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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM S-1  
REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF 1933

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**CELLECTAR BIOSCIENCES, INC.**  
*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**04-3321804**  
*(I.R.S. Employer  
Identification Number)*

**3301 Agriculture Drive  
Madison, WI 53716  
(608) 441-8120**  
*(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)*

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**James Caruso  
President and Chief Executive Officer  
3301 Agriculture Drive  
Madison, WI 53716  
(608) 441-8120**  
*(Name, address, including zip code, and telephone number,  
including area code, of agent for service)*

**Copy to:**

**Paul Bork, Esq.  
Foley Hoag LLP  
155 Seaport Boulevard  
Boston, Massachusetts 02210  
(617) 832-1000**

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*Approximate date of commencement of proposed sale to the public:* As soon as practicable after this registration statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer       Accelerated filer       Non-accelerated filer       Smaller reporting company   
(Do not check if a smaller reporting company)

**CALCULATION OF REGISTRATION FEE**

<b>Title of Each Class of Securities to be Registered</b>	<b>Amount to be Registered (1)</b>	<b>Proposed Maximum Offering Price per Share (2)</b>	<b>Proposed Maximum Aggregate Offering Price (2)</b>	<b>Amount of Registration Fee</b>
Common Stock	300,006	\$ 2.23	\$ 669,013	\$ 77.54
Total	300,006	\$ 2.23	\$ 669,013	\$ 77.54

- (1) Consists of 300,006 shares of common stock of the registrant, par value \$0.00001 per share, issuable upon exercise of certain outstanding warrants at an exercise price of \$2.13 per share, to be offered and sold by the selling stockholders identified in this registration statement. This registration statement also relates to an indeterminate number of shares of common stock that may be issued upon stock splits, stock dividends or similar transactions in accordance with Rule 416 under the Securities Act of 1933 (the "Securities Act").
- (2) Estimated solely for the purpose of calculating the registration fee for the shares of common stock issuable upon the exercise of warrants to be registered in accordance with Rule 457(g) under the Securities Act, based upon the higher of (i) the price at which the warrants may be exercised and (ii) the average of the high and low prices for a share of the registrant's common stock as reported on the Nasdaq Capital Market on October 17, 2016.

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**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and the selling stockholders are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

## PROSPECTUS

SUBJECT TO COMPLETION, DATED OCTOBER 21, 2016



**300,006 SHARES OF COMMON STOCK**

**OFFERED BY SELLING STOCKHOLDERS**

This prospectus relates to the resale of up to 300,006 shares of our common stock issuable upon the exercise of outstanding warrants to purchase common stock issued on April 20, 2016. We are not selling any shares of our common stock under this prospectus and will not receive any proceeds from the sale of shares by the selling stockholders. The selling stockholders will bear all commissions and discounts, if any, attributable to the sale of the shares. We will bear all costs, expenses and fees in connection with the registration of the shares.

The selling stockholders may sell the shares of our common stock offered by this prospectus from time to time on terms to be determined at the time of sale through ordinary brokerage transactions or through any other means described in this prospectus under “Plan of Distribution.” The prices at which the selling stockholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions.

Our common stock is listed on the Nasdaq Capital Market under the symbol “CLR.B.” On October 17, 2016, the last reported sale price of our common stock on the Nasdaq Capital Market was \$2.10 per share.

On March 4, 2016 at 5:00 p.m. Eastern Standard Time, the Company effected a reverse stock split at a ratio of 1-for-10. All share and per share information presented herein has been retroactively restated to reflect the reverse split.

**Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page [●] of this prospectus for more information.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

**The date of this prospectus is October [●], 2016.**

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No dealer, salesperson or other person has been authorized to give any information or to make any representations other than those contained in this prospectus in connection with the offer contained in this prospectus and, if given or made, such information or representations must not be relied upon as having been authorized by us.

Neither the delivery of this prospectus nor any sale made hereunder shall under any circumstances create an implication that there has been no change in our affairs since the date hereof. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy securities other than those specifically offered hereby or of any securities offered hereby in any jurisdiction where, or to any person to whom, it is unlawful to make such offer or solicitation. The information contained in this prospectus speaks only as of the date of this prospectus unless the information specifically indicates that another date applies. In this prospectus, references to “Collectar Biosciences, Inc.,” “Collectar Bio,” “the Company,” “we,” “us,” and “our,” refer to Collectar Biosciences, Inc.

This prospectus has been prepared based on information provided by us and by other sources that we believe are reliable. This prospectus summarizes certain documents and other information in a manner we believe to be accurate, but we refer you to the actual documents, if any, for a more complete understanding of what we discuss in this prospectus. All of such documents are filed as exhibits to the registration statement of which this prospectus is a part. In making a decision to invest in the securities offered in this prospectus, you must rely on your own examination of us and the terms of the offering and securities offered in this prospectus, including the merits and risks involved.

We are not making any representation to you regarding the legality of an investment in the securities offered in this prospectus under any legal investment or similar laws or regulations. You should not consider any information in this prospectus to be legal, business, tax or other advice. You should consult your own attorney, business advisor and tax advisor for legal, business and tax advice regarding an investment in our securities. You may only rely on the information contained in or incorporated by reference into this prospectus or that we have referred you to.

You should also read and consider the information in the documents to which we have referred you under the captions “Where You Can Find More Information” and “Incorporation of Documents by Reference” in this prospectus.

On March 4, 2016 at 5:00 p.m. Eastern Standard Time, the Company effected a reverse stock split at a ratio of 1-for-10. All share and per share information presented herein has been retroactively restated to reflect the reverse split.

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this entire prospectus, including the documents to which we have referred you under the headings “Where You Can Find More Information” and “Incorporation of Documents by Reference” and the information set forth under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in each case included elsewhere in this prospectus.*

**Please refer to the Glossary of Certain Scientific Terms on page [●] of this prospectus for definitions of certain technical and scientific terms used throughout this prospectus.**

### Overview

Collectar Biosciences, Inc. (the Company) is a clinical stage biopharmaceutical company focused on the development of targeted phospholipid drug conjugates (PDCs) for the treatment and imaging of cancer. The Company’s research and development program is based on its proprietary PDC cancer targeting delivery platform. The delivery platform possesses the potential for the discovery and development of a broad range of cancer targeting agents. The Company’s pipeline is comprised of pre-clinical and clinical product candidates including radiotherapeutic and chemotherapeutic PDC’s. The pipeline also includes diagnostic and optical imaging assets. The Company’s research and development resources are focused on the clinical advancement of its therapeutic PDC’s.

Our core Company strategy is to leverage our industry leading PDC, proprietary cancer targeting delivery platform to generate capital, supplement internal resources and accelerate and broaden product candidate clinical development through strategic asset and research collaborations.

Our shares are listed on the Nasdaq® Capital Market under the symbol CLRB; prior to August 15, 2014, our shares were quoted on the OTCQX® marketplace, and prior to February 12, 2014 were quoted under the symbol NVLT.

Our PDC platform is based on our cancer-targeting and delivery technology which provides selective delivery of a diverse range of oncologic payloads to cancer cells and cancer stem cells. By linking various drug payloads to our proprietary phospholipid ether cancer-targeting vehicle, we believe we can generate PDCs with the potential to provide highly targeted delivery of chemotherapeutic and radiotherapeutic payloads to a broad range of cancers. As a result, our PDC platform has the potential to improve the therapeutic index of drug payloads, enhancing or maintaining efficacy while reducing adverse events by minimizing drug delivery to healthy cells, increasing delivery to cancer cells and cancer stem cells in a broad range of cancerous tumors. The PDC product portfolio includes:

CLR 131 is a small-molecule, broad-spectrum, cancer-targeting radiotherapeutic PDC that is designed to deliver cytotoxic (cell-killing) 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 a Phase 1 study for the treatment of relapse or refractory multiple myeloma. Multiple myeloma is the second most common hematologic cancer and an incurable cancer of plasma cells. This cancer type was selected for clinical, regulatory and commercial rationales, including multiple myeloma’s highly radiosensitive nature, continued unmet medical need in the relapse/refractory setting and the receipt of an orphan drug designation. The primary goals of the Phase 1 study are to assess the compound’s safety and tolerability in patients with relapsed or refractory multiple myeloma. Secondary objectives includes establishment of a recommended Phase II dose, both with and without dexamethasone, as well as an assessment of therapeutic activity, including progression free survival (PFS) and efficacy endpoints.

- The Investigational New Drug (IND) application was accepted by the U.S. Food and Drug Administration (FDA) in March 2014. In December 2014, the FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma. The Phase 1 study was initiated in April 2015 and we announced positive performance results from the first patient cohort in January 2016. The study’s Data Monitoring Committee (DMC), unanimously agreed to our request to increase the dose of CLR 131 by 50% and advance into the second cohort. The DMC reviewed Cohort 2 patient data in September 2016, and unanimously agreed to our request to increase the dose by 33% and advance to Cohort 3; patients are currently being enrolled. In July 2016, the Company was awarded a \$2,000,000 National Cancer Institute Fast-Track Small Business Innovation Research (SBIR) grant to further advance CLR 131. The funds will support a Phase 2 study the company plans to initiate in the first half of 2017 to further define the clinical benefits of CLR 131 in multiple myeloma and other hematologic malignancies.

- The Company is exploring the creation of additional PDCs ranging from newly discovered to well-characterized chemotherapeutic payloads under its CLR CTX Chemotherapeutic PDC program. The objective of our CTX program is to develop PDC chemotherapeutics through conjugation of our delivery vehicle and non-targeted anti-cancer agents to improve therapeutic indices and expand potential indications through the targeted delivery of chemotherapeutic payloads. Initial CTX product candidates include CLR 1601-PTX, CLR 1602-PTX and CLR 1603-PTX; all are small-molecule, broad-spectrum, cancer-targeting chemotherapeutics in pre-clinical research. These PDCs are designed to selectively deliver paclitaxel, a chemotherapeutic payload to cancer cells and cancer stem cells to increase the therapeutic index of paclitaxel as a monotherapy. Each of our paclitaxel PDC's have been evaluated in vitro to demonstrate formulation stability and CLR 1602-PTX is currently being studied in vivo to further explore the PDC's cancer targeting selectivity. In December 2015, the Company initiated a research collaboration for our PDC technology with Pierre Fabre Laboratories, the third largest French pharmaceutical company. The objective of the research collaboration is to co-design a library of PDC's employing Pierre Fabre's natural product derived chemotherapeutics in combination with our proprietary cancer targeting delivery vehicle. The newly developed PDC's may provide enhanced therapeutic indices to otherwise highly potent, non-targeted payloads through the targeted delivery to cancer cells provided by our cancer targeted delivery vehicle.
- CLR 125 is a broad-spectrum, cancer-targeting radiotherapeutic currently under pre-clinical investigation for the treatment of micrometastatic disease. Similar to CLR 131, the selective uptake and retention of CLR 125 has been observed in malignant tissues during pre-clinical studies.
- CLR 124 is a small-molecule, broad-spectrum, cancer-targeting positron emission tomography (PET) imaging PDC that we believe has the potential to be the first of its kind for the selective detection of tumors and metastases in a broad range of cancers. CLR 124 has been used for PET/CT imaging in a broad array of tumor types through Company and investigator-sponsored clinical trials. We are in the process of evaluating the data from those studies. In April 2014, the FDA granted CLR 124 orphan status as a diagnostic for the management of glioma.
- CLR 1502 is a small-molecule, broad-spectrum, cancer-targeting near-infrared (NIR)-fluorophore optical imaging PDC for intraoperative tumor and tumor margin illumination. After review of the Company's IND application, the FDA determined that CLR 1502 will be evaluated as a combination product and assigned to the Center for Devices and Radiological Health (CDRH). As a result of this classification, the FDA has advised Celectar that it will need to submit a new investigational application for the combination product prior to initiating its Phase 1 study in breast cancer surgery. Celectar is working to identify the optimal clinical development and value optimizing strategic pathway. Based on our assessment, the Company believes that product will be similarly treated post marketing approval regardless of the regulatory pathway.

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 above, that may result in improvements upon current standard of care (SOC) for the treatment and imaging of a broad range of human cancers.

### **Key Risks and Uncertainties**

We are subject to numerous risks and uncertainties, including the following:

- We will require additional capital in order to continue our operations, and may have difficulty raising additional capital;
- We are a clinical-stage company with a going concern qualification to our financial statements and a history of losses, and we can provide no assurance as to our future operating results;
- We have a history of recurring losses and an accumulated deficit, which, among other factors, raise substantial doubt about our ability to continue as a going concern, which in turn may hinder our ability to obtain future financing;
- We have had significant management turnover in the last year, we continue to depend on key personnel who may terminate their employment with us at any time and our success will depend on our ability to hire additional qualified personnel;
- At present, our success depends solely on the successful development and commercialization of our compounds in development, which cannot be assured;
- The failure to complete development of our technology, to obtain government approvals, including required FDA approvals, or to comply with ongoing governmental regulations could prevent, delay or limit the introduction or sale of proposed products and result in failure to achieve revenues or maintain our ongoing business;
- Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results;
- We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates;

- We have limited in-house research and manufacturing capacity and will continue to rely, to some extent, on research and manufacturing facilities at various universities, hospitals, contract research organizations and contract manufacturers for a portion of our research, development and manufacturing. In the event we exceed our in-house capacity or lose access to those facilities, our ability to gain FDA approval and commercialization of our drug delivery technology and products could be delayed or impaired;
- We expect to rely heavily on orphan drug status to develop and commercialize our product candidates, but our orphan drug designations may not confer marketing exclusivity or other expected benefits;
- We are exposed to product, clinical and pre-clinical liability risks that could create a substantial financial burden should we be sued;
- Acceptance of our products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues;
- We may face litigation from third parties who claim that our products infringe on their intellectual property rights, particularly because there is often substantial uncertainty about the validity and breadth of medical patents;
- If we are unable to protect or enforce our rights to intellectual property adequately or to secure rights to third-party patents, we may lose valuable rights, experience reduced market share, assuming any, or incur costly litigation to protect our intellectual property rights;
- Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete;
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers;
- The use of hazardous materials, including radioactive materials, in our research and development imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials;
- Due to our limited marketing, sales and distribution experience, we may be unsuccessful in our efforts to sell our proposed products, enter into relationships with third parties or develop a direct sales organization;
- If we are unable to convince physicians of the benefits of our intended products, we may incur delays or additional expense in our attempt to establish market acceptance;
- The market for our proposed products is rapidly changing and competitive, and new therapeutics, new drugs and new treatments that may be developed by others could impair our ability to maintain and grow our business and remain competitive;
- If users of our products are unable to obtain adequate reimbursement from third-party payers, or if additional healthcare reform measures are adopted, it could hinder or prevent our product candidates' commercial success;
- Our stock price has experienced price fluctuations;
- Four of our stockholders own in the aggregate approximately 27% of our outstanding common stock, which limits the influence of other stockholders;
- If we fail to maintain effective internal controls over financial reporting, the price of our common stock may be adversely affected;
- We are required to comply with certain provisions of Section 404 of the Sarbanes-Oxley Act of 2002 and if we fail to continue to comply, our business could be harmed and our stock price could decline;
- Our common stock could be further diluted as the result of the issuance of additional shares of common stock, convertible securities, warrants or options;
- Provisions of our charter, bylaws, and Delaware law may make an acquisition of us or a change in our management more difficult; and
- We have not paid dividends in the past and do not expect to pay dividends for the foreseeable future. Any return on investment may be limited to the value of our common stock.

For more information regarding the material risks and uncertainties we face, please see "Risk Factors" beginning on page [●] of this prospectus.

## Corporate Information

Our headquarters and manufacturing operation is located at 3301 Agriculture Drive, Madison, Wisconsin 53716. We maintain a website at [www.cellectar.com](http://www.cellectar.com). The information included or referred to on, or accessible through, our website does not constitute part of, and is not incorporated by reference into, this prospectus.

## The Offering

<i>Shares of common stock offered by us:</i>	None
<i>Shares of common stock offered by the selling stockholders:</i>	300,006 shares issuable upon the exercise of outstanding warrants to purchase common stock
<i>Shares of common stock outstanding before this offering, assuming no exercise of the New Warrants:</i>	5,368,235 shares
<i>Shares of common stock outstanding after completion of this offering, assuming full exercise of the New Warrants:</i>	5,668,241 shares
<i>Use of Proceeds:</i>	We will not receive any proceeds from the resale of the shares of common stock by the selling stockholders.
<i>Risk Factors:</i>	See “Risk Factors” on page 4 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding whether to purchase our securities.
<i>NASDAQ symbol for our common stock:</i>	CLRB

Unless we specifically state otherwise, the share information in this prospectus, including the number of shares of common stock outstanding before this offering, is as of October 17, 2016 and reflects or assumes no exercise of outstanding options or warrants to purchase shares of our common stock.

The number of shares of our common stock outstanding before and after this offering is based on 5,368,235 shares of common stock outstanding as of October 17, 2016 and excludes, as of that date:

- an aggregate of 488,142 shares of common stock issuable upon the exercise of outstanding stock options issued to employees, directors and consultants;
- an aggregate of 4,629,842 additional shares of common stock reserved for issuance under outstanding warrants having expiration dates between December 6, 2016 and October 20, 2021, and exercise prices ranging from \$2.13 per share to \$250.00 per share.



### Summary Historical Financial Information

The following table summarizes our financial data. We derived the following summary of our statements of operations data for the six months ended June 30, 2016 and 2015 and the summary of our balance sheet data as of June 30, 2016 from our unaudited consolidated financial statements, for the applicable periods, which have been incorporated by reference in this prospectus. We derived the following summary of our statements of operations data for the years ended December 31, 2015 and 2014 and the summary of our balance sheet data as of December 31, 2015 and 2014 from our audited consolidated financial statements, for the applicable periods, which have been incorporated by reference in this prospectus. The summary of our financial data set forth below should be read together with our financial statements and the related notes to those statements referred to under the heading “Documents Incorporated by Reference.”

	<b>Six Months Ended June 30,</b>		<b>Year Ended December 31,</b>	
	<b>2016</b>	<b>2015</b>	<b>2015</b>	<b>2014</b>
	(Unaudited)			
<b>Statement of Operations Data:</b>				
Costs and expenses:				
Research and development	\$ 2,004,638	\$ 3,026,961	\$ 5,158,874	\$ 5,964,453
General and administrative	2,328,981	1,761,090	3,395,360	3,704,676
Restructuring costs	—	90,500	203,631	221,816
Total costs and expenses	<u>4,333,619</u>	<u>4,878,551</u>	<u>8,757,865</u>	<u>9,890,945</u>
Loss from operations	<u>(4,333,619)</u>	<u>(4,878,551)</u>	<u>(8,757,865)</u>	<u>(9,890,945)</u>
Other income:				
Gain on revaluation of derivative warrants	3,023,092	292,375	3,667,826	2,285,157
Loss on issuance of derivative warrants	—	—	(404,150)	—
Interest income (expense), net	2,187	(1,530)	(841)	(446,314)
Total other income, net	<u>3,025,279</u>	<u>290,845</u>	<u>3,262,835</u>	<u>1,838,843</u>
Net loss	<u>\$ (1,308,340)</u>	<u>\$ (4,587,706)</u>	<u>\$ (5,495,030)</u>	<u>\$ (8,052,102)</u>
Basic and diluted net loss per common share	<u>\$ (0.50)</u>	<u>\$ (6.07)</u>	<u>\$ (7.03)</u>	<u>\$ (17.53)</u>
Shares used in computing basic and diluted net loss per common share	<u>2,617,341</u>	<u>756,276</u>	<u>781,975</u>	<u>459,266</u>
			<b>December 31,</b>	
			<b>2015</b>	<b>2014</b>
	(Unaudited)			
<b>Balance Sheet Data:</b>				
Current assets	\$ 8,139,359		\$ 4,180,574	\$ 9,698,238
Working capital	6,745,558		(1,522,471)	3,465,232
Total assets	11,377,910		7,596,379	13,419,516
Long term debt, including current portion	208,892		330,222	450,000
Total stockholders' equity	9,829,187		1,649,803	6,697,533

## RISK FACTORS

### Risks Related to Our Business and Industry

#### **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 operating losses for the foreseeable future. At June 30, 2016, our consolidated cash balance was approximately \$7,922,000. We believe our cash balance at June 30, 2016 is adequate to fund operations into the first quarter of 2017. 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 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 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;
- 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 will require additional funds to conduct research and development, establish and conduct preclinical and clinical trials, establish commercial-scale manufacturing arrangements and provide for the marketing and distribution of our products. Our ability to execute our operating plan depends on our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise.

We have incurred net losses of approximately \$65.9 million, 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. 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 June 30, 2016, we had a stockholders' equity of approximately \$9,829,000. The operating loss for the six months ended June 30, 2016 was approximately \$4,334,000 and we may never achieve profitability.

**We have received notices from Nasdaq of non-compliance with its continuing listing rules.**

On August 14, 2015 we received a notice from Nasdaq of non-compliance with its continuing listing rules, namely that our stockholders' equity at June 30, 2015 of \$2,373,371, as reported in our Form 10-Q for the quarter then ended, was less than \$2,500,000 minimum. The failure to meet continuing compliance standards subjects our common stock to delisting. The Company submitted a plan to Nasdaq to regain compliance, which was approved by Nasdaq that required a number of actions to be completed by February 10, 2016, including the filing of a registration statement with the SEC for an underwritten public offering of equity and the closing of that offering. The registration statement was timely filed, however the Company did not complete the offering by that date. Nasdaq issued a second notice of noncompliance on February 11, 2016, which the Company appealed. At a hearing on March 31, 2016, the Company requested, and Nasdaq subsequently granted, an extension of time to effect transactions to allow us to regain compliance and to report the same. On April 20, 2016, we closed the 2016 Underwritten Offering, and on May 16, 2016, Nasdaq issued a determination that the Company had evidenced compliance with all requirements for continued listing on The Nasdaq Capital Market and, accordingly, the listing qualifications matter had been closed.

On January 21, 2016 we received a notice from NASDAQ of non-compliance with its listing rules regarding the requirement that the listed securities maintain a minimum bid price of \$1 per share. Based upon the closing bid price for the 30 consecutive business days preceding the notice, the Company no longer met this requirement. However, the Rules also provide the Company a period of 180 calendar days in which to regain compliance. On March 4, 2016, the Company effected a reverse stock split at a ratio of 1-for-10, which, among other things, resulted in an increase in the bid price adequate to allow the Company to regain compliance with the minimum bid price requirement. On March 21, 2016, Nasdaq notified the Company that we had regained compliance with the minimum bid price requirement.

**We are a clinical-stage company with a going concern qualification to our financial statements and a history of losses, and we can provide no assurance as to our future operating results.**

We are a clinical-stage company and 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. In addition, development of our product candidates requires a process of pre-clinical 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 a history of recurring losses and an accumulated deficit, which, among other factors, raise substantial doubt about our ability to continue as a going concern, which in turn may hinder our ability to obtain future financing.**

Our financial statements as of December 31, 2015 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2015 financial statements, in their report, included an explanatory paragraph referring to our recurring losses since inception and expressing substantial doubt in our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our ability to continue as a going concern depends on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue.

**We depend on key personnel who may terminate their employment with us at any time, and our success will depend on our ability to hire additional qualified personnel.**

Our success will depend to a significant degree on the continued services of our executive officers. There can be no assurance that these individuals will continue to provide services to us. In addition, our success may depend on our ability to attract and retain other highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources. To date, we have not experienced difficulties in attracting and retaining highly qualified personnel, but there can be no assurance we will be successful in doing so in the future.

At present, our success is dependent on one or more of the following to occur: The successful development of CLR 131 for the treatment of multiple myeloma or another cancer type, the development of new phospholipid drug conjugates, specifically new products developed from our CTX program and the advancement of our therapeutic or diagnostic imaging agents through research and development and/or commercialization partnerships, none of which can be assured.

We are focused on the development of radiotherapeutic and chemotherapeutic compounds for the treatment of cancer. We possess cancer diagnostic imaging agents also based on our PDC Platform. Our PDC platform is based on our cancer-targeting and delivery technology which provides selective delivery of a diverse range of oncologic payloads to cancer cells and cancer stem cells. By linking various payloads to our proprietary phospholipid ether cancer-targeting vehicle, we believe we can create PDCs with the potential to provide highly targeted delivery of chemotherapeutic and radiotherapeutic payloads to a broad range of cancers. As a result, our PDC platform has the potential to improve the therapeutic index of payloads by minimizing delivery to healthy cells while enhancing delivery to a broad range of cancers.

Our proposed products and their potential applications are in an early stage of clinical and manufacturing/process development and face a variety of risks and uncertainties. Principally, these risks include the following:

- future clinical trial results may show that our cancer-targeting technologies are not well tolerated by recipients at its effective doses or are not efficacious;
- future clinical trial results may be inconsistent with testing results obtained to-date;
- even if our cancer-targeting technologies are shown to be safe and effective for their intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities at reasonable prices or at all;
- our ability to complete the development and commercialization of our cancer-targeting technologies for their intended use is substantially dependent upon our ability to raise sufficient capital or to obtain and maintain experienced and committed partners to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of, our products;
- even if our cancer-targeting technologies are successfully developed, commercially produced and receive all necessary regulatory approvals, there is no guarantee that there will be market acceptance of our products; and
- our competitors may develop therapeutics or other treatments which are superior or less costly than our own with the result that our product candidates, even if they are successfully developed, manufactured and approved, may not generate sufficient revenues to offset the development and manufacturing costs of our product candidates.

If we are unsuccessful in dealing with any of these risks, or if we are unable to successfully advance the development of our cancer-targeting technologies for some other reason, our business, prospects, financial condition, and results of operations may be adversely affected.

**The failure to complete development of our technology, to obtain government approvals, including required FDA approvals, or to comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of proposed products and result in failure to achieve revenues or maintain our ongoing business.**

Our research and development activities and the manufacture and marketing of our intended products are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the U.S. and abroad. Before receiving clearance to market our proposed products by the FDA, we will have to demonstrate that our products are safe and effective for the patient population for the diseases that are to be treated. Clinical trials, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacturing, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, clinical trials and regulatory approval can take many years to accomplish and require the expenditure of substantial financial, managerial and other resources.

In order to be commercially viable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our technologies. This includes meeting a number of critical developmental milestones including:

- demonstrating benefit from delivery of each specific drug for specific medical indications;
- demonstrating through pre-clinical and clinical trials that each drug is safe and effective; and
- demonstrating that we have established viable Good Manufacturing Practices capable of potential scale-up.

The timeframe necessary to achieve these developmental milestones may be long and uncertain, and we may not successfully complete these milestones for any of our intended products in development.

In addition to the risks previously discussed, our technology is subject to developmental risks that include the following:

- uncertainties arising from the rapidly growing scientific aspects of drug therapies and potential treatments;
- uncertainties arising as a result of the broad array of alternative potential treatments related to cancer and other diseases; and
- expense and time associated with the development and regulatory approval of treatments for cancer and other diseases.

In order to conduct the clinical trials that are necessary to obtain approval by the FDA to market a product, it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because we or our clinical investigators do not follow the FDA's requirements for conducting clinical trials. If any of our trials are halted, we will not be able to obtain FDA approval until and unless we can address the FDA's concerns. If we are unable to receive clearance to conduct clinical trials for a product, we will not be able to achieve any revenue from such product in the U.S. as it is illegal to sell any drug for use in humans in the U.S. without FDA approval.

Even if we do ultimately receive FDA approval for any of our products, these products will be subject to extensive ongoing regulation, including regulations governing manufacturing, labeling, packaging, testing, dispensing, prescription and procurement quotas, record keeping, reporting, handling, shipment and disposal of any such drug. Failure to obtain and maintain required registrations or to comply with any applicable regulations could further delay or preclude development and commercialization of our drugs and subject us to enforcement action.

**Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.**

In order to obtain regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive clinical trials to demonstrate safety and efficacy of these product candidates. Clinical testing is expensive, it can take many years to complete and its outcome is uncertain. Failure can occur at any time during the clinical trial process.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board approval to conduct a trial at a prospective site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials and new drugs approved for the conditions we are investigating. Prescribing physicians will also have to decide to use our product candidates over existing drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and delay our ability to generate revenue.

In addition, the results of pre-clinical studies and early clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

Our clinical trials may not demonstrate sufficient levels of efficacy necessary to obtain the requisite regulatory approvals for our drugs, and our proposed drugs may not be approved for marketing.

**We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.**

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any product candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

**We have limited in-house research and manufacturing capacity and will continue to rely, to some extent, on research and manufacturing facilities at various universities, hospitals, contract research organizations and contract manufacturers for a portion of our research, development, and manufacturing. In the event we exceed our in-house capacity or lose access to those facilities, our ability to gain FDA approval and commercialization of our drug delivery technology and products could be delayed or impaired.**

We remain in the research and development and clinical and pre-clinical trial phase of product commercialization and have limited experience in establishing, supervising and conducting commercial manufacturing. Accordingly, if our products are approved for commercial sale, we will need to establish the capability, work with our existing contract manufacturer to expand their capability, or engage a contract manufacturer that has the capability, to commercially manufacture our products in accordance with FDA and other regulatory requirements. There can be no assurance that we would be able to successfully establish any such capability, or identify a suitable manufacturing partner on acceptable terms.

At the present time, we have limited research, development or manufacturing capabilities within our facilities. Our manufacturing facility in Madison, Wisconsin has capacity to supply drug product for Phase 2 studies of CLR 131. The Company would need to expand internal capacity for a Phase 3 study, or engage a third party current Good Manufacturing Practices (cGMP) manufacturing vendor. cGMP manufacturing of CLR 124 is currently conducted by our collaborator, the University of Wisconsin in Madison, using drug substance produced in our Madison manufacturing facility. CLR 1502 is synthesized at our facility in Madison, WI facility. We rely and expect to continue to rely, to some extent, on contracting with third parties to use their facilities to conduct research, development and manufacturing. The limited facilities we have to conduct research, development and manufacturing may delay or impair our ability to gain FDA approval and commercialization of our drug delivery technology and products.

We may rely on third-party contract research organizations, service providers and suppliers to support development and clinical testing of our products. This may expose us to the risks of not being able to directly oversee the production and quality of the manufacturing process. Furthermore, these contractors, whether foreign or domestic, may experience regulatory compliance difficulties, mechanical shutdowns, employee strikes or other unforeseeable acts that may delay production. Failure of any of these contractors to provide the required services in a timely manner or on commercially reasonable terms could materially delay the development and approval of our products, increase our expenses and materially harm our business, prospects, financial condition and results of operations.

We believe that we have a good working relationship with our contractors. However, should the situation change, we may be required to relocate these activities on short notice, and we do not currently have access to alternate facilities to which we could relocate our research, development and/or manufacturing activities. The cost and time to establish or locate an alternate research, development and/or manufacturing facility to develop our technology would be substantial and would delay obtaining FDA approval and commercializing our products.

**We expect to rely heavily on orphan drug status to develop and commercialize our product candidates, but our orphan drug designations may not confer marketing exclusivity or other expected commercial benefits.**

We expect to rely heavily on orphan drug exclusivity for our product candidates. Orphan drug status confers seven years of marketing exclusivity under the Federal Food, Drug, and Cosmetic Act, and up to ten years of marketing exclusivity in Europe for a particular product in a specified indication. We have been granted orphan drug designation in the United States for CLR 124 as a diagnostic for the management of glioma and for CLR 131 as a therapeutic for the treatment of multiple myeloma. While we have been granted these orphan designations, we will not be able to rely on them to exclude other companies from manufacturing or selling products using the same principal molecular structural features for the same indication beyond these timeframes. For any product candidate for which we have been or will be granted orphan drug designation in a particular indication, it is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. Even if we are the first to obtain marketing authorization for an orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during the seven-year period of marketing exclusivity, such as if the later product is shown to be clinically superior to the orphan product, or if the later product is deemed a different product than ours. Further, the seven-year marketing exclusivity would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation, or for the use of other types of products in the same indications as our orphan product, or during such seven-year period for other indications.

**We are exposed to product, clinical and pre-clinical liability risks that could create a substantial financial burden should we be sued.**

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. In addition, the use, in our clinical trials, of pharmaceutical products that we or our current or potential collaborators may develop and then subsequently sell may cause us to bear a portion of or all product liability risks. While we carry an insurance policy covering up to \$5,000,000 per occurrence and \$5,000,000 in the aggregate of liability incurred in connection with such claims should they arise, there can be no assurance that our insurance will be adequate to cover all situations. Moreover, there can be no assurance that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Furthermore, our current and potential partners with whom we have collaborative agreements or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have a net worth sufficient to satisfy any product liability claims. A successful product liability claim or series of claims brought against us could have a material adverse effect on our business, prospects, financial condition and results of operations.

**Acceptance of our products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues.**

Our future financial performance will depend, at least in part, on the introduction and customer acceptance of our proposed products. Even if approved for marketing by the necessary regulatory authorities, our products may not achieve market acceptance. The degree of market acceptance will depend on a number of factors including:

- receiving regulatory clearance of marketing claims for the uses that we are developing;
- establishing and demonstrating the advantages, safety and efficacy of our technologies;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;
- our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our intended products; and
- our ability to market our products.

Physicians, patients, payers, or the medical community in general, may be unwilling to accept, use or recommend any of our products. If we are unable to obtain regulatory approval or commercialize and market our proposed products as planned, we may not achieve any market acceptance or generate revenue.

**We may face litigation from third parties who claim that our products infringe on their intellectual property rights, particularly because there is often substantial uncertainty about the validity and breadth of medical patents.**

We may be exposed to future litigation by third parties based on claims that our technologies, products or activities infringe on the intellectual property rights of others or that we have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents and the breadth and scope of trade-secret protection involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us, whether or not valid, could result in substantial costs, could place a significant strain on our financial and managerial resources and could harm our reputation. The U. Mich. License does require, and license agreements that we may enter into in the future would likely require, that we pay the costs associated with defending this type of litigation. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease selling, incorporating or using any of our technologies and/or products that incorporate the challenged intellectual property, which would adversely affect our ability to generate revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our products, which would be costly and time-consuming.

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

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

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

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

We may have to resort to litigation to protect our rights for certain intellectual property or to determine their scope, validity or enforceability of our intellectual property rights. Enforcing or defending our rights is expensive, could cause diversion of our resources and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

**Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.**

We operate in the highly technical field of research and development of small molecule drugs, and rely in part on trade-secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that our competitors will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties that provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party has illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade-secret protection could adversely affect our competitive position.

**We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.**

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or these employees have used or disclosed trade secrets or other proprietary information of their former employers, either inadvertently or otherwise. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

**The use of hazardous materials, including radioactive materials, in our research and development imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials.**

Our research and development, manufacturing and administration of our drugs involve the controlled use of hazardous materials, including chemicals and radioactive materials, such as radioactive isotopes. We are subject to federal, state and local laws and regulations governing the storage, use and disposal of these materials and some waste products and are required to maintain both a manufacturer's license and a radioactive materials license with State of Wisconsin agencies. We believe that our safety procedures for the storage, use and disposal of these materials comply with the standards prescribed by federal, state and local regulations. However, we cannot completely eliminate the risk of accidental contamination or injury from these materials. If there were to be an accident, we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage, with limits of up to \$2,500,000 depending on the nature of the claim, for damages resulting from the hazardous materials we use; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with federal, state and local regulations are not significant, and consist primarily of waste disposal expenses and permitting fees. However, they could become expensive, and current or future environmental regulations may impair our research, development, production and commercialization efforts. If we are unable to maintain the required licenses and permits for any reason, it will negatively impact our research and development activities.



**Due to our limited marketing, sales and distribution experience, we may be unsuccessful in our efforts to sell our proposed products, enter into relationships with third parties or develop a direct sales organization.**

We have not established marketing, sales or distribution capabilities for our proposed products. Until such time as our proposed products are further along in the development process, we will not devote any meaningful time and resources to this effort. At the appropriate time, we will determine whether we will develop our own sales and marketing capabilities or enter into agreements with third parties to sell our products.

We have limited experience in developing, training or managing a sales force. If we choose to establish a direct sales force, we may incur substantial additional expenses in developing, training and managing such an organization. We may be unable to build a sales force on a cost-effective basis or at all. Any such direct marketing and sales efforts may prove to be unsuccessful. In addition, we will compete with many other companies that currently have extensive marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all.

If we choose to enter into agreements with third parties to sell our proposed products, we may be unable to establish or maintain third-party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors.

We may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to adequately market our products;
- fail to satisfy financial or contractual obligations to us;
- offer, design, manufacture or promote competing products; or
- cease operations with little or no notice.

If we fail to develop sales, marketing and distribution channels, we would experience delays in product sales and incur increased costs, which would have a material adverse effect on our business, prospects, financial condition, and results of operation.

**If we are unable to convince physicians of the benefits of our intended products, we may incur delays or additional expense in our attempt to establish market acceptance.**

Achieving use of our products in the target market of cancer diagnosis and treatment may require physicians to be informed regarding these products and their intended benefits. The time and cost of such an educational process may be substantial. Inability to successfully carry out this physician education process may adversely affect market acceptance of our proposed products. We may be unable to timely educate physicians regarding our intended proposed products in sufficient numbers to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our proposed products. In addition, we may expend significant funds towards physician education before any acceptance or demand for our proposed products is created, if at all.

**The market for our proposed products is rapidly changing and competitive, and new therapeutics, new drugs and new treatments that may be developed by others could impair our ability to maintain and grow our business and remain competitive.**

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our technologies and intended products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Most of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase our competitors' financial, marketing, manufacturing and other resources.

Our resources are limited and we may experience management, operational or technical challenges inherent in such activities and novel technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may accomplish therapeutic effects similar to those of our technology, but through different means. Our competitors may develop drugs and drug delivery technologies that are more effective than our intended products and, therefore, present a serious competitive threat to us.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our products even if they are commercialized. Many of our targeted diseases and conditions can also be treated by other medication or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our technologies and products to receive widespread acceptance if commercialized.

**If users of our products are unable to obtain adequate reimbursement from third-party payers, or if additional healthcare reform measures are adopted, it could hinder or prevent our product candidates' commercial success.**

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of healthcare may adversely affect our ability to generate future revenues and achieve profitability, including by limiting the future revenues and profitability of our potential customers, suppliers and collaborative partners. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. The U.S. government is implementing, and other governments have shown significant interest in pursuing, healthcare reform. Any government-adopted reform measures could adversely affect the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payers. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set prices for our products, should we be successful in commercializing them, and this would negatively affect our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for healthcare products and services, or sales, marketing or pricing of healthcare products and services, also may limit our potential revenue and may require us to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging for several reasons, including policies advanced by the current or future executive administrations in the U.S., new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. In the U.S., changes in federal healthcare policy were enacted in 2010 and are being implemented. Some reforms could result in reduced reimbursement rates for our product candidates, which would adversely affect our business strategy, operations and financial results. Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations (HMOs). Third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed healthcare in the U.S. and the concurrent growth of organizations such as HMOs that could control or significantly influence the purchase of healthcare services and drugs, as well as legislative proposals to reform healthcare or change government insurance programs, may all result in lower prices for or rejection of our drugs. The cost containment measures that healthcare payers and providers are instituting and the effect of any healthcare reform could materially harm our ability to operate profitably.

**Our stock price has experienced price fluctuations.**

There can be no assurance that the market price for our common stock will remain at its current level and a decrease in the market price could result in substantial losses for investors. The market price of our common stock may be significantly affected by one or more of the following factors:

- announcements or press releases relating to the biopharmaceutical sector or to our own business or prospects;
- regulatory, legislative, or other developments affecting us or the healthcare industry generally;
- sales by holders of restricted securities pursuant to effective registration statements, or exemptions from registration;
- market conditions specific to biopharmaceutical companies, the healthcare industry and the stock market generally; and
- our ability to maintain our status on the Nasdaq exchange.

## **Risks Related to Our Common Stock**

### **Four of our stockholders own approximately 27% of our outstanding common stock, which limits the influence of other stockholders.**

As of October 17, 2016, approximately 27% of our outstanding common stock is owned by four stockholders. The interests of these stockholders may differ from those of other stockholders. These stockholders will likely continue to have the ability to significantly affect the outcome of all corporate actions requiring stockholder approval, including the following actions:

- the election of directors;
- the amendment of charter documents; and
- the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets.

### **If we fail to maintain effective internal controls over financial reporting, the price of our common stock may be adversely affected.**

We identified a material weakness in our internal control over financial reporting, the disclosure of which may have an adverse impact on the price of our common stock. We are required to establish and maintain appropriate internal controls over financial reporting. Failure to establish those controls, or any failure of those controls once established, could adversely affect our public disclosures regarding our business, prospects, financial condition or results of operations. In addition, management's assessment of internal controls over financial reporting may identify weaknesses and conditions that need to be addressed in our internal controls over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting or disclosure of management's assessment of our internal controls over financial reporting may have an adverse impact on the price of our common stock.

### **We are required to comply with certain provisions of Section 404 of the Sarbanes-Oxley Act of 2002 and if we fail to continue to comply, our business could be harmed and our stock price could decline.**

Rules adopted by the SEC pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 require an annual assessment of internal controls over financial reporting, and for certain issuers an attestation of this assessment by the issuer's independent registered public accounting firm. The standards that must be met for management to assess the internal controls over financial reporting as effective are evolving and complex, and require significant documentation, testing, and possible remediation to meet the detailed standards. We expect to incur significant expenses and to devote resources to Section 404 compliance on an ongoing basis. It is difficult for us to predict how long it will take or costly it will be to complete the assessment of the effectiveness of our internal control over financial reporting for each year and to remediate any deficiencies in our internal control over financial reporting. As a result, we may not be able to complete the assessment and remediation process on a timely basis. In addition, although attestation requirements by our independent registered public accounting firm are not presently applicable to us we could become subject to these requirements in the future and we may encounter problems or delays in completing the implementation of any resulting changes to internal controls over financial reporting. In the event that our Chief Executive Officer or Chief Financial Officer determine that our internal control over financial reporting is not effective as defined under Section 404, we cannot predict how regulators will react or how the market prices of our shares will be affected; however, we believe that there is a risk that investor confidence and share value may be negatively affected.

### **Our common stock could be further diluted as the result of the issuance of additional shares of common stock, convertible securities, warrants or options.**

In the past, we have issued common stock, convertible securities (such as convertible preferred stock and notes) and warrants in order to raise capital. We have also issued options as compensation for services and incentive compensation for our employees and directors. We have shares of common stock reserved for issuance upon the exercise of certain of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional common stock, convertible securities, options and warrants could affect the rights of our stockholders, could reduce the market price of our common stock or could result in adjustments to exercise prices of outstanding warrants (resulting in these securities becoming exercisable for, as the case may be, a greater number of shares of our common stock), or could obligate us to issue additional shares of common stock to certain of our stockholders.

### **Provisions of our charter, bylaws, and Delaware law may make an acquisition of us or a change in our management more difficult.**

Certain provisions of our certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which an investor might otherwise receive a premium for their shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock or warrants, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so.

Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions:

- provide for the division of our board into three classes as nearly equal in size as possible with staggered three-year terms and further limit the removal of directors and the filling of vacancies;
- authorize our board of directors to issue without stockholder approval blank-check preferred stock that, if issued, could operate as a “poison pill” to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings; and
- require the approval of the holders of 75% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our certificate of incorporation and bylaws.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a prescribed period of time.

**We have not paid dividends in the past and do not expect to pay dividends for the foreseeable future. Any return on investment may be limited to the value of our common stock.**

No cash dividends have been paid on our common stock. We do not expect to pay cash dividends in the near future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investor’s investment will only occur if our stock price appreciates.

## FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Exchange Act. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

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. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus.

You should read this prospectus and the documents that we reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus is part, 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 prospectus is accurate as of the date on the front cover of this prospectus or such prospectus supplement only. Because the risk factors referred to above 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 prospectus and any accompanying prospectus supplement, and particularly our forward-looking statements, by these cautionary statements.

## USE OF PROCEEDS

All proceeds from the resale of the shares of our common stock offered by this prospectus will belong to the selling stockholders. We will not receive any proceeds from the sale or other disposition by the selling stockholders of the shares of our common stock covered by this prospectus. However, we will receive proceeds upon any cash exercise of the New Warrants, the underlying shares of which are offered by this prospectus. If the New Warrants are all exercised for cash, we will receive gross proceeds of approximately \$639,000. We intend to use any proceeds from any such exercise to fund our research and development activities and for general corporate purposes. There is no assurance that the New Warrants will ever be exercised.

## SELLING STOCKHOLDERS

This prospectus relates to the offering by the selling stockholders of up to 300,006 shares of common stock issuable upon exercise of warrants issued on April 20, 2016 (the “New Warrants”).

The following table sets forth, based on information provided to us by the selling stockholders or known to us, the name of the selling stockholders, the nature of any position, office or other material relationship, if any, which the selling stockholders have had, within the past three years, with us or with any of our predecessors or affiliates, and the number of shares of our common stock beneficially owned by the selling stockholders before this offering, in each case as of October 17, 2016. The number of shares owned are those beneficially owned, as determined under the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares of common stock as to which a person has sole or shared voting power or investment power and any shares of common stock which the person has the right to acquire within 60 days through the exercise of any option, warrant or right, through conversion of any security or pursuant to the automatic termination of a power of attorney or revocation of a trust, discretionary account or similar arrangement. No selling stockholder is a broker-dealer or an affiliate of a broker-dealer.

We have assumed all shares of common stock reflected on the table will be sold from time to time in the offering covered by this prospectus. Because the selling stockholders may offer all or any portions of the shares of common stock listed in the table below, no estimate can be given as to the amount of those shares of common stock covered by this prospectus that will be held by the selling stockholders upon the termination of the offering. As of October 17, 2016, there were 5,368,235 shares of our common stock issued and outstanding.

<b>Selling Stockholder</b>	<b>Number of Shares Beneficially Owned Before Offering</b>	<b>Number of Shares Offered</b>	<b>Number of Shares Beneficially Owned After Offering</b>	<b>Percentage of Shares Beneficially Owned After Offering</b>
Lincoln Park Capital Fund LLC (1)	127,274	127,274	—	0.00%
Sabby Healthcare Master Fund, Ltd. (2)	723,650	84,850	638,800	4.99%
Sabby Volatility Warrant Master Fund, Ltd. (2)	261,226	42,426	218,800	3.92%
Greenway Properties, Inc. (3)	526,798	45,456	481,342	8.77%

(1) Based on information provided by Selling Stockholder.

(2) Based on information contained in a report on Schedule 13G filed with the Securities and Exchange Commission on January 11, 2016. In a Schedule 13F filing as of June 30, 2016, Sabby Management LLC, the investment manager for this fund, indicated that a total of 230,013 shares were beneficially owned by the investment manager on that date. The percentage beneficially owned after the offering, where appropriate, reflects blocker provisions in the respective warrant agreements that restrict the exercise of the warrants if the resultant ownership percentage would exceed 4.99%.

(3) Based on information contained in a report on Schedule 13G filed with the Securities and Exchange Commission on July 25, 2016.

## PLAN OF DISTRIBUTION

Each selling stockholder (the “Selling Stockholders”) of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the Nasdaq Stock Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.



We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the Selling Stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization, each as of June 30, 2016:

- on an actual basis; and
- on a pro forma basis assuming the full exercise of the New Warrants and giving effect to the issuance of the securities offered hereby.

You should consider this table in conjunction with our financial statements and the notes to those financial statements included elsewhere in this prospectus.

	<b>As of June 30, 2016</b>	
	<b>(Unaudited)</b>	
	<b>Actual</b>	<b>Pro Forma <sup>(1)</sup></b>
Cash and cash equivalents	\$ 7,922,144	\$ 8,561,157
Notes payable	208,892	208,892
Deferred rent	148,273	148,273
Capital lease obligations	9,233	9,233
<b>Total debt obligations</b>	<b>366,398</b>	<b>366,398</b>
Stockholders' equity:		
Preferred stock, par value \$0.00001 per share: 7,000 shares authorized; none actual; none pro forma	—	—
Common stock, par value \$0.00001 per share: 40,000,000 shares authorized; 5,368,235 actual; 5,668,241 pro forma	54	57
Additional paid in capital	75,744,174	76,383,184
Accumulated deficit	(65,915,041)	(65,915,041)
<b>Total stockholders' equity</b>	<b>9,829,187</b>	<b>10,468,200</b>
<b>Total capitalization</b>	<b>\$ 10,195,585</b>	<b>\$ 10,834,598</b>

(1) The Pro Forma column reflects the impact of the exercise of 300,006 warrants at \$2.13, generating total proceeds of \$639,013, and the resulting change in common stock par value and additional paid-in capital.

## MARKET FOR COMMON EQUITY

Prior to February 12, 2014, our stock was quoted under the ticker symbol NVLT; on that date, our ticker symbol was changed to CLRB in connection with the change in our corporate name. Our common stock was quoted under the CLRB ticker symbol on the OTCQX platform until August 15, 2014, since which time it has been listed on the NASDAQ Capital Market.

The following table provides, for the periods indicated, the high and low intraday sale prices for our common stock as reported by Nasdaq. Historical stock prices have been adjusted to give effect to a 1-for-10 reverse split of the Company's common stock effective at the close of business on March 4, 2016.

<b>Fiscal Year 2016</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 12.30	\$ 3.25
Second Quarter	5.05	1.00
Third Quarter	3.57	2.06
Fourth Quarter (through October 17, 2016)	2.91	2.05

  

<b>Fiscal Year 2015</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 32.90	\$ 21.50
Second Quarter	34.90	25.00
Third Quarter	38.90	1.80
Fourth Quarter	22.30	6.20

  

<b>Fiscal Year 2014</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 90.00	\$ 70.00
Second Quarter	92.00	60.00
Third Quarter	72.00	20.90
Fourth Quarter	37.00	17.60

On October 17, 2016 there were 357 holders of record of our common stock. This number does not include stockholders for whom shares were held in a "nominee" or "street" name.

We have not declared or paid any cash dividends on our common stock and do not anticipate declaring or paying any cash dividends in the foreseeable future. We currently expect to retain future earnings, if any, for the continued development of our business.

Our transfer agent and registrar is American Stock Transfer and Trust Company, 6201 15<sup>th</sup> Avenue, Brooklyn, NY 11219.

## BUSINESS

### Business Overview

Collectar Biosciences, Inc. (the Company) is a clinical stage biopharmaceutical company focused on the development of targeted phospholipid drug conjugates (PDCs) for the treatment and imaging of cancer. The Company's research and development program is based on its proprietary PDC cancer targeting delivery platform. The delivery platform possesses the potential for the discovery and development of a broad range of cancer targeting agents. The Company's pipeline is comprised of pre-clinical and clinical product candidates including radiotherapeutic and chemotherapeutic PDC's. The pipeline also includes diagnostic and optical imaging assets. The Company's research and development resources are focused on the clinical advancement of its therapeutic PDC's.

Our core Company strategy is to leverage our industry leading PDC, proprietary cancer targeting delivery platform to generate capital, supplement internal resources and accelerate and broaden product candidate clinical development through strategic asset and research collaborations.

Our shares are listed on the NASDAQ® Capital Market under the symbol CLRB; prior to August 15, 2014, our shares were quoted on the OTCQX® marketplace, and prior to February 12, 2014 were quoted under the symbol NVLT.

Our PDC platform is based on our cancer-targeting and delivery technology which provides selective delivery of a diverse range of oncologic payloads to cancer cells and cancer stem cells. By linking various drug payloads to our proprietary phospholipid ether cancer-targeting vehicle, we believe we can generate PDCs with the potential to provide highly targeted delivery of chemotherapeutic and radiotherapeutic payloads to a broad range of cancers. As a result, our PDC platform has the potential to improve the therapeutic index of drug payloads, enhancing or maintaining efficacy while reducing adverse events by minimizing drug delivery to healthy cells, increasing delivery to cancer cells and cancer stem cells in a broad range of cancerous tumors. The PDC product portfolio includes:

- CLR 131 is our lead therapeutic PDC product candidate and is currently being evaluated in a Phase 1 study for the treatment of relapse or refractory multiple myeloma. Multiple myeloma is the second most common hematologic cancer and an incurable cancer of plasma cells. This cancer type was selected for clinical, regulatory and commercial rationales, including multiple myeloma's highly radiosensitive nature, continued unmet medical need in the relapse/refractory setting and the receipt of an orphan drug designation. The primary goals of the Phase 1 study are to assess the compound's safety and tolerability in patients with relapsed or refractory multiple myeloma. Secondary objectives includes establishment of a recommended Phase II dose, both with and without dexamethasone, as well as an assessment of therapeutic activity, including progression free survival (PFS) and efficacy endpoints. The Investigational New Drug (IND) application was accepted by the U.S. Food and Drug Administration (FDA) in March 2014. In December 2014, the FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma. The Phase 1 study was initiated in April 2015 and we announced positive performance results from the first patient cohort in January 2016. The study's Data Monitoring Committee (DMC), unanimously agreed to our request to increase the dose of CLR 131 by 50% and advance into the second cohort. The DMC reviewed Cohort 2 patient data in September 2016, and unanimously agreed to our request to increase the dose by 33% and advance to Cohort 3; patients are currently being enrolled. In July 2016, the Company was awarded a \$2,000,000 National Cancer Institute Fast-Track Small Business Innovation Research (SBIR) grant to further advance CLR 131. The funds will support a Phase 2 study the company plans to initiate in the first half of 2017 to further define the clinical benefits of CLR 131 in multiple myeloma and other hematologic malignancies.
- The Company is exploring the creation of additional PDCs ranging from newly discovered to well-characterized chemotherapeutic payloads under its CLR CTX Chemotherapeutic PDC program. The objective of our CTX program is to develop PDC chemotherapeutics through conjugation of our delivery vehicle and non-targeted anti-cancer agents to improve therapeutic indices and expand potential indications through the targeted delivery of chemotherapeutic payloads. Initial CTX product candidates include CLR 1601-PTX, CLR 1602-PTX and CLR 1603-PTX; all are small-molecule, broad-spectrum, cancer-targeting chemotherapeutics in pre-clinical research. These PDCs are designed to selectively deliver paclitaxel, a chemotherapeutic payload to cancer cells and cancer stem cells to increase the therapeutic index of paclitaxel as a monotherapy. Each of our paclitaxel PDC's have been evaluated in vitro to demonstrate formulation stability and CLR 1602-PTX is currently being studied in vivo to further explore the PDC's cancer targeting selectivity. In December of 2015, the Company initiated a research collaboration for our PDC technology with Pierre Fabre Laboratories, the third largest French pharmaceutical company. The objective of the research collaboration is to co-design a library of PDC's employing Pierre Fabre's natural product derived chemotherapeutics in combination with our proprietary cancer targeting delivery vehicle. The newly developed PDC's may provide enhanced therapeutic indices to otherwise highly potent, non-targeted payloads through the targeted delivery to cancer cells provided by our cancer targeted delivery vehicle.
- CLR 125 is a broad-spectrum, cancer-targeting radiotherapeutic currently under pre-clinical investigation for the treatment of micrometastatic disease. Similar to CLR 131, the selective uptake and retention of CLR 125 has been observed in malignant tissues during pre-clinical studies. CLR 125 uses the radioisotope Iodine-125 (which has a 60-day half-life), which may provide an excellent tumor kinetics match with Collectar's proprietary delivery vehicle. CLR 125 has shown efficacy in a pre-clinical xenograft tumor models of triple negative breast cancer.

- CLR 124 is a small-molecule, broad-spectrum, cancer-targeting positron emission tomography (PET) imaging PDC that we believe has the potential to be the first of its kind for the selective detection of tumors and metastases in a broad range of cancers. CLR 124 has been used for PET/CT imaging in a broad array of tumor types through Company and investigator-sponsored clinical trials. We are in the process of evaluating the data from those studies. In April 2014, the FDA granted CLR 124 orphan status as a diagnostic for the management of glioma.
- CLR 1502 is a small-molecule, broad-spectrum, cancer-targeting NIR-fluorophore optical imaging PDC for intraoperative tumor and tumor margin illumination. After review of the Company's IND application, the FDA determined that CLR 1502 will be evaluated as a combination product and assigned to the Center for Devices and Radiological Health (CDRH). As a result of this classification, the FDA has advised Collectar that it will need to submit a new investigational application for the combination product prior to initiating its Phase 1 study in breast cancer surgery. Collectar is working to identify the optimal clinical development and value optimizing strategic pathway. Based on our assessment, the Company believes that product will be similarly treated post marketing approval regardless of the regulatory pathway.

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 above, that may result in improvements upon current standard of care (SOC) for the treatment and imaging of a broad range of human cancers.

## Technology Overview

Our product candidates are based on a cancer-targeting delivery platform of optimized PLE analogs (phospholipid ether proprietary delivery vehicle) that interact with lipid rafts. Lipid rafts are specialized regions of a cell's membrane phospholipid bilayer that contain high concentrations of cholesterol and sphingolipids and serve to organize cell surface and intracellular signaling molecules. As a result of enrichment of lipid rafts in cancer cells, including cancer stem cells, our products provide selective targeting preferentially over normal healthy cells. The cancer-targeting PLE delivery vehicle was deliberately designed to be combined with therapeutic, diagnostic and imaging molecules. For example, iodine can be attached via a very stable covalent bond resulting in distinct products differing only with respect to the isotope of iodine they contain; CLR 131 contains radioactive I-131, CLR 125 contains radioactive I-125, and CLR 124 contains the shorter-lived radioactive I-124. In addition, non-radioactive molecules, including cytotoxic compounds can also be attached to the delivery vehicle.

The Company is focused on exploring the creation of additional PDCs ranging from newly discovered to well-characterized chemotherapeutic payloads under its CLR CTX Chemotherapeutic PDC program. The objective of our CTX program is to develop PDC chemotherapeutics through conjugation of our delivery vehicle and non-targeted anti-cancer agents to improve therapeutic indices and expand potential indications through the targeted delivery of chemotherapeutic payloads. Initial CTX product candidates include CLR 1601-PTX, CLR 1602-PTX and CLR 1603-PTX; all are small-molecule, broad-spectrum, cancer-targeting chemotherapeutics in pre-clinical research. To date, multiple cancer-targeting product profiles have been generated from a single chemical core structure that is the foundation of our technology platform. We also believe that additional cytotoxic PDCs may be developed possessing enhanced therapeutic indices versus the original, non-targeted cytotoxic payload as a monotherapy.

In the case of CLR 1502, this is a near-infrared (800 nm) emitting fluorophore whose signal can penetrate through up to approximately 1 cm of tissue. This may enable the use of CLR 1502 to visualize tumor margins during cancer surgery, effectively acting as an adjunct to a therapeutic agent, and to non-invasively detect relatively superficial tumors

Malignant tumor targeting, including targeting of cancer stem cells, has been demonstrated *in vivo*. Mice without intact immune systems, and inoculated with Panc-1 (pancreatic carcinoma) cells, were injected with CLR 1502, 24 or 96 hours prior to imaging. *In vivo* optical imaging showed pronounced accumulation of CLR 1502 in tumors versus non-target organs and tissues. Similarly, PET imaging of tumor-bearing animals (colon, glioma, triple negative breast and pancreatic tumor xenograft models) administered the imaging agent CLR 124 clearly shows selective uptake and retention by both primary tumors and metastases, including cancer stem cells. PET/CT analysis following co-injection of CLR 131 (for therapy) and CLR 124 (for imaging) revealed time-dependent tumor responses and disappearance over nine days in a cancer xenograft model. We believe that the capability of our technology to target and be selectively retained by cancer stem cells *in vivo*, was demonstrated by treating glioma stem cell-derived orthotopic tumor-bearing mice with another fluorescent-labeled PDC (CLR 1501), and then removing the tumor and isolating cancer stem cells, which continued to display CLR 1501 labeling even after three weeks in cell culture.

The basis for selective tumor targeting of our compounds lies in differences between the plasma membranes of cancer cells as compared to those of most normal cells. Data suggests that lipid rafts serve as portals of entry for PDCs such as CLR 131, CLR 124 and CLR 1502. The marked selectivity of our compounds for cancer cells versus non-cancer cells is due to the fact that cancer cells are over-expressed with lipid rafts as compared to normal cells. Following cell entry via lipid rafts, CLR 131, CLR 124 and CLR 1502 are transported into the cytoplasm, where they distribute to organelle membranes (mitochondria, ER, lysosomes) but not the nucleus. The pivotal role played by lipid rafts is underscored by the fact that disruption of lipid raft architecture significantly suppresses uptake of our PDC delivery vehicle into cancer cells.

Our core technology platform is based on research conducted by Collectar, Inc.'s founder and former Chief Scientific Officer, beginning in 1994 at the University of Michigan (U. Mich.), where phospholipid ether analogs were initially designed, synthesized, radiolabeled, and evaluated. Our founder had continued his research at the University of Wisconsin (U. Wisc.) between 1998 and the subsequent founding of Collectar, Inc. in 2002 to further develop and commercialize the technology. Collectar, Inc. obtained exclusive rights to the related technology patents owned by U. Mich. in 2003 and continued development of the PDC platform while obtaining ownership of numerous additional patents and patent applications (lasting until 2025, 2028, 2030 and 2034 without extensions).

## Products in Development

### *CLR 131*

CLR 131 is a small-molecule, broad-spectrum, cancer-targeting molecular radiotherapeutic PDC that we believe has the potential to be the first radiotherapeutic agent to use PLEs to target cancer cells. CLR 131 is comprised of our proprietary PLE, 18-(p-[I-131]iodophenyl) octadecyl phosphocholine, acting as a cancer-targeting delivery and retention vehicle, covalently labeled with iodine-131, a cytotoxic (cell-killing) radioisotope with a half-life of eight days that is already in common use to treat thyroid and other cancer types. It is this "intracellular radiation" mechanism of cancer cell killing, coupled with delivery to a wide range of malignant tumor types that we believe provides CLR 131 with broad-spectrum anti-cancer activity. Selective uptake and retention has been demonstrated in cancer stem cells compared with normal cells, offering the prospect of longer lasting cancer activity.

Pre-clinical experiments in tumor models have demonstrated selective killing of cancer cells along with a benign safety profile. CLR 131's anti-tumor/survival-prolonging activities have been demonstrated in more than a dozen models including breast, prostate, lung, brain, pancreatic, ovarian, uterine, renal, and colorectal cancers as well as, melanoma and multiple myeloma. In all but two models, a single administration of a well-tolerated dose of CLR 131 was sufficient to demonstrate efficacy. Moreover, efficacy was also seen in a model employing human uterine sarcoma cells that have known resistance to many standard chemotherapeutic drugs. CLR 131 was also tested in combination with a standard efficacious dose of gemcitabine in a pancreatic cancer model. Single doses of CLR 131 or gemcitabine given alone were equally efficacious while the combination therapy was significantly more efficacious than either treatment alone (additive). In each study, the dose of CLR 131 was ~100  $\mu$ Ci, which is approximately 50-fold less than the maximum tolerated dose (MTD) of CLR 131 determined in a six-month rat radiotoxicity study.

Extensive IND-enabling, Good Laboratory Practices (GLP) *in vivo* and *in vitro* pre-clinical pharmacokinetic/ distribution, toxicology and drug safety studies were successfully completed in 2007 through 2009 using non-pharmacological concentrations/doses of PLE consistent with its role as a delivery/retention vehicle in CLR 131. Tissue distribution studies supported prediction of acceptable human organ exposures and body clearance for CLR 131. Importantly, and in sharp distinction from biological products labeled with I-131, the small-molecule CLR 131 showed very minimal variation in excretion kinetics and tissue distribution among individuals within species or across a 500-fold variation in dose. Single- and repeated-dose animal toxicology studies indicated very high margins of safety with our PLE delivery and retention vehicle even when administered at 80-200x over the amount required to deliver the anticipated maximum human therapy dose of CLR 131.

In 2009, we filed an IND with the FDA to study CLR 131 in humans. In February 2010, we completed a Phase 1 dosimetry trial with a single intravenous dose of 10 mCi/m<sup>2</sup> CLR 131 in eight patients with relapsed or refractory advanced solid tumors. Single doses of CLR 131 were well tolerated. The reported adverse events were all considered minimal, manageable and either not dose limiting or not related to CLR 131. There were no serious adverse events reported. Analysis of total body imaging and blood and urine samples collected over 42 days following injection indicated that doses of CLR 131 expected to be therapeutically effective could be administered without harming vital organs. Two subjects (one with colorectal cancer metastasized to lung and another with prostate cancer) had tumors that were imaged with 3D nuclear scanning (SPECT/CT) on day 6 after administration of CLR 131. Uptake of CLR 131 into tumor tissue (but not adjacent normal tissue or bone marrow) was clearly demonstrated in both subjects. Echoing animal studies, pharmacokinetic analyses demonstrated a prolonged half-life of radioactivity in the plasma after CLR 131 administration (approximately 200 hours) and that there was no significant variation in excretion or radiation dosimetry among subjects. The trial established an initial dose of 12.5 mCi/m<sup>2</sup>, for the Phase 1b escalating dose trial that commenced in January 2012.

The primary objective of the multicenter Phase 1b dose-escalation trial in patients with a range of advanced solid tumors was to define the MTD of CLR 131. In addition to determining the MTD, the Phase 1b trial was intended to evaluate overall tumor response (using standard RESIST 1.1 criteria) and safety. In September 2012, we announced that we had successfully completed the second cohort in this Phase 1b dose-escalation trial. The second two-patient cohort was successfully dosed with 25 mCi/m<sup>2</sup> of CLR 131, triggering enrollment into the third cohort at 37.5 mCi/m<sup>2</sup>. Data from the second cohort indicated CLR 131 was well-tolerated, without any dose limiting or sub-dose limiting toxicities, enabling enrollment of the third cohort. Data from the two-patient, third cohort indicated the onset of dose-limiting hematologic toxicities with CLR 131, triggering enrollment into a five-patient, fourth cohort at a dose midway between those used in the second and third cohorts, as per trial protocol. Four patients were enrolled in the fourth cohort and we ended enrollment in November 2013. Complete study results, including data from the fourth cohort of this trial were completed in the first quarter 2014. The results of the trial were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2014.

Tumor treatment with radioactive isotopes has been used as a fundamental cancer therapeutic for decades. The goals of targeted cancer therapy — selective delivery of effective doses of isotopes that destroy tumor tissue, sparing of surrounding normal tissue, and non-accumulation in vital organs such as the liver and kidneys — remains the focus of new therapies as well. We believe our isotope delivery technology is poised to achieve these goals. Because, to date, CLR 131 has been shown to reliably and near-universally accumulate in cancer cells, including cancer stem cells, and because the therapeutic properties of iodine-131 are well known, we believe the risk of non-efficacy in human clinical trials is less than that of other cancer therapies at this stage of development, although no assurance can be given.

In view of CLR 131's selective uptake and retention in a wide range of solid tumors and in cancer stem cells, its single-agent efficacy in animal models and its non-specific mechanism of cancer-killing (radiation), we are initially developing CLR 131 as a monotherapy for cancer indications with significant unmet medical need. While a number of indications were evaluated as the initial target treatment, multiple myeloma was selected principally because it is an incurable hematologic disease that is highly radiosensitive with significant unmet medical need in the relapse or refractory clinical setting, and is designated as an orphan disease. All of which may provide an accelerated regulatory pathway due to CLR 131 unique benefits versus existing therapeutic treatment options such as a novel mechanism of action and single dose treatment. The Investigational New Drug (IND) application was accepted by the FDA in September 2014. In December 2014, the FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma. We initiated our Phase 1 Study of CLR 131 for the treatment of Relapsed or Refractory multiple myeloma in April 2015, and provided a performance update on the first patient cohort and initiated the second study cohort in January 2016. CLR 131 is being evaluated as a monotherapy and will subsequently be explored as a combination therapy with chemotherapeutic agents, immunomodulatory agents and in combination with external beam radiotherapy. CLR 131 will also be evaluated in a Phase 2 clinical study examining relapse refractory multiple myeloma patients as well as selected other hematological malignancies. This study is funded through a Fast Track NCI SBIR award. The SBIR award was granted to the company in July 2016.

### ***CTX Product Portfolio***

The Company is exploring the creation of additional PDCs ranging from newly discovered to well-characterized chemotherapeutic payloads under its CLR CTX Chemotherapeutic PDC program. The objective of our CTX program is to develop PDC chemotherapeutics through conjugation of our delivery vehicle and non-targeted anti-cancer agents to improve therapeutic indices and expand potential indications through the targeted delivery of chemotherapeutic payloads. Initial CTX product candidates include CLR 1601-PTX, CLR 1602-PTX and CLR 1603-PTX; both all are small-molecule, broad-spectrum, cancer-targeting chemotherapeutics in pre-clinical research. These PDCs are designed to selectively deliver paclitaxel, a chemotherapeutic payload to cancer cells and cancer stem cells increasing the therapeutic index of paclitaxel as a monotherapy. Each of our paclitaxel PDC's are being have been evaluated *in vitro* to demonstrate formulation stability and CLR 1602-PTX is currently being studied *in vivo* to demonstrate formulation stability and further explore the PDC's cancer targeting selectivity. In December of 2015, the Company entered into a research collaboration for our PDC technology with Pierre Fabre laboratories, the third largest French pharmaceutical company. The objective of the research collaboration is to co-design a library of PDC's employing Pierre Fabre's natural product derived chemotherapeutics in combination with our proprietary cancer targeting delivery vehicle. The newly developed PDC's may provide enhanced therapeutic indices to otherwise highly potent, non-targeted payloads through the targeted delivery to cancer cells provided by our cancer targeted delivery vehicle.

### ***CLR 125***

CLR 125 is a broad-spectrum, cancer-targeting, radiotherapeutic currently under pre-clinical investigation for the treatment of micrometastatic disease. Similar to CLR 131, the selective uptake and retention of CLR 125 has been observed in malignant tissues during pre-clinical studies. CLR 125 uses the radioisotope iodine-125. CLR 125 research has recently been funded through an NCI SBIR award. The feasibility and safety of CLR 125 was being investigated for the treatment of triple-negative breast cancer (TNBC) in the (neo) adjuvant setting. This program was successfully completed on June 30, 2016 showing appropriate biodistribution, tolerability, and dose response.

### **Additional Assets**

#### ***CLR 124***

CLR 124 is a small-molecule, broad-spectrum, cancer-targeting imaging agent that we believe has first-in-class potential for selective detection of primary tumors and metastases in a broad range of cancers. Chemically, CLR 124 is comprised of our proprietary PLE, 18-(p-[I-124] iodophenyl) octadacyl phosphocholine, acting as a cancer-targeting delivery and retention vehicle, covalently labeled with iodine-124, a PET imaging radioisotope with a radiation half-life of four days. PET imaging used in conjunction with CT scanning has now become the imaging method of choice in much of oncology. In pre-clinical studies to date, CLR 124 selectively illuminated malignant tumors in over 60 animal models of different cancer types, demonstrating broad-spectrum, cancer-selective uptake and retention. Investigator-sponsored Phase 1/2 clinical trials of CLR 124 as a PET imaging agent are ongoing across multiple solid tumor indications. These trials have demonstrated positive initial imaging results in multiple tumor types. Based on positive initial CLR 124 imaging results in 29 primary and metastatic brain cancer patients, we believe CLR 124 has potential to address a significant unmet medical need for post-treatment efficacy assessment and differentiating tumor growth from pseudo-progression. In brain cancer, this has the potential to avoid unnecessary surgeries, biopsies and inappropriate treatment, resulting in better patient management and lower healthcare costs. We expect glioblastoma to be our lead indication for CLR 124 with additional development opportunities that could include brain metastases and other primary brain tumors.

These human trials are intended to provide proof-of-concept for CLR 124 as a PET imaging agent with the potential to supplant current imaging standards of care, FDG for various solid tumors, or MRI in the case of brain cancers. This is due to what we believe to be CLR 124's superior cancer selectivity. Furthermore, the radiation half-life of only 110 minutes for fluorine-18 labeled agents, such as FDG, severely limits their use to locations close to the point of manufacture. CLR 124's much longer radiation half-life affords a longer imaging window of up to seven days following injection, resulting in more favorable logistics of clinical use, including the ability to be distributed to clinics throughout the U.S. from a single manufacturing site. As a chemically identical biomarker for CLR 131, CLR 124 imaging may also be capable of estimating an efficacious dose of CLR 131 in individual cancer patients.

A three-part investigator-sponsored Phase 1/2 trial of radiolabeled CLR 1404 for patients with advanced non-small cell lung cancer (NSCLC) was initiated in February 2004 at the University of Wisconsin Carbone Cancer Center (UWCCC). The first part of the trial evaluated imaging characteristics of CLR 131 in seven patients and the second part of the trial evaluated tumor accumulation in one patient. The third part of the trial is now evaluating tumor imaging with CLR 124 at increasing doses. Dr. Anne M. Traynor at UWCCC is the principal investigator for this trial. We provided funding and the data was shared with us while the study progressed and at the conclusion of the study. A total of 11 patients were enrolled across four dose levels (1.5 mCi/m<sup>2</sup>, 3 mCi/m<sup>2</sup>, 5 mCi/m<sup>2</sup> and 7.5 mCi/m<sup>2</sup>) in this part of the Phase 1/2 trial. With the 5 mCi/m<sup>2</sup> dose level, we saw clear and sustained uptake of CLR 124 in cancerous tumors against low background and have not observed any adverse safety signals. In addition, in one patient, three brain metastases were detected with CLR 124 that were not identified with FDG PET, which following confirmation with current standard of care (SOC), prompted an alteration to the treatment plan for this patient. Having observed initial cancer-specific uptake with CLR 124 at a 7.5 mCi/m<sup>2</sup> dose in NSCLC patients, study investigators continued exploration of dose and imaging time points in an effort to optimize dosing and results.

An investigator-sponsored Phase 1/2 trial of CLR 124 as a PET imaging agent for brain cancer was initiated in December 2011 at UWCCC and the first patient was enrolled in March 2012. This trial was funded by both the UWCCC and an Institute for Clinical and Translational Research (ICTR) grant, and the data is shared with the Company. Enrollment to the trial is complete; 12 patients were dosed with 5 mCi/m<sup>2</sup> of CLR 124. The preliminary results showed avid and sustained uptake of CLR 124 in cancerous tumors against very low background and no adverse safety signals were observed.

An investigator-sponsored Phase 1/2 trial of CLR 124 as a PET imaging agent for glioma was initiated in January 2012 at UWCCC and the clinical trial protocol evaluates 7.5 mCi/m<sup>2</sup> and 10 mCi/m<sup>2</sup> doses of CLR 124. A total of 19 patients were enrolled.

An investigator-sponsored Phase 1/2 trial of CLR 124 as a PET imaging agent for patients with multiple solid tumor types (triple negative breast, prostate, colorectal, gastric, ovarian, pancreatic, esophageal, soft tissue sarcoma, and head & neck cancer) was initiated in August 2012 at the UWCCC and the first patient was enrolled in October 2012. We provided funding for the trial and the data was shared with us. Twelve patients were enrolled, completing the enrollment of the trial.

### ***CLR 1502***

CLR 1502 is a small-molecule, broad-spectrum, cancer-targeting, non-radioactive optical imaging agent that we believe has the potential to be the first of its kind for intraoperative tumor margin illumination and non-invasive tumor imaging. CLR 1502 is comprised of a proprietary PLE, acting as a cancer-targeting delivery and retention vehicle, covalently attached to a near-infrared (800nm) fluorophore. According to the American Cancer Society, the majority of cancer patients were expected to have some type of surgery and more than 1.6 million new cancers diagnosed in the U.S. alone in 2014. CLR 1502 may facilitate and enable diagnostic, staging, debulking and curative cancer surgeries, intraoperatively in real-time, by defining tumor margins and regional lymph node involvement, resulting in more complete tumor resections and improving outcome and prognosis. In this context, CLR 1502 could effectively act as an adjunct therapeutic agent. In pre-clinical tumor models, non-invasive optical imaging showed pronounced accumulation of CLR 1502 in tumors versus normal tissues and successfully delineated tumor margins during tumor resection. CLR 1502 may also have utility for non-invasive imaging of relatively superficial tumor types (e.g., melanoma, head & neck, colon, esophageal).



## Market Overview

Our target market is broad and represents the market for the treatment and imaging of cancer. The American Cancer Society estimated that approximately 1.67 million new cancer cases were diagnosed in the U.S. in 2015 and approximately 590,000 are expected to die of cancer. The global market for cancer drugs has reached \$100 billion in annual sales (May 2015), and could reach \$147 billion by 2018, according to a new report by the IMS Institute for Healthcare Informatics, a unit of drug data provider IMS Health. This growth will be driven by emerging targeted therapies, which are expected to change the cancer treatment landscape (Cowen), and an increased use of cancer drug combination regimens. The National Institutes of Health (NIH) estimated that the direct medical cost for treating cancer in 2010 (the latest figure available) was \$124.6 billion in the U.S., and projects that by 2020, this cost will have risen to at least \$158 billion.

According to the National Cancer Institute SEER data base, multiple myeloma is the second most common hematologic cancer with a U.S. incidence rate of 24,050 and a relapse or refractory patient population of 10,000 to 15,000. A Market Research Engine report from December 2015 indicated the global cancer diagnostics market is expected to grow at a compound annual growth rate of 7.6% during 2015 to 2022.

## Manufacturing

We maintain a current Good Manufacturing Practices compliant (cGMP) radiopharmaceutical manufacturing facility in Madison, Wisconsin, in which we manufacture drug substance for CLR 131, CLR 124, and CLR 1502 product candidates and also manufacture CLR 131 for clinical trials. This facility, consisting of approximately 19,500 square feet, contains offices, laboratories, a radiopharmaceutical research lab, a cGMP radiopharmaceutical manufacturing suite and a cGMP analytical laboratory for product release. Our manufacturing facility holds a State of Wisconsin Department of Health Services Radioactive Materials License which authorizes the use and possession of radioactive material for both manufacturing and distribution activities. The facility also holds a State of Wisconsin DHS Radioactive Materials License that authorizes the use and possession of radioactive materials for research and development. The research and development license permits the use and possession of iodine-125, iodine-131 and iodine-124 in quantities sufficient to support in-house drug substance and CLR 131 manufacturing for current clinical programs and other research needs. Each of these iodine isotopes is purchased from third party vendors.

Manufacturing of cGMP CLR 124 is currently conducted by our collaborator, the University of Wisconsin-Madison, using drug substance produced in our Madison manufacturing facility. The agreement contains standard provisions for the protection of data and intellectual property and may be terminated by either party with 60-days' notice, pending the completion of any obligations by either party set forth in an outstanding statement of work. The proprietary contract manufacturing process is sufficient to provide materials for Phase 2 trials and is scalable for larger trials. We do not plan to build in-house manufacturing capability for CLR 124.

The drug substance is identical for CLR 131 and CLR 124 products. The base molecule is a dry powder produced via a six-step synthetic scheme. The release specifications for drug substance have been established and validated. The impurity levels at small scale are very low, suggesting that larger scale production is feasible. We have also demonstrated 60-month stability for the drug substance in desiccated and refrigerated forms. We believe our laboratories are well equipped with the appropriate equipment for manufacturing pilot and small-scale batches in accordance with cGMP. We believe we have adequate drug substance manufacturing and CLR 131 drug product manufacturing capacity expertise and capacity for non-pivotal clinical trials.

CLR 1502 drug substance is synthesized at the Madison facility via a cGMP process from the same chemical precursor used in the manufacture of CLR 131. The facility has the capability to manufacture the CLR 1502 drug product to support Phase 1 clinical trials. Manufacturing of drug substance and drug product for subsequent clinical trials will likely be achieved through contract manufacturing.

All investigational drug substance and product intended for human use during clinical studies will be manufactured according to the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, FDA requirements (21 CFR part 211) and cGMP.

## Sales and Marketing

We have not entered into any joint development, licensing or similar partnering agreements with respect to any of our clinical stage product candidates or pre-clinical compounds. We plan to pursue and evaluate all available options to develop, launch and commercialize our compounds. These options presently include, but are not limited to: entering into a partnering arrangement with one or more pharmaceutical, imaging agent or imaging device companies with strong development and commercial expertise and infrastructure in the U.S., Europe and/or Japan. While we currently do not plan to build our own sales force or utilize a contract sales organization for launch and commercialization of our compounds, we may reconsider that in the future.

## Competition for Our Clinical-Stage Compounds

### *CLR 131*

Currently, several classes of approved products with various mechanisms of action exist, including: immune-modulating agents, proteasome inhibitors, histone deacetylase inhibitors, monoclonal antibodies, corticosteroids, and traditional chemotherapeutics. While a number of indications were evaluated as the initial target treatment for CLR 131, multiple myeloma was selected principally because of its highly radiosensitive nature, single dose treatment, and novel mechanism of action relative to all existing classes of approved drugs. As a result, we believe CLR 131 is an ideal therapeutic option in the relapse or refractory setting either as a monotherapy or in combination with currently approved agents, some of which are radiosensitive and maintain exclusive adverse event profiles.



### **CLR 124**

FDG is the current SOC for cancer PET imaging. FDG accumulates in any tissue having increased glucose metabolism (i.e. energy utilization) compared to surrounding tissue. As a result, and in contrast to CLR 124, FDG is not selective for malignant tumors. FDG localizes in certain normal tissue such as heart, liver and brain tissues that also have high glucose metabolism as well as kidney and bladder due to FDG excretion paths. FDG is also known to localize in inflammatory sites, which are often found in the vicinity of malignancies and can result in diagnostic and treatment plan uncertainties. Other major limitations to the use of FDG are found in pelvic imaging due to the high renal (kidney) clearance of the compound. Moreover, there are clinically important malignancies that do not demonstrate reliable FDG activity such as prostate cancer. We believe these characteristics of FDG decrease its diagnostic specificity for certain malignancies. FDG is no longer covered by patent and is typically manufactured at or extremely proximate to PET imaging medical facilities because of its very short (110 minute) radiation half-life. I-124 has a four-day half-life that permits worldwide distribution of CLR 124 from one manufacturing location. Additionally, the longer half-life affords a longer imaging window of up to seven days following injection.

MRI is the current SOC for imaging brain cancer, due in part to FDG PET's limited utility in brain imaging. While MRI can differentiate tissue densities and demark structural changes in tissue, it is not cancer-selective. This imaging can result in a diagnostic dilemma for clinicians, particularly with respect to glioma; the most common form of primary brain cancer. After chemo-radiation - commonly employed in glioma management - MRI changes suggestive of tumor recurrence are seen in approximately 50% of high-grade glioma patients. However, in approximately 50% of these cases, the MRI changes actually represent treatment-related changes that do not truly represent disease progression. This is termed pseudo-progression. The dilemma facing clinicians is the decision whether to re-treat the patient (surgery, chemotherapy, biological therapy, re-irradiation) with associated risks to the patient (e.g. damage to normal brain tissue and consequent loss of function), or monitor with periodic re-imaging with the risk of the imaging changes actually representing tumor recurrence, and with the costs associated with re-imaging.

In Phase 1/2 investigator-sponsored trials at the UWCCC, preliminary results suggest that CLR 124 may provide a more accurate assessment of the post-treatment progression of glioma when compared to MRI. Specifically, CLR 124 appears to be capable of distinguishing malignant tumors from tissue changes associated with pseudo-progression.

### **CLR 1502**

CLR 1502 is a pre-clinical, broad-spectrum, cancer-targeting, non-radioactive optical imaging agent for intraoperative tumor margin illumination and non-invasive tumor imaging. The topic of providing cancer surgeons with better technology for intraoperative assessment of tumor margins designed to result in more complete tumor removal has gained considerable attention in recent years. While there are a number of technologies in various stages of development, some of the most common categories include the use of fluorescence agents: either alone, or attached to cancer delivery vehicles, nanoparticle technologies or electromagnetic technologies. At present, the only known FDA approved technology for tumor margin assessment is believed to be MarginProbe™, marketed by Dune Medical Devices, which received FDA approval in January, 2013, as an intraoperative tissue assessment tool for early-stage breast cancer surgery. MarginProbe™ claims to use electromagnetic "signatures" to identify healthy and cancerous tissue.

5-aminolevulinic acid (5-ALA), a technology approved in Europe for use with intraoperative tumor margin assessment, is a small molecule that is preferentially taken up by tumor cells leading to biosynthesis and accumulation of protoporphyrin IX, a natural fluorophore with red fluorescence emission. Investigator sponsored trials of 5-ALA are ongoing in the U.S., primarily in newly diagnosed and recurrent brain cancer indications.

Other technologies known to be in development include Blaze Biosciences' Tumor Paint™, a combination of a targeting peptide and a fluorescent beacon, under development for cancer surgery in multiple solid tumor types. Additionally, Avelas Biosciences, based in San Diego, CA, is developing a fluorescence peptide based compound named AVB-620 for fluorescence image-guided cancer surgery.

While a number of technologies are in development to provide intraoperative tumor margin guidance we are leveraging our cancer-targeting delivery platform to provide cancer selectivity and specificity for accurate tumor margin illumination. Further, CLR 1502 may be able to demonstrate application with a broad spectrum of cancer types based on data that includes our other product candidates utilizing the same cancer-targeting delivery platform in pre-clinical studies and human clinical trials (CLR 124 and CLR 131).

## Intellectual Property

We have established a broad U.S. and international intellectual property rights portfolio around our proprietary cancer-targeting PLE technology platform including our CLR CTX Program, CLR 131, CLR 1502, CLR 124, and CLR 125.

**CLR CTX Program:** In November 2015, we converted our previously filed provisional patent application for Phospholipid-Ether Analogs as Cancer Targeting Drug Vehicles to non-provisional US and International (PCT) patent applications. These patent applications further protect PDCs developed with Cellectar's proprietary phospholipid-ether delivery vehicle conjugated with any existing or future cytotoxic agents, including chemotherapeutics such as paclitaxel, for targeted delivery to cancer cells and cancer stem cells. Both composition of matter and methods of use are covered by these patent applications and provide intellectual property protection in the United States and up to 148 additional countries. This protection extends through at least November 2034 in the US and key international markets.

**CLR 131:** We have been granted orphan status designation for CLR 131 for the treatment of multiple myeloma. Orphan status designation provides for seven years of marketing exclusivity following US approval of CLR 131 for treatment of multiple myeloma. It is also covered by an additional series of our patents and applications aside from the Michigan patents (see below). The first is directed to a method of use for cancer therapy and has also been filed in Europe, Japan, and China, in addition to the U.S. We have two issued patents in the U.S., two in Europe and one in China, in addition to pending applications in the U.S. and Japan. These are expected to expire in 2025. Some of these resulting patents may be extendable on a country-by-country basis.

**CLR 1502** is covered by patents and patent applications directed to the compound, methods of use and method of manufacture that have been filed in U.S., Europe and Japan. A U.S. patent covering the composition and methods of use has already been issued and is expected to expire in 2030. Any additional patents resulting from these applications are also expected to expire in 2029. Some of these resulting patents may be extendable on a country-by-country basis.

**CLR 124:** We have been granted orphan status designation for CLR 124 as a diagnostic for the management of glioma by the US FDA. Orphan status designation provides for seven years of marketing exclusivity following US approval of CLR 124 as a diagnostic for the management of gliomas. It is also covered by the Michigan patents (see below) as well as four of our U.S. patents, two of which are generally directed to detecting cancers, one of which is directed to its use for virtual colonoscopy that expires in 2029 and one of which is directed to its use for *in vitro* diagnostics that expires in 2027. CLR 124 is also covered by an issued European patent, and pending U.S., Japanese and Hong Kong patent applications that expire in 2025. Any patents issued from these applications would be expected to expire in 2025.

Our proprietary rights also include patents and patent applications that are either owned by us or exclusively licensed to us by the University of Michigan (the "Michigan patents"). CLR 131, CLR 125 and CLR 124 are covered by the Michigan patents that provide compound (composition of matter) coverage in the U.S. and Canada and expire in 2016. Our patents and applications cover methods of use, composition and method of manufacture related to CLR 124, CLR 131, CLR 1502, CLR 125 and other PLEs. These patents and applications are filed in key commercial markets worldwide. These patents will generally expire between 2025 and 2030 unless extended, most likely under clinical development extensions.

Separate from any patent protection and following product approval by regulatory authorities, data exclusivity may be available for various compounds for up to 10 years on a country-by-country basis (e.g., up to 5 years in the U.S. and up to ten years in Europe).

In addition to the above noted patents/applications directed to CLR 131, CLR 125, CLR 124 and CLR 1502, we own other patents/applications directed to different forms of phospholipid ethers and methods of manufacturing of phospholipid ethers.

We also own all intellectual property rights in the U.S. related to our clinical-stage pipeline compound, NOV-002, and other pre-clinical compounds based on oxidized glutathione. Issued composition-of-matter patents cover proprietary formulations of oxidized glutathione that expire in 2019, and these patents include methods of manufacture for oxidized glutathione formulated with various metals.

## Licenses / Collaborations

On December 14, 2015 the Company initiated a collaboration with Institut de Recherche Pierre Fabre ("IRPF"). Under this collaboration, IRPF will provide a selection of its proprietary cytotoxics to the Company for use in an *in vivo* proof-of-concept study to evaluate the potential to create new drug conjugates ("NDCs") in combination with the Company's proprietary Phospholipid Drug Conjugate platform technology. The Company will own all intellectual property associated with the NDCs developed as part of the research collaboration. If the Company decides to further develop any of the NDCs for preclinical studies, the Company will enter into good faith discussions with IRPF to acquire an option to in-license the IRPF Materials. In the event that the Company proposes to enter into a business relationship with a third party for advancement of the NDCs, the Company will grant IRPF a right of first refusal to enter into the same business relationship, which will be exercisable by IRPF within 60 days. In the event that the Company does not choose to further develop the NDCs for preclinical studies and IRPF desires to do so within four years following expiration of this arrangement, the Company and IRPF will enter into good faith business discussions relating to IRPF's use of the results of the study and certain of the Company's proprietary technologies relating to the IRPF Materials. The Company has agreed to perform the study by December 14, 2017, and the Company's obligation to grant a right of first refusal will continue for four years following the date on which the Company provides the results of the study to IRPF.

In September 2003, Collectar, Inc. entered into a license agreement with the University of Michigan (the U. Mich. License), which granted Collectar, Inc. exclusive rights to the development, manufacture and marketing of products under several composition of matter patents in North America that expire in December 2016. The U. Mich. License expires upon the expiration of the last covered patent. We are responsible for an annual license fee of \$10,000 and are required to pay costs associated with the maintenance of the patents covered by the U. Mich. License. Additionally, we are required to make milestone payments of \$50,000 upon the filing of a NDA for a licensed product intended for use in a therapeutic or diagnostic application (such milestone fees may be deferred and paid within twelve months of the first commercial sale of such product) and make certain milestone payments within a year following the first commercial sale of any licensed products. The sales milestones range from \$100,000 to \$200,000, dependent upon whether the drug is for use in a diagnostic or therapeutic application. If sales in the first 12 months are less than the amount of the milestone, then we are required to pay 50% of all sales until the milestone is satisfied. The milestone payments may total up to \$400,000.

The U. Mich. License provides that we pay a royalty equal to 3% of net sales of any licensed products sold by us or our sub licensees for such licensed products unless the sublicense fee payable to us is between 4% and 5% of net sales, then the royalties payable to U. Mich. shall be equal to 50% of the sublicense fee. Furthermore, the U. Mich. License provides for a reduction in the royalties owed by up to 50% if we are required to pay royalties to any third parties related to the sale of the licensed products. If we receive any revenue in consideration of rights to the licensed technology that is not based on net sales, excluding any funded research and development, we are required to pay U. Mich. 10% of amounts received. During 2003, pursuant to the U. Mich. License, Collectar, Inc. paid approximately \$54,000 of back patent costs and issued 203,483 shares of common stock to U. Mich. as partial consideration for the rights described above. U. Mich. may terminate the license agreement if we cease operations, fail to make any required payment under the license agreement, or otherwise materially breach the license agreement, subject to applicable notice and cure periods. To date, we have made all payments as they have become due, there have been no defaults under the U. Mich. License, nor have we ever been notified of a default by U. Mich. We may terminate the U Mich. License agreement with six months' notice to U. Mich. and the return of licensed product and related data. The U. Mich. License contains milestones that required certain development activities to be completed by specified dates. All such development milestones have been either completed or removed by subsequent amendment to the agreement. U. Mich. has provided no warranties as to validity or otherwise with respect to the licensed technology. The early termination of the University of Michigan License agreement would result in the loss of our rights to use the covered patents.

## **Research and Development**

Our primary activity to date has been research and development. We conduct our research and development program at our manufacturing facility in Madison, Wisconsin. Our research and development expenses were approximately \$5,159,000 and \$5,964,000 for 2015 and 2014, respectively.

## **Regulation**

The production, distribution, and marketing of products employing our technology, and our development activities, are subject to extensive governmental regulation in the United States and in other countries. In the United States, we are subject to the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations of the FDA, as well as to other federal, state, and local statutes and regulations, including the federal, state and local laws and regulations governing the storage, use and disposal of hazardous materials, including radioactive isotopes. These laws, and similar laws outside the United States, govern the clinical and pre-clinical testing, manufacture, safety, effectiveness, approval, labeling, distribution, sale, import, export, storage, record-keeping, reporting, advertising, and promotion of drugs. Product development and approval within this regulatory framework, if successful, will take many years and involve the expenditure of substantial resources. Violations of regulatory requirements at any stage may result in various adverse consequences, including the FDA's and other health authorities' delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions.

The following paragraphs provide further information on certain legal and regulatory issues with a particular potential to affect our operations or future marketing of products employing our technology.

## **Research, Development, and Product Approval Process**

The research, development, and approval process in the United States and elsewhere is intensive and rigorous and generally takes many years to complete. The typical process required by the FDA before a therapeutic drug may be marketed in the United States includes:

- pre-clinical laboratory and animal tests performed under the FDA's Good Laboratory Practices regulations, referred to herein as GLP;
- submission to the FDA of an IND application, which must become effective before human clinical trials may commence;

- human clinical studies performed under the FDA’s Good Clinical Practices regulations, to evaluate the drug’s safety and effectiveness for its intended uses;
- FDA review of whether the facility in which the drug is manufactured, processed, packed, or held meets standards designed to assure the product’s continued quality; and
- submission of a marketing application to the FDA, and approval of the application by the FDA.

During pre-clinical testing, studies are performed with respect to the chemical and physical properties of candidate formulations. These studies are subject to GLP requirements. Biological testing is typically done in animal models to demonstrate the activity of the compound against the targeted disease or condition and to assess the apparent effects of the new product candidate on various organ systems, as well as its relative therapeutic effectiveness and safety.

#### *Submission of IND*

An IND must be submitted to the FDA and become effective before studies in humans may commence. The IND must include a sufficient amount of data and other information concerning the safety and effectiveness of the compound from laboratory, animal, and human clinical testing, as well as data and information on manufacturing, product quality and stability, and proposed product labeling.

#### *Clinical Trials*

Clinical trial programs in humans generally follow a three-phase process. Typically, Phase 1 studies are conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease. Phase 1 studies are conducted to determine the metabolic and pharmacological action of the product candidate in humans and the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. In Phase 2, studies are generally conducted in larger groups of patients having the target disease or condition in order to validate clinical endpoints, and to obtain preliminary data on the effectiveness of the product candidate and optimal dosing. This phase also helps determine further the safety profile of the product candidate. In Phase 3, large-scale clinical trials are generally conducted in patients having the target disease or condition to provide sufficient data for the statistical proof of effectiveness and safety of the product candidate as required by United States regulatory agencies.

In the case of products for certain serious or life-threatening diseases, the initial human testing may be done in patients with the disease rather than in healthy volunteers. Because these patients are already afflicted with the target disease or condition, it is possible that such studies will also provide results traditionally obtained in Phase 2 studies. These studies are often referred to as “Phase 1/2” studies. However, even if patients participate in initial human testing and a Phase 1/2 study carried out, the sponsor is still responsible for obtaining all the data usually obtained in both Phase 1 and Phase 2 studies.

Before proceeding with a study, sponsors may seek a written agreement from the FDA regarding the design, size, and conduct of a clinical trial. This is known as a Special Protocol Assessment (SPA). Among other things, SPAs can cover clinical studies for pivotal trials whose data will form the primary basis to establish a product’s efficacy. SPAs help establish upfront agreement with the FDA about the adequacy of a clinical trial design to support a regulatory approval, but the agreement is not binding if new circumstances arise. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

United States law requires that studies conducted to support approval for product marketing be “adequate and well controlled.” In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control. Studies must also be conducted in compliance with good clinical practice requirements, and informed consent must be obtained from all study subjects. The clinical trial process for a new compound can take ten years or more to complete. The FDA may prevent clinical trials from beginning or may place clinical trials on hold at any point in this process if, among other reasons, it concludes that study subjects are being exposed to an unacceptable health risk. Trials may also be prevented from beginning or may be terminated by institutional review boards, which must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing authorization. Similarly, adverse events that are reported after marketing authorization can result in additional limitations being placed on a product’s use and, potentially, withdrawal of the product from the market.

#### *Submission of NDA*

Following the completion of clinical trials, the data is analyzed to determine whether the trials successfully demonstrated safety and effectiveness and whether a product approval application may be submitted. In the United States, if the product is regulated as a drug, a NDA must be submitted and approved before commercial marketing may begin. The NDA must include a substantial amount of data and other information concerning the safety and effectiveness of the compound from laboratory, animal, and human clinical testing, as well as data and information on manufacturing, product quality and stability, and proposed product labeling.

Each domestic and foreign manufacturing establishment, including any contract manufacturers we may decide to use, must be listed in the NDA and must be registered with the FDA. The application generally will not be approved until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process and determines that the facility is in compliance with cGMP requirements.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing an NDA and supplements thereto, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant. For fiscal year 2015, the NDA review fee alone is \$2,335,200, although certain limited deferral, waivers, and reductions may be available.

Each NDA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will “file” the NDA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable. The FDA has established performance goals for the review of NDAs— six months for priority applications and 10 months for standard applications. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time.

Moreover, the outcome of the review, even if generally favorable, typically is not an actual approval but an “action letter” that describes additional work that must be done before the application can be approved. The FDA’s review of an application may involve review and recommendations by an independent FDA advisory committee. Even if the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval.

#### *Post NDA Regulation*

Significant legal and regulatory requirements also apply after FDA approval to market under an NDA. These include, among other things, requirements related to adverse event and other reporting, product advertising and promotion and ongoing adherence to cGMPs, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product labeling, or manufacturing process. The FDA also enforces the requirements of the Prescription Drug Marketing Act which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

The regulatory framework applicable to the production, distribution, marketing and/or sale of our product pipeline may change significantly from the current descriptions provided herein in the time that it may take for any of our products to reach a point at which an NDA is approved.

Overall research, development, and approval times depend on a number of factors, including the period of review at FDA, the number of questions posed by the FDA during review, how long it takes to respond to the FDA’s questions, the severity or life-threatening nature of the disease in question, the availability of alternative treatments, the availability of clinical investigators and eligible patients, the rate of enrollment of patients in clinical trials, and the risks and benefits demonstrated in the clinical trials.

#### **Other United States Regulatory Requirements**

In the United States, the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state, and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provision of the Health Insurance Portability and Accountability Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection, unfair competition, and other laws.

Our research and development, manufacturing and administration of our drugs involve the controlled use of hazardous materials, including chemicals and radioactive materials, such as radioactive isotopes. Therefore, we are subject to federal, state and local laws and regulations governing the storage, use and disposal of these materials and some waste products and are required to maintain both a manufacturer’s license and a radioactive materials license with State of Wisconsin agencies.

Moreover, we are now, and may become subject to, additional federal, state, and local laws, regulations, and policies relating to safe working conditions, laboratory practices, the experimental use of animals, and/or the use, storage, handling, transportation, and disposal of human tissue, waste, and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

## **Foreign Regulatory Requirements**

We, and any future collaborative partners, may be subject to widely varying foreign regulations that may be quite different from those of the FDA governing clinical trials, manufacture, product registration and approval, and pharmaceutical sales. Whether or not FDA approval has been obtained, we or any future collaboration partners must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in these countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current United States law, there are restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

## **Reimbursement and Pricing Controls**

In many of the markets where we or any future collaborative partners would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls by law and to drug reimbursement programs with varying price control mechanisms. Public and private health care payers control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payers also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payers limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or that are supported by other appropriate evidence (for example, published medical literature) and appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA. For example, in the case of Medicare coverage for physician-administered oncology drugs, the Omnibus Budget Reconciliation Act of 1993, with certain exceptions, prohibits Medicare carriers from refusing to cover unapproved uses of an FDA-approved drug if the unapproved use is supported by one or more citations in the American Hospital Formulary Service Drug Information, the American Medical Association Drug Evaluations, or the United States Pharmacopoeia Drug Information. Another commonly cited compendium, for example under Medicaid, is the DRUGDEX Information System.

## **Employees**

As of October 17, 2016, we had 17 full-time employees.

## **Corporate Information**

The Company, formerly known as Novelos Therapeutics, Inc., was incorporated in Delaware in June 1996. On April 8, 2011, the Company entered into a business combination with Collectar, Inc., a privately held Wisconsin corporation that designed and developed products to detect, treat and monitor a wide variety of human cancers. On February 11, 2014, the Company changed its name to Collectar Biosciences, Inc. Our common stock is listed on the NASDAQ® Capital Market under the symbol “CLRB.”

## **Legal Proceedings**

We are not a party to any pending legal proceedings.



## MANAGEMENT

Our executive officers and directors are as follows:

Name	Age	Position
James Caruso	57	President, Chief Executive Officer and Director
Chad J. Kolean	52	Vice President, Chief Financial Officer and Treasurer
Stephen A. Hill, B.M. B.Ch., M.A., F.R.C.S. (1)(2)(3)	58	Director
John Neis (1)(2)(3)	61	Director
Stefan D. Loren, Ph.D. (2)(3)	52	Director
Jarrold Longcor	43	Senior Vice President of Corporate Development and Operations

- (1) Member of the Compensation Committee.
- (2) Member of the Audit Committee.
- (3) Member of the Nominating and Corporate Governance Committee.

Our executive officers are appointed by, and serve at the discretion of, the Board.

**James Caruso.** Mr. Caruso was appointed our President and Chief Executive Officer and a director in June 2015. A life sciences executive with 27 years of success with multinational and specialty pharmaceutical companies, mid-tier biotechnology and medical device start-ups, Mr. Caruso has an established track record of enhancing value through a clear focus on strategic corporate value drivers and operational excellence; advancing product development and commercialization programs through internal execution or collaborations. He came to Collectar from Hip Innovation Technology, a medical device company where he was a founder and served as Executive Vice President and Chief Operating Officer. Prior to his time at Hip Innovation Technology, he was Executive Vice President and Chief Commercial Officer of Allos Therapeutics, Inc., an oncology company acquired by Spectrum Pharmaceuticals, and Senior Vice President, Sales and Marketing, at Bone Care International, Inc., a specialty pharmaceutical company that was acquired by Genzyme Corporation. In addition, Mr. Caruso has held key positions at several well-known pharmaceutical companies, including Novartis, where he was Vice President of Neuroscience Specialty Sales; BASF Pharmaceuticals-Knoll, where we was Vice President, Sales; and 12 years at Bristol-Myers Squibb in several senior roles. Mr. Caruso earned a Bachelor of Science degree in Finance from the University of Nevada. He currently serves on the Board of Directors for Hip Innovation Technology.

**Stephen A. Hill.** Dr. Hill has been a member of the Board of Directors since 2007, and served as its Chairman from 2007 until 2015. Dr. Hill was appointed Chief Executive Officer of Faraday Pharmaceuticals, Inc. in September 2015. Dr. Hill was the President and CEO of Targacept Inc. from December 2012 until the company merged with Catalyst Biosciences, Inc. in August 2015, and he remains a director of the new company. Dr. Hill was the President and CEO of 21CB, a nonprofit initiative of UPMC designed to provide the United States government with a domestic solution for its biodefense and infectious disease biologics portfolio, from March 2011 until December 2011. Dr. Hill served as the President and Chief Executive Officer of Solvay Pharmaceuticals, Inc. from April 2008 until its acquisition by Abbott Laboratories in 2010. Prior to joining Solvay, Dr. Hill had served as ArQule's President and Chief Executive Officer since April 1999. Prior to his tenure at ArQule, Dr. Hill was the Head of Global Drug Development at F. Hoffmann-La Roche Ltd. from 1997 to 1999. Dr. Hill joined Roche in 1989 as Medical Adviser to Roche Products in the United Kingdom. He held several senior positions at Roche, including Medical Director where he was responsible for clinical trials of compounds across a broad range of therapeutic areas, including CNS, HIV, cardiovascular, metabolic and oncology products. Subsequently, he served as Head of International Drug Regulatory Affairs at Roche headquarters in Basel, Switzerland, where he led the regulatory submissions for seven major new chemical entities. Dr. Hill also was a member of Roche's Portfolio Management, Research, Development and Pharmaceutical Division Executive Boards. Prior to Roche, Dr. Hill served seven years with the National Health Service in the United Kingdom in General and Orthopedic Surgery. Dr. Hill has served as the lead director of the board of directors of Lipocine Inc. since January 2014. Dr. Hill is a Fellow of the Royal College of Surgeons of England and holds his scientific and medical degrees from St. Catherine's College at Oxford University. Dr. Hill currently chairs the Compensation Committee. Dr. Hill's extensive experience in a broad range of senior management positions with companies in the life sciences sector make him a highly qualified member of our Board of Directors.

**John Neis.** Mr. Neis has served as a director of Collectar since February 2008. Mr. Neis has been Managing Director of Venture Investors LLC since 1986 and heads the firm's Healthcare practice. He has over 23 years' experience in the venture capital industry and has served on the Board of Directors of numerous companies from formation through initial public offering or sale. Mr. Neis currently serves on the Boards of Directors of Virent, Inc., Deltanoid Pharmaceuticals, Inc., and Inviragen, Inc. He is a former member of the Boards of Directors of several firms including TomoTherapy, Third Wave Technologies (acquired by Hologic) and NimbleGen Systems (acquired by Roche). Mr. Neis was appointed to the Board of the Wisconsin Technology Council and the Wisconsin Growth Capital Coalition. He also serves on the advisory boards for the Business School, the Weinert Applied Ventures Program and Tandem Press at the University of Wisconsin – Madison. Mr. Neis has a B.S. in Finance from the University of Utah, and a M.S. in Marketing and Finance from the University of Wisconsin – Madison. He is a Chartered Financial Analyst. Mr. Neis chairs the Audit Committee. Mr. Neis' extensive experience leading emerging companies makes him a highly qualified member of the Board.

**Stefan D. Loren.** Stefan D. Loren, Ph.D. began serving as director of Collectar in June 2015. Dr. Loren is a member of the Audit Committee and Chair of the Nominating and Corporate Governance Committee. Dr. Loren is the founder of Loren Capital Strategy (LCS), a strategic investment firm focused on life science companies. Most recently, he headed the life science practice of Westwicke Partners, a healthcare-focused consulting firm. Prior to joining Westwicke, he worked as an Analyst/Portfolio Manager with Perceptive Advisors, a health care hedge fund, and MTB Investment Advisors, a long-term oriented family of equity funds. His focus areas included biotechnology, specialty pharmaceuticals, life science tools, and health care service companies. Prior to moving to the buy side, Dr. Loren was Managing Director, Health Care Specialist/Desk Analyst for Legg Mason where he discovered, evaluated, and communicated investment opportunities in the health care area to select clients. In addition, he assisted both advising management teams on strategic options. He started his Wall Street career as a sell side analyst at Legg Mason covering biotechnology, specialty pharmaceuticals, life science tools, pharmaceuticals, and chemistry outsourcing companies. In his research career, Dr. Loren was an early member of Abbott Laboratories Advanced Technologies Division, analyzing and integrating new technological advances in Abbott's pharmaceutical research. Before industry, he was a researcher at The Scripps Research Institute, working with Nobel Laureate K. Barry Sharpless on novel synthetic routes to chiral drugs. Dr. Loren received a doctorate in Organic Chemistry from the University of California at Berkeley and an undergraduate degree in Chemistry from UCSD. His scientific work has been featured in *Scientific American*, *Time*, *Newsweek*, and *Discover*, as well as other periodicals and journals.

**Chad J. Kolean.** Mr. Kolean was appointed Vice President of Finance, Chief Financial Officer and Treasurer of the Company in May 2014, and has over 25 years of experience in finance management. He most recently served as CFO and Treasurer for Pioneer Surgical Technology, Inc., a global manufacturer and distributor of spinal, biological and orthopedic implants acquired by RTI Biologics in July 2013. From 2010 until its merger in 2011 with Accuray, Inc., Mr. Kolean served as Corporate Controller for TomoTherapy, Inc., a publicly traded global leader in developing and manufacturing innovative radiation oncology equipment. From 2001 through 2008, Mr. Kolean held multiple leadership positions of increasing responsibility at Metavante Corporation, a provider of banking and payments technologies and services to financial institutions, businesses and individual consumers worldwide. He brings additional financial and operational leadership experience from companies including Snap-On Inc., Herman Miller and Kaydon Corporation. Mr. Kolean began his career at Arthur Andersen LLP, where he practiced as a Certified Public Accountant. Mr. Kolean earned his B.A. Business Administration and Finance from Hope College.

**Jarrold Longcor.** Mr. Longcor was appointed Senior Vice President of Corporate Development and Operations of the Company in July 2016, and has more than 20 years of pharmaceutical and biotech experience. Prior to joining the Company, he served as chief business officer for Avