

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, 2019

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: 9,396,036 shares of common stock, \$0.00001 par value per share, as of November 7, 2019.

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 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 our Phospholipid Drug Conjugates™;
- our ability to maintain orphan drug designation in the United States for CLR 131 as a therapeutic for the treatment of multiple myeloma, neuroblastoma, osteosarcoma, rhabdomyosarcoma and Ewing’s sarcoma, and the expected benefits of orphan drug status;
- 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;
- 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, 2019 (Unaudited)	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 13,301,612	\$ 13,255,616
Restricted cash	—	55,000
Prepaid expenses and other current assets	1,450,364	641,218
Total current assets	14,751,976	13,951,834
Fixed assets, net	461,940	543,339
Right-of-use asset, net	363,861	—
Long-term assets	75,000	540,823
Other assets	6,214	18,086
TOTAL ASSETS	\$ 15,658,991	\$ 15,054,082
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 2,875,342	\$ 1,543,819
Derivative liability	—	43,000
Capital lease obligations, current portion	—	2,213
Deferred rent	—	33,090
Lease liability	102,597	—
Total current liabilities	2,977,939	1,622,122
LONG-TERM LIABILITIES:		
Deferred rent, less current portion	—	170,999
Lease liability	449,632	—
Total long-term liabilities	449,632	170,999
TOTAL LIABILITIES	3,427,571	1,793,121
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY:		
Series C preferred stock: 215 and 473 issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	1,148,204	2,526,049
Common stock, \$0.00001 par value; 80,000,000 shares authorized; 9,386,703 and 4,732,387 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	94	47
Additional paid-in capital	119,384,474	108,323,208
Accumulated deficit	(108,301,352)	(97,588,343)
Total stockholders' equity	12,231,420	13,260,961
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 15,658,991	\$ 15,054,082

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,	
	2019	2018	2019	2018
COSTS AND EXPENSES:				
Research and development	\$ 2,703,831	\$ 1,995,571	\$ 6,821,775	\$ 5,798,526
General and administrative	1,260,048	1,091,921	3,972,275	3,647,412
Total costs and expenses	<u>3,963,879</u>	<u>3,087,492</u>	<u>10,794,050</u>	<u>9,445,938</u>
LOSS FROM OPERATIONS	<u>(3,963,879)</u>	<u>(3,087,492)</u>	<u>(10,794,050)</u>	<u>(9,445,938)</u>
OTHER INCOME:				
Gain on revaluation of derivative warrants	46,000	66,000	43,000	19,050
Interest income, net	14,072	6,558	38,041	15,440
Total other income, net	<u>60,072</u>	<u>72,558</u>	<u>81,041</u>	<u>34,490</u>
NET LOSS	<u>(3,903,807)</u>	<u>(3,014,934)</u>	<u>(10,713,009)</u>	<u>(9,411,448)</u>
DEEMED DIVIDEND ON PREFERRED STOCK	<u>—</u>	<u>(2,241,795)</u>	<u>—</u>	<u>(2,241,795)</u>
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (3,903,807)</u>	<u>\$ (5,256,729)</u>	<u>\$ (10,713,009)</u>	<u>\$ (11,653,243)</u>
BASIC AND DILUTED NET LOSS PER COMMON SHARE	<u>\$ (0.42)</u>	<u>\$ (1.65)</u>	<u>\$ (1.51)</u>	<u>\$ (5.29)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS				
ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>9,386,703</u>	<u>3,184,856</u>	<u>7,098,285</u>	<u>2,204,554</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, 2017	18	\$ 995,782	1,666,144	\$ 16	\$ 94,107,981	\$ (84,349,316)	\$ 10,754,463
Conversion of preferred shares into common shares	(6.5)	(358,765)	34,690	1	358,764	—	—
Stock-based compensation	—	—	—	—	173,438	—	173,438
Vested restricted stock	—	—	9,333	—	—	—	—
Net loss	—	—	—	—	—	(3,475,823)	(3,475,823)
BALANCE AT MARCH 31, 2018	11.5	637,017	1,710,167	17	94,640,183	(87,825,139)	7,452,078
Conversion of preferred shares into common shares	(11.5)	(637,017)	61,594	1	637,016	—	—
Stock-based compensation	—	—	—	—	175,579	—	175,579
Vested restricted stock	—	—	3,333	—	—	—	—
Net loss	—	—	—	—	—	(2,920,691)	(2,920,691)
BALANCE AT JUNE 30, 2018	—	—	1,775,094	18	95,452,778	(90,745,830)	4,706,966
Issuance of common stock, warrants and preferred stock, net of issuance costs	1,114	5,949,301	1,355,000	14	9,075,762	—	15,025,077
Conversion of preferred shares into common shares	(456)	(2,435,262)	1,140,000	11	2,435,251	—	—
Stock-based compensation	—	—	—	—	163,896	—	163,896
Reverse stock split fractional shares	—	—	(105)	—	(762)	—	(762)
Net loss	—	—	—	—	—	(3,014,934)	(3,014,934)
BALANCE AT SEPTEMBER 30, 2018	658	\$ 3,514,039	4,269,989	\$ 43	\$ 107,126,925	\$ (93,760,764)	\$ 16,880,243
BALANCE AT DECEMBER 31, 2018	473	\$ 2,526,049	4,732,387	\$ 47	\$ 108,323,208	\$ (97,588,343)	\$ 13,260,961
Conversion of preferred shares into common shares	(138)	(736,987)	345,000	4	736,983	—	—
Stock-based compensation	—	—	—	—	207,654	—	207,654
Retired shares	—	—	(12)	—	—	—	—
Vested restricted stock	—	—	9,334	—	—	—	—
Net loss	—	—	—	—	—	(3,621,641)	(3,621,641)
BALANCE AT MARCH 31, 2019	335	1,789,062	5,086,709	51	109,267,845	(101,209,984)	9,846,974
Issuance of common stock and warrants, net of issuance costs	—	—	4,000,000	40	9,024,529	—	9,024,569
Conversion of preferred shares into common shares	(120)	(640,858)	300,000	3	640,855	—	—
Stock-based compensation	—	—	—	—	301,471	—	301,471
Retired shares	—	—	(6)	—	—	—	—
Net loss	—	—	—	—	—	(3,187,561)	(3,187,561)
BALANCE AT JUNE 30, 2019	215	1,148,204	9,386,703	94	119,234,700	(104,397,545)	15,985,453
Stock-based compensation	—	—	—	—	149,774	—	149,774
Net loss	—	—	—	—	—	(3,903,807)	(3,903,807)
BALANCE AT SEPTEMBER 30, 2019	215	\$ 1,148,204	9,386,703	\$ 94	\$ 119,384,474	\$ (108,301,352)	\$ 12,231,420

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,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (10,713,009)	\$ (9,411,448)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	100,216	50,051
Stock-based compensation expense	658,899	512,913
Noncash lease expense	41,542	—
Gain on revaluation of derivative warrants	(43,000)	(19,050)
Gain on disposal of assets	—	(40,898)
Changes in:		
Accounts payable and accrued liabilities	1,331,523	703,792
Lease liability	(57,263)	—
Prepaid expenses and other current assets	(331,451)	(273,794)
Other assets and liabilities	—	(220,158)
Cash used in operating activities	<u>(9,012,543)</u>	<u>(8,698,592)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(18,817)	(1,425)
Proceeds from sale of fixed assets	—	45,000
Cash used in investing activities	<u>(18,817)</u>	<u>43,575</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of underwriting issuance costs	9,024,569	9,075,777
Proceeds from issuance of preferred stock, net of underwriting issuance costs	—	5,949,301
Reverse stock split fractional shares	—	(762)
Payments on capital lease obligations	(2,213)	(2,246)
Cash provided by financing activities	<u>9,022,356</u>	<u>15,022,070</u>
NET DECREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(9,004)	6,367,053
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF PERIOD	<u>13,310,616</u>	<u>10,061,421</u>
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF PERIOD	<u>\$ 13,301,612</u>	<u>\$ 16,428,474</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest expense	\$ 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 clinical stage biopharmaceutical company focused on the discovery, development, and commercialization of drugs for the treatment of cancer. The Company plans to develop targeted oncology therapeutics independently and through research and development collaborations with a core objective to leverage our proprietary Phospholipid Drug Conjugate™ (“PDC™” or “PDC”) delivery platform to develop PDCs that specifically target cancer cells to 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 independently and through research and development collaborations.

The Company is subject to a number of risks similar to those of other small pharmaceutical companies. Principal among these risks are dependence on key individuals, competition from substitute products and larger companies, the successful development and marketing of its products in a highly regulated environment and the need to obtain additional financing necessary to fund future operations.

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 \$108,301,000 at September 30, 2019. The Company has devoted substantially all its efforts toward research and development and has, during the nine months ended September 30, 2019, generated an operating loss of approximately \$10,794,000. 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. We plan to continue to actively pursue financing alternatives as there can be no assurance that it will obtain the necessary funding.

The accompanying Condensed Consolidated Balance Sheet as of December 31, 2018 has been derived from audited financial statements. The accompanying unaudited Condensed Consolidated Balance Sheet as of September 30, 2019, the Condensed Consolidated Statements of Operations and the Condensed Statements of Stockholders’ Equity for the three and nine months ended September 30, 2019 and 2018, the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018 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, 2019 and consolidated results of its operations, stockholders’ equity and cash flows for the nine months ended September 30, 2019 and 2018. The results for the three or nine months ended September 30, 2019 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, 2018, which was filed with the SEC on February 26, 2019.

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.

Restricted Cash — The Company accounts for cash that is restricted for other than current operations as restricted cash. Restricted cash at December 31, 2018 consisted of a Certificate of Deposit of \$55,000 required under the Company’s lease agreement for its Madison, Wisconsin facility. As of March 31, 2019, the Company had fulfilled the remaining obligations under its lease thereby facilitating the release of all restrictions against the cash. No restrictions exist on our cash as of September 30, 2019.

Fixed Assets — Property and equipment are stated at cost. Depreciation on property and equipment is provided using the straight-line method over the estimated useful lives of the assets (3 to 10 years). Because of the significant value of leasehold improvements purchased, leasehold improvements are depreciated over 64 months (their estimated useful life), which represents the full term of the lease. Our only long-lived assets are property and equipment. The Company periodically evaluates long-lived assets for potential impairment. Whenever events or circumstances change, an assessment is made as to whether there has been impairment to the value of long-lived assets by determining whether projected undiscounted cash flows generated by the applicable asset exceed its net book value as of the assessment date. There were no long-lived Fixed Asset impairment charges recorded during the nine months ended September 30, 2019 or year ended December 31, 2018.

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 requires 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. See **Leases** below for additional details.

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 2019 and 2018 ranged from seven months 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 stockholder approved 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, 2019 and December 31, 2018.

