basic budgeted operations for at least 12 months from the filing of these financial statements. However, our future results of operations involve significant risks and uncertainties. Our ability to execute our operating plan beyond that time depends on our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. We plan to actively pursue all available financing alternatives; however, there can be no assurance that we will obtain the necessary funding. Other than the uncertainties regarding our ability to obtain additional funding, there are currently no known trends, demands, commitments, events or uncertainties that are likely to materially affect our liquidity. Because we have had recurring losses and negative cash flows from operating activities, and in light of our expected expenditures, the report of our independent auditors with respect to the financial statements as of December 31, 2019 and for the year ended December 31, 2019 contains an explanatory paragraph as to the potential inability to continue as a going concern. This opinion indicated at that time, that substantial doubt existed regarding our ability to remain in business.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Based on our management’s evaluation (with the participation of our principal executive officer and principal financial officer), as of September 30, 2020, 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. 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 June 30, 2020 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

None.

Item 1A. Risk Factors

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 9, 2020 pursuant to Section 13 or 15(d) of the Exchange Act (the “2019 10-K”). This information should be considered carefully, together with other information in this report and other reports and materials we file with the SEC. In addition, the following risk factor included substantive changes from those disclosed in the 2019 10-K:

Our operations and financial condition may be adversely impacted by the COVID-19 pandemic.

While we have not yet experienced any significant impacts as a result of the pandemic and have continued to enroll patients in our clinical studies, we anticipate that the COVID-19 pandemic and a prolonged public health crisis may negatively impact our future financial condition and operating results. However, given the evolving health, economic, social, and governmental environments, the breadth and duration of any such impacts remains uncertain. Due to the pandemic, our clinical study recruiting and participants and supply chain could also be slowed or delayed, or in a more severe scenario, our business, financial condition and operating results could be more severely affected. Given the dynamic nature of these circumstances, the duration of any business disruption or potential impact to our business resulting from the COVID-19 coronavirus is difficult to predict, but it may increase our costs or expenses.

The potential effects of the COVID-19 pandemic could impact many of our risk factors, included in Part 1, Item A of our 2019 Form 10-K. However, given the evolving health, economic, social, and governmental environments, the potential impact that the COVID-19 pandemic could have on our risk factors that are described in our 2019 Form 10-K remain uncertain.

We will require additional capital in order to continue our operations, and may have difficulty raising additional capital.

We expect that we will continue to generate significant operating losses for the foreseeable future. At September 30, 2020, our consolidated cash balance was approximately \$18.8 million. We believe our cash balance at September 30, 2020, is adequate to fund basic operations at budgeted levels for at least 12 months from the filing of these financial statements. We will require additional funds to conduct research and development, establish and conduct clinical and preclinical studies, establish commercial-scale manufacturing arrangements and provide for the marketing and distribution of our products. Our ability to execute our operating plan depends on our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. We continue to actively pursue financing alternatives. However, there can be no assurance that we will obtain the necessary funding in the amounts we seek or that it will be available on a timely basis or upon terms acceptable to us. If we obtain capital by issuing debt or preferred stock, the holders of such securities would likely obtain rights that are superior to those of holders of our common stock. Our capital requirements and our ability to meet them depend on many factors, including:

- current and future impacts of the COVID-19 pandemic on all aspects of our business;
- the number of potential products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with preclinical studies and clinical studies;
- the time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and our ability to sell our drugs;
- costs involved in establishing manufacturing capabilities for clinical study and commercial quantities of our drugs;
- competing technological and market developments;
- claims or enforcement actions with respect to our products or operations;
- market acceptance of ourTM products;
- costs for recruiting and retaining management, employees and consultants;
- our ability to manage computer system failures or security breaches;
- costs for educating physicians regarding the application and use of our products;
- whether we are able to maintain our listing on a national exchange;
- 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; and
- the condition of capital markets and the economy generally, both in the U.S. and globally.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than expected. We may seek to raise any necessary additional funds through the issuance of warrants, equity or debt financings or executing collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or have a material effect on our current or future business prospects. In addition, in the event that additional funds are obtained through arrangements with collaborative partners or other sources, we may have to relinquish economic and/or proprietary rights to some of our technologies or products under development that we would otherwise seek to develop or commercialize by ourselves. If we cannot secure adequate financing when needed, we may be required to delay, scale back or eliminate one or more of our research and development programs or to enter into license or other arrangements with third parties to commercialize products or technologies that we would otherwise seek to develop ourselves and commercialize ourselves. In such an event, our business, prospects, financial condition, and results of operations may be adversely affected.

We have incurred net losses and negative cash flows since inception. We currently have no product revenues and may not succeed in developing or commercializing any products that will generate product or licensing revenues. We do not expect to have any products on the market for several years. Our primary activity to date has been research and development and conducting clinical studies. Development of our product candidates requires a process of preclinical and clinical testing, during which our product candidates could fail. We may not be able to enter into agreements with one or more companies experienced in the manufacturing and marketing of therapeutic drugs and, to the extent that we are unable to do so, we may not be able to market our product candidates. Whether we achieve profitability or not will depend on our success in developing, manufacturing, and marketing our product candidates. We have experienced net losses and negative cash flows from operating activities since inception and we expect such losses and negative cash flows to continue for the foreseeable future. As of September 30, 2020, we had a stockholders' equity of approximately \$16,224,000. The net loss for the nine months ended September 30, 2020 was approximately \$11,479,000, and we may never achieve profitability.

Item 6. Exhibits

Exhibit No.	Description	Filed with this Form 10-Q	Incorporation by Reference		
			Form	Filing Date	Exhibit No.
10.1	Equity Distribution Agreement between Collectar Biosciences, Inc. and Oppenheimer & Co. Inc., dated August 11, 2020		8-K	August 11, 2020	10.1
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
101	Interactive Data Files	X			

* Filed herewith.

SIGNATURES

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

CELLECTAR BIOSCIENCES, INC.

Date: November 9, 2020

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 9, 2020

/s/ James V. Caruso

James V. Caruso

President and Chief Executive Officer (Principal Executive Officer)

I, DOV ELEFANT, 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 9, 2020

/s/ Dov Elefant

Dov Elefant

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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, James V. Caruso, President and Chief Executive Officer of the Company, and Dov Elefant, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to our knowledge, that:

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

/s/ James V. Caruso

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

Date: November 9, 2020

/s/ Dov Elefant

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

Date: November 9, 2020