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 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 and December 31, 2018, respectively. 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 December 31, 2018, these warrants represented the only outstanding derivative instruments issued or held by the Company and expired as of 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, 2019 and December 31, 2018 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, 2019, and December 31, 2018, uninsured cash balances totaled approximately \$12,800,000 and \$12,800,000, respectfully.

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 requires 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. ASU 2016-02 allows a modified retrospective approach for all leases existing at, or entered into after the date of initial adoption, with an option to elect to use certain transition relief. The FASB also proposed a transition method to allow entities to not apply the new leases standard in the comparative periods they present in their financial statements in the year of adoption. 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.

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. See **Note 8** for additional details. The Company elected to apply the practical expedients in ASC 842-10-65-1 (f) and (gg) and therefore:

1. did not reassess expired contracts for presence of lease components therein and if it was already concluded that such contracts had lease components then the classification of the respective lease components therein was not re-assessed.
2. did not re-assess initial direct costs for any existing leases.
3. will not separate the lease and non-lease components.
4. will continue applying its current policy for accounting for land easements that existed as of, or expired before effective date.

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. The following table approximates the impact that the adoption of ASC 842 had to the Company's September 30, 2019 Condensed Consolidated Balance Sheet as impacted by landlord provided incentives and the present value of future cash flows calculation against both the asset and liability:

	Balance without adoption of ASC 842	Adjustment as of January 1, 2019	As reported balance as of September 30, 2019
Lease incentive liability	\$ (176,000)	\$ 176,000	\$ -
Deferred rent	\$ (28,000)	\$ 28,000	\$ -
Right-of-use asset (net)	\$ -	\$ 405,000	\$ 364,000
Lease liability	\$ -	\$ (609,000)	\$ (552,000)

Recent Accounting Pronouncements - In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815). The amendments in Part I of this update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company believes that its adoption of ASU 2017-11 has not had a material impact on its results of operations, cash flows and financial position.

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.

In August 2014, as part of an underwritten public offering, the Company issued 49,425 warrants to purchase common stock (the "August 2014 Warrants"). The August 2014 Warrants were listed on the NASDAQ Capital Market under the symbol "CLR BW", however, there were certain periods where trading volume is low; therefore, they were classified as Level 2 within the hierarchy.

The following tables set forth the Company's financial instruments carried at fair value using the lowest level of input applicable to each financial instrument as of September 30, 2019 and December 31, 2018:

	September 30, 2019			Fair Value
	Level 1	Level 2	Level 3	
Liabilities:				
August 2014 Warrants	\$ —	\$ —	\$ —	\$ —
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

	December 31, 2018			Fair Value
	Level 1	Level 2	Level 3	
Liabilities:				
August 2014 Warrants	\$ —	\$ 43,000	\$ —	\$ 43,000
Total	<u>\$ —</u>	<u>\$ 43,000</u>	<u>\$ —</u>	<u>\$ 43,000</u>

To estimate the fair value of the August 2014 Warrants, the Company calculated the weighted average closing price for the trailing 10-day period with trades that ended on the balance sheet date. These warrants expired as of August 20, 2019.

3. STOCKHOLDERS' EQUITY

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, we 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, we 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 million, but is an internal proportionate calculation allocating the gross proceeds of approximately \$6 million to common stock and \$4 million to warrants.

Gross offering proceeds to the Company were \$10 million, with net proceeds to the Company of approximately \$9.0 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 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 Securities Act of 1933, as amended (the "Act"), and Regulation D promulgated thereunder. Such common shares, warrants and common shares issuable upon exercise of such warrants had not been registered under the Act, and therefore could not be offered or sold in the United States. 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.

July 2018 Public Offering

On July 31, 2018, the Company sold 1,355,000 shares of common stock, 1,114 shares of Series C Convertible Preferred Stock (the "Series C Preferred Stock") convertible into 2,785,000 shares of common stock and Series E warrants to purchase 4,140,000 shares of common stock. The public offering price of a share of common stock together with a Series E warrant to purchase one share of common stock was \$4.00. The public offering price of a share of Series C Preferred Stock, each of which is convertible into 2,500 shares of Common Stock, together with a Series E warrant to purchase 2,500 shares of common stock was \$10,000. The Series E warrants have an exercise price of \$4.00 per share and are exercisable until July 31, 2023. Gross offering proceeds to the Company were \$16.56 million, with net proceeds to the Company of approximately \$15.0 million after deducting underwriting discounts and commissions and related offering expenses.

In order to account for the July 2018 public offering, the Company allocated the proceeds to the common stock, the Series C Preferred Stock and the Series E warrants on a relative fair value basis. Then using the effective conversion price of the Series C Preferred Stock, the Company determined that there was a beneficial conversion feature ("BCF") of \$2,241,795. The BCF did not impact total Stockholders' Equity but was reflected as a deemed dividend in arriving at net loss attributable to common stockholders in July 2018.

The Series C Preferred Stock includes a beneficial ownership blocker but has no dividend rights (except to the extent that dividends are also paid on the common stock), liquidation preference or other preferences over common stock, and subject to limited exceptions, has no voting rights. For the nine and twelve months ended September 30, 2019 and December 31, 2018, 258 and 641 shares of Series C Preferred Stock were converted into 645,000 and 1,602,500 shares of common stock, respectively.

Reverse Stock Split

At a special meeting held on July 12, 2018, our stockholders approved an amendment to our certificate of incorporation to affect a reverse split of our common stock at a ratio between 1:5 to 1:10 and authorized the Board to determine the ratio at which the reverse split would be. The Board authorized the ratio of the reverse split, and effective at the close of business on July 16, 2018, the Company implemented a 1-for-10 reverse stock split of its outstanding common stock. The accompanying consolidated financial statements and accompanying notes to the consolidated financial statements give retroactive effect to the reverse stock split for all periods presented. The shares of common stock that the Company is authorized to issue remains unchanged at 80,000,000 and the par value remains at \$0.00001 per share. Accordingly, stockholders' equity reflects the reverse stock split by reclassifying from common stock to additional paid-in capital an amount equal to the par value of the decreased shares resulting from the reverse stock split.

Common Stock Warrants

The following table summarizes information with regard to outstanding warrants to purchase common stock as of September 30, 2019:

Offering	Number of Shares Issuable Upon Exercise of Outstanding Warrants	Exercise Price	Expiration Date
May 2019 Series G Warrants	2,018,000	\$ 2.40	May 20, 2024
May 2019 Series F Warrants	1,982,000	\$ 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>9,268,352</u>		

4. STOCK-BASED COMPENSATION

Accounting for Stock-Based Compensation

During the nine-month periods ended September 30, 2019 and 2018 options granted were 411,930 and 8,000, 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,	
	2019	2018
Employee and director stock option grants:		
Research and development	\$ 47,825	\$ 102,161
General and administrative	611,074	410,752
Total stock-based compensation	<u>\$ 658,899</u>	<u>\$ 512,913</u>

On October 12, 2018, we granted 167,430, net of forfeitures, contingent non-statutory stock option awards at an exercise price of \$2.61 per share to our current non-employee directors and our employees, and on January 17, 2019, we granted 118,750, net of forfeitures, contingent non-statutory stock option awards at an exercise price of \$1.99 per share to our current employees. Each of these grants was contingent on approval by the Company's stockholders of the amendment to the 2015 Stock Incentive Plan at the 2019 Annual Meeting of Stockholders, and stockholders approved the amendment on June 13, 2019. In accordance with the timing of the stockholder approval, all related expenses were recognized by the Company in June 2019, including the catch-up for compensation expenses for recognition of contingent non-statutory stock option awards from October 2018.

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 an average of (1) the Company's historical volatility since its common stock has been publicly traded and (2) review of volatility estimates of publicly held drug development companies with similar market capitalizations.

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 no forfeiture rate to directors for the nine months ended September 30, 2019 and for the year ended December 31, 2018. 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, 2019 and 2018 were equal to the market value of the Company's common stock on the date of grant. There were 244,500 stock option grants during the nine months ended September 30, 2019. Additionally, in June 2019, 167,430, net of forfeitures, stock option grants from October 12, 2018 were recognized upon approval by the Company's stockholders of the amendment to the 2015 Stock Incentive Plan at the 2019 Annual Meeting of Stockholders.

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, 2018	232,343	\$ 14.37	9.30	\$ —
Granted	411,930	\$ 2.33		
Expired	—	\$ —		
Forfeited	(33,559)	\$ 4.78		
Outstanding at September 30, 2019	<u>610,714</u>	\$ 6.78	9.08	\$ —
Exercisable, September 30, 2019	<u>118,515</u>	\$ 24.72	8.14	\$ —
Unvested, September 30, 2019	<u>492,199</u>	\$ 2.45	9.31	<u>\$ 1,188</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, 2019, there was approximately \$688,035 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, the Company expects to recognize approximately \$137,370, \$313,312, \$199,084 and \$38,269 during 2019, 2020, 2021 and 2022, 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, 2019 was \$20.09 and \$1.87, 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 vest 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, 2018	18,668	\$ 21.00	\$ 392,000
Granted	—	\$ —	\$ —
Vested	(9,334)	\$ 21.00	\$ (196,000)
Forfeited	—	\$ —	\$ —
Outstanding at September 30, 2019	<u>9,334</u>	<u>\$ 21.00</u>	<u>\$ 196,000</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, 2019 or 2018 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, 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 warrants. Since there is a net loss attributable to common stockholders for the three and nine months ended September 30, 2019 and 2018, 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,	
	2019	2018
Warrants	9,268,352	5,318,747
Preferred shares as convertible into common stock	537,500	—
Stock options	610,714	56,354
Non-vested restricted stock	9,334	25,334
Total potentially dilutive shares	<u>10,425,900</u>	<u>5,400,435</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's corporate offices and manufacturing facilities in Madison were vacated in 2018 as a result of its decision to outsource manufacturing. The Company extended the lease on a month by month basis through February 6, 2019 to accommodate certain alterations required under the lease agreement. As of March 31, 2019, the Company had fulfilled the remaining obligations under the lease, which facilitated the release of the Certificate of Deposit of \$55,000 required under the Company's lease agreement for the facility.

The Company presently rents office space in Madison which consists of approximately 300 square feet and is rented for approximately \$3,300 per month under an agreement that was scheduled to expire on August 31, 2019. On July 10, 2019, the Company agreed to terms to rent this same office space through August 31, 2020 at approximately the same monthly fee.

Legal

From time to time, we may become engaged in litigation or other legal proceedings as part of our ordinary course of business. We 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 our 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 for which we 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 as 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 \$364,000 and (\$552,000), respectively, as of September 30, 2019 and rental expense for the nine months ended September 30, 2019 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 presents future minimum lease payments, excluding reimbursements under noncancelable operating leases at December 31, 2018 under ASC 840 and is being presented for comparative purposes:

Years ending December 31,	
2019	\$ 145,126
2020	156,046
2021	158,823
2022	161,085
2023	161,123
2024 and thereafter	13,610
Total	<u>\$ 795,813</u>

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, 2019:

Remainder of 2019	\$ 38,000
Years ending December 31,	
2020	153,000
2021	155,000
2022	158,000
2023	161,000
2024	14,000
Total undiscounted lease payments	679,000
Less: Imputed interest	(127,000)
Present value of lease liabilities	<u>\$ 552,000</u>

9. SUBSEQUENT EVENT

None.

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

Overview

We are a clinical stage biopharmaceutical company focused on the discovery, development, and commercialization of drugs for the treatment of cancer. We plan to develop targeted oncology therapeutics independently and through research and development collaborations. Our core objective is to leverage our proprietary Phospholipid Drug Conjugate™ ("PDC™" or "PDC") delivery platform to develop PDCs that specifically target cancer cells to 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 independently and through research and development collaborations.

Our lead PDC candidate, CLR 131 is a small-molecule, targeted PDC™ designed to deliver cytotoxic radiation directly to cancer cells, while limiting exposure to healthy cells. CLR 131 was granted Orphan Drug designation and Fast Track designation for the treatment of multiple myeloma, a Fast Track designation for Diffuse large B-cell Lymphoma ("DLBCL") and Orphan Drug and Rare Pediatric Disease designations ("RPDD") for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. CLR 131 is currently being evaluated in three clinical studies, a Phase 2 study, and two Phase 1 studies. The Phase 2 clinical study (CLOVER-1) is in relapsed or refractory ("R/R") B-cell malignancies, including multiple myeloma ("MM"), chronic lymphocytic leukemia/small lymphocytic lymphoma ("CLL/SLL"), Waldenstrom's macroglobulinemia or lymphoplasmacytic lymphoma ("LPL"), marginal zone lymphoma ("MZL"), mantle cell lymphoma ("MCL"), and DLBCL. We are also conducting a Phase 1 dose escalation study in patients with Relapsed or Refractory Multiple Myeloma ("R/R MM") and a Phase 1 study in pediatric solid tumors and lymphoma.

In order to enhance the impact of our financial resources, we have focused our proprietary early stage research efforts on projects that we believe can provide the greatest near-term value. Our pipeline includes a PDC chemotherapeutic program in drug discovery, CLR 1900. 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, the primary tumor, a metastatic tumor or 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 life cycle. Tumor cells modify regions on the cell surface as a result of the utilization of this metabolic pathway, our PDCs bind to these cell regions and directly enter the intracellular compartment. This 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 expressed in limited total numbers on the cell surface, have longer cycling time from internalization to being present on the cell surface again upon binding and are not present on all tumor cells of a particular cancer type. This means a subpopulation of tumor cells will always exist that will be non-targetable 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 that can be 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 reducing adverse events by minimizing drug delivery to healthy cells while 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.

Clinical Pipeline

CLR 131 is a small-molecule, cancer-targeting radiotherapeutic PDC designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. CLR 131 is our lead therapeutic PDC product candidate and is currently being evaluated in both Phase 2 and Phase 1 clinical studies. The initial 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 2 study is to assess the compound's efficacy in a broad range of hematologic cancers. The Phase 1 study is designed to assess the compound's safety and tolerability in patients with R/R MM (to determine maximum tolerated dose) and was initiated in April 2015. 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 relapse/refractory setting, and have been determined to be rare diseases by the FDA based upon the current definition within the Orphan Drug Act.

In 2014, the FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma. In 2018, the FDA granted orphan drug and RPDDs for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. The FDA may award priority review vouchers to sponsors of rare pediatric disease products that meet its specified criteria. The key criteria to receiving a priority review voucher is that the disease being treated is life-threatening and that it primarily 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 priority review voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. Additionally, these priority review vouchers can be exchanged or sold to other companies for them to use the voucher. In May 2019, the FDA granted Fast Track designation for CLR 131 for the treatment of multiple myeloma and in July 2019 for the treatment of DLBCL.

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

On July 9, 2019, we announced that the FDA had granted Fast Track Designation for CLR 131 in relapsed or refractory DLBCL. This indication is currently being evaluated in our ongoing Phase 2 CLOVER-1 clinical study in patients with relapsed or refractory select B-cell lymphomas.

On May 21, 2019, we announced that initial results from the third cohort of our ongoing Phase 2 CLOVER-1 study of CLR 131 have exceeded our pre-specified performance criteria. As a result, we intend to expand the number of CLL/SLL, LPL and MZL patients that will be enrolled in the cohort. We expect to report top-line data from the Phase 2 CLOVER-1 study in the fourth quarter of 2019.

On February 25, 2019 we announced positive top-line results from our ongoing Phase 2 clinical study of CLR 131. To date, CLR 131 has demonstrated activity in four different hematologic malignancies. In the relapse refractory multiple myeloma cohort of this Phase 2 study, patients were administered a single infusion up to 30 minutes of 25mCi/m^2 and low dose dexamethasone (40mg weekly for up to 12 weeks). CLR 131 achieved a 30% overall response rate (“ORR”) in the first 10 evaluable patients. ORR means patients achieved a partial response or better. One patient had a very good partial response (a 90% or greater decrease in a surrogate marker) and two had partial responses (a 50% to 89% decrease in a surrogate marker) as defined by the International Myeloma Working Group. The patients in this cohort averaged six prior lines of systemic therapy. All patients in the multiple myeloma cohort achieved a minimum of stable disease for a disease control rate of 100%. As a result of these outcomes, we have expanded this cohort to include up to 30 additional patients. Historically, patients receiving 4th line chemotherapy treatment have shown a 15% (“RR”), and patients receiving 5th line chemotherapy have shown an 8% RR, whether dosed as mono-therapy or in combination. The historic multiple myeloma average treatment RR provided by line of therapy were obtained through Decision Resource Group, a global information and technology vendor specializing in healthcare data analysis utilizing over 12.5 billion U.S. insurance claims and 90 million electronic medical records.

Based upon Phase 1 data, the dosing of CLR 131 in this study was recently modified to a 37.5mCi/m^2 fractionated dose administered 18.75mCi/m^2 on days 1 and 8 which is approximately 50% more drug than the 25mCi/m^2 single infusion. Based upon meeting eligibility requirements, patients can receive a second cycle of CLR 131 between day 75 and 180 post initial infusion.

In July 2018, we announced that after a single 25mCi/m^2 IV administration of CLR 131, patients with relapsed/refractory aggressive DLBCL were assessed for response. These interim data showed a 33% ORR and a 50% clinical benefit response (“CBR”). In addition, the observed responses to date show overall tumor reduction ranged from 60% to greater than 90%. As a result of these favorable outcomes, we have expanded this cohort to include up to 30 additional patients. We also announced that a patient in the LPL or Waldenstrom’s macroglobulinemia arm showed a greater than 90% reduction in tumor burden and complete resolution in four of five masses with the fifth tumor being reduced by over 90% of its initial tumor volume after two doses of CLR 131 separated by 123 days. Efficacy for all lymphoma patients will be determined according to Lugano criteria.

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 hematologic malignancies with unmet clinical need. These hematologic malignancies include CLL/SLL, MZL, LPL 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 CBR, with additional endpoints of ORR, progression free survival (“PFS”), median overall survival (“OS”) and other markers of efficacy.

Phase 1 Study in Patients with Relapsed or Refractory Multiple Myeloma (“R/R MM”)

CLR 131 in combination with dexamethasone is currently under investigation in a Phase 1 study in adult patients with R/R MM. To enroll in the trial, 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 5 prior lines of therapy. CLR 131 was deemed by an independent data monitoring committee to be safe and tolerable up to its planned maximum single, bolus dose of 31.25mCi/m^2 . The four single dose cohorts examined were: 12.5mCi/m^2 , 18.75mCi/m^2 , 25mCi/m^2 , and 31.25mCi/m^2 , 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 that have been admitted to the second cohort, four achieved stable disease and one patient progressed at Day 41 after administration and was taken off the study. Four patients were enrolled to the third cohort and all achieved stable disease. In September 2017, we announced results for cohort 4, showing that a single infusion up to 30 minutes of 31.25mCi/m^2 of CLR 131 was safe and tolerated by the three patients in the cohort. Additionally, all three patients experienced clinical benefit 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. On January 7, 2019, we announced that the pooled median Overall Survival (“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.

The first fractionated dose cohort was cohort 5 in which patients received a 31.25mCi/m² fractionated dose administered 15.625mCi/m² on days 1 and 8. Results from cohort 5 indicated enhanced tolerability and safety in comparison to cohort 4 despite an 18% increase in average total dose from 55.29 mCi to 65.15 mCi of CLR 131. Patients in cohort 5 required less supportive care such as transfusions of platelets or packed red blood cells than seen in previous cohorts. Similar to previous cohorts, patients experienced few off-target adverse events, i.e. no peripheral neuropathy, embolisms, gastrointestinal upset, etc. Furthermore, surrogate efficacy markers demonstrated that patients in cohort 5 monitored by M-protein showed a nearly 50% further reduction in M-Protein than seen in cohort 4. Based on these results, on December 4, 2018 the independent Data Monitoring Committee (“IDMC”) recommended, advancement to a sixth cohort. Cohort 6 was initiated in late December where patients received a 37.5mCi/m² fractionated dose administered 18.75mCi/m² on days 1 and 8.

On May 15, 2019, we announced initial results from Cohort 6 in our ongoing Phase 1 clinical study with CLR 131 in R/R MM. The 37.5mCi/m² fractionated dose was determined to be safe and tolerable by the independent Data Monitoring Committee. Following the determination, we initiated a Cohort 7 utilizing a 40mCi/m² fractionated dose administered 20mCi/m² on days 1 and day 8. Data from Cohort 6 showed improved efficacy and a clear dose response compared to prior cohorts, including a 50% partial response rate, a 50% minimal response rate and 100% disease control rate. The International Myeloma Working Group defines a partial response as a 50% to 89.9% reduction in the marker of disease and minimal response as 25% to 49.9% reduction in the marker of disease. One patient achieved a minimal response with a 48% reduction in their disease marker.

On May 13, 2019, we announced that the FDA has granted Fast Track Designation for CLR 131 in fourth line or later relapse/refractory multiple myeloma. 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

On December 21, 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. On December 14, 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 up to 30 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 Phase 2 dose of CLR 131 and to determine preliminary antitumor activity (treatment response) of CLR 131 in children and adolescents. In 2018, the FDA granted orphan drug and a 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.

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 plan to initiate the first human clinical trial enrolling up to 30 patients combining CLR 131 and external beam radiation with recurrent HNC in Q4 2019.

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 1800 Series was a collaborative PDC program with Pierre Fabre that expired in January 2019. The program has been successful in demonstrating improved tolerability and efficacy in multiple animal models. The newly developed PDCs may provide enhanced therapeutic indices to otherwise highly potent, nontargeted payloads through the targeted delivery of the chemotherapeutic payload to cancer cells via our proprietary phospholipid ether delivery platform. The CLR 1800 Series remains under evaluation by the company as a number of PDC molecules have the potential to be progressed toward and into IND enabling studies.
- 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 preclinical development and if the Company elects to progress any molecules further, we would 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. A candidate molecule and a back-up have been selected for further advancement.
- CLR 2100 and 2200 Series are collaborative PDC programs with Onconova Therapeutics, Inc. (“Onconova”), that we entered into in September 2017. Onconova is a biotechnology company specializing in the discovery and development of novel small molecule cancer therapies. The collaboration is structured such that we will design and develop a series of PDCs utilizing different small molecules that Onconova was developing as payloads with the intent to show improved targeting and specificity to the tumor. At least one of the molecules was taken into Phase 1 clinical studies previously by Onconova. We would own all new intellectual property associated with the design of the new PDCs, and both companies will have the option to advance compounds.
- 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 (PLE); the companies intend to evaluate the new PDCs in up to three oncology indications. Currently, this series has shown efficacy in the first two animals 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, costs of our research and manufacturing facility, cost of manufacturing materials and contract manufacturing fees paid to contract research organizations, fees paid to medical institutions for clinical trials, and costs to secure intellectual property. The Company analyzes its research and development expenses based on four categories as follows: clinical project costs, pre-clinical project costs, manufacturing and related costs, and general research and development costs that are not allocated to the functional project costs, including personnel costs, facility costs, related overhead costs and patent costs.

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

Three Months Ended September 30, 2019 and 2018

Research and Development. Research and development expense for the three months ended September 30, 2019 was approximately \$2,704,000 compared to approximately \$1,996,000 for the three months ended September 30, 2018.

The following table is an approximate comparison summary of research and development costs for the three months ended September 30, 2019 and September 30, 2018:

	Three Months Ended September 30,		Variance
	2019	2018	
Clinical project costs	\$ 1,377,000	\$ 415,000	\$ 962,000
Manufacturing and related costs	677,000	164,000	513,000
Pre-clinical project costs	39,000	437,000	(398,000)
General research and development costs	611,000	980,000	(369,000)
	<u>\$ 2,704,000</u>	<u>\$ 1,996,000</u>	<u>\$ 708,000</u>

The overall increase in research and development expense of \$708,000, or 35%, was primarily a result of an increase in clinical project costs of approximately \$962,000 related to the start-up of the pediatric study as well as an increase in patient recruitments for the ongoing clinical trials. Manufacturing and related costs also increased by approximately \$513,000 as a result of an increase in patient recruitments for the ongoing clinical trials. The cost of pre-clinical studies decreased as some studies were concluding. The general research and development costs decreased as a result of a reduction in personnel.

General and Administrative. General and administrative expense for the three months ended September 30, 2019 was approximately \$1,260,000, compared to approximately \$1,092,000 in the three months ended September 30, 2018. The \$168,000 or 15% increase was resulted from \$96,000 in purchased services primarily related to consulting and legal fees, increases in public company expenses and rent in the amount of \$105,000 offset by a decrease in accounting fees of \$46,000.

Nine Months Ended September 30, 2019 and 2018

Research and Development. Research and development expense for the nine months ended September 30, 2019 was approximately \$6,822,000 compared to approximately \$5,799,000 for the nine months ended September 30, 2018.

The following table is a comparison summary of research and development costs for the nine months ended September 30, 2019 and September 30, 2018:

	Nine Months Ended September 30,		Variance
	2019	2018	
Clinical project costs	\$ 2,690,000	\$ 999,000	\$ 1,691,000
Manufacturing and related costs	2,321,000	1,214,000	1,107,000
Pre-clinical project costs	285,000	1,453,000	(1,168,000)
General research and development costs	1,526,000	2,133,000	(607,000)
	<u>\$ 6,822,000</u>	<u>\$ 5,799,000</u>	<u>\$ 1,023,000</u>

The overall increase in research and development expense of approximately \$1,023,000, or 18%, was primarily attributable to an increase in clinical project costs of approximately \$1,691,000 primarily related to the startup of the pediatric study as well as an increase in patient recruitments for the ongoing clinical trials. Manufacturing and related costs also increased by approximately \$1,107,000 as a result of an increase in patient recruitments for the ongoing clinical trials. The cost of pre-clinical studies decreased as some studies were concluding. The general research and development costs decreased as a result of a decrease in personnel.

General and Administrative. General and administrative expense for the nine months ended September 30, 2019 was approximately \$3,972,000, compared to approximately \$3,647,000 in the nine months ended September 30, 2018. The increase of approximately \$325,000, or 9%, primarily the result of \$153,000 in personnel related costs and \$311,000 in public company expenses, rent and depreciation. These costs were offset by decrease in accounting fees of approximately \$55,000 and restructuring charges of approximately \$81,000.

Liquidity and Capital Resources

As of September 30, 2019, we had cash and cash equivalents of approximately \$13,302,000 compared to \$13,310,000 as of December 31, 2018. This increase was due to the approximately \$9,000,000 of net proceeds received in connection with the May 20, 2019 public and private offerings. Net cash used in operating activities was approximately \$9,013,000 during the nine months ended September 30, 2019, as compared to \$8,699,000 used during the nine months ended September 30, 2018.

Our cash requirements have historically been for our research and development activities, clinical trials, 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, 2019, we had an accumulated deficit of approximately \$108,301,000.

On May 20, 2019, we issued and sold 1,982,000 shares of common stock at an offering price of \$2.50 per share. In a concurrent private placement, we 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, we 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.

We believe that the cash balance is adequate to fund our budgeted operations for at least 12 months from the filing of these financial statements and into the first quarter 2021. 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, 2018 and for the year ended December 31, 2018 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, 2019, 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 September 30, 2019 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 February 26, 2019 pursuant to Section 13 or 15(d) of the Exchange Act (the "2018 10-K") and the prospectus filed with the SEC on May 31, 2019 pursuant to Rule 424(b) of the Securities Act (the "Prospectus"). 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 2018 10-K:

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, 2019, our consolidated cash balance was approximately \$13.3 million. We believe our cash balance at September 30, 2019, is adequate to fund operations at budgeted levels into the first quarter 2021. We will require additional funds to conduct research and development, establish and conduct clinical and preclinical trials, establish commercial-scale manufacturing arrangements and provide for the marketing and distribution of our products. Our ability to execute our operating plan into the first quarter 2021 and beyond depends on our ability to control costs and 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:

- 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 trials;
- 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 trial and commercial quantities of our drugs;
- competing technological and market developments;
- market acceptance of our products;
- costs for recruiting and retaining management, employees and consultants;
- costs for educating physicians regarding the application and use of our products;
- the volatile market for priority review vouchers;
- whether we are able to maintain our listing on a national exchange;
- uncertainty and economic instability resulting from terrorist acts and other acts of violence or war; 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 trials. 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, 2019, we had a stockholders' equity of approximately \$12,231,000. The net loss for the nine months ended September 30, 2019 was approximately \$10,713,000, and we may never achieve profitability.

Item 6. Exhibits

Exhibit No.	Description	Filed with this Form 10-Q	Incorporation by Reference		Exhibit No.
			Form	Filing Date	
10.1	Employment Agreement between the Company and Dov Elefant dated August 15, 2019		8-K	August 15, 2019	10.1
10.2 *	Amendment to Amended and Restated Employment Agreement between the Company and Jarrod Longcor, dated November 10, 2019	X			
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 12, 2019

By: /s/ James V. Caruso
James V. Caruso
President and Chief Executive Officer

AMENDMENT TO
AMENDED AND RESTATED EMPLOYMENT AGREEMENT

THIS AMENDMENT TO AMENDED AND RESTATED EMPLOYMENT AGREEMENT (this "Amendment") is made and entered into as of November 10, 2019, between CELLECTAR BIOSCIENCES, INC., a Delaware corporation (the "Company"), and Jarrod Longcor ("Executive").

RECITALS

On April 15, 2019, the Company and Executive entered into an Amended and Restated Employment Agreement (the "Agreement") to reflect certain changes approved by the Company's Board of Directors (the "Board"). The parties hereto agree that the Agreement shall be amended as follows:

1. Section 4(e) is amended to read as follows:

(e) Termination by the Company Without Cause, or by Executive for Good Reason If Executive's employment is terminated by (i) the Company without Cause, or (ii) by Executive for "Good Reason," Executive will be entitled to receive (A) his Accrued Obligations, (B) a cash severance payment equal to seventy-five percent (75%) of Executive's Annual Base Salary, payable in regular installments in accordance with the Company's general payroll practices (in effect from time to time) beginning on the first pay date following the date of termination and ending on the ninth monthly anniversary date of the first pay date; provided, however, that if the Executive is terminated by (i) the Company without Cause, or (ii) by Executive for "Good Reason," within 12 months after a Change in Control, Executive will be entitled to receive an increased severance payment equal to one hundred percent (100%) of Executive's Annual Base Salary, payable in 12 monthly installments pursuant to the terms of this Section 4(e)(B), (C) addition of the cost of Company-provided health insurance to each severance payment made in accordance with Section 4(e)(B) above (for nine or 12 months as applicable), and (D) the bonus described in Section 3(a)(ii) above for the calendar year in which such termination occurs if Executive would have otherwise been entitled to receive such bonus had his employment not been terminated (provided that if the date of such termination occurs prior to the last day of the calendar year in respect of which such bonus is awarded, then such bonus will be prorated upon the number of days elapsed prior to Executive's date of termination). Any such bonus amount payable under this Section 4(e) will be payable at such time as such amount would have been payable had Executive's employment not been terminated. In addition to the foregoing, the Company shall provide to Executive, for a period of up to nine (9) months following the date of termination of employment with the Company, outplacement services, including, but not limited to: instruction and counseling to assess and develop job goals and interviewing, networking and negotiating skills; assistance with resume preparation and initiation of a job search; secretarial support, and the use of private offices at the outplacement firm's premises. Executive and the Company shall agree upon the outplacement services provider, and the aggregate cost of such services under this Section 4(e) shall not exceed Seventy Five Hundred Dollars (\$7,500).

As a condition to the Company's obligations to make the payments described in this Section 4(e), the Company and Executive will execute and deliver within 30 days after the date of termination of employment a general mutual release in the form reasonably required by the Company. Notwithstanding anything in this Agreement to the contrary, the Company will have no obligation to pay any amounts payable under this Section 4(e) during such times as Executive is in breach of Sections 5, 6, or 7 hereof.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first written above.

CELLECTAR BIOSCIENCES, INC.

By: /s/ James V. Caruso

Its: President and Chief Executive Officer

EXECUTIVE

 /s/ Jarrod Longcor
Jarrod Longcor

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 effect, 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 12, 2019

/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 effect, 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 12, 2019

/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, 2019, 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 12, 2019

/s/ Dov Elefant

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

Date: November 12, 2019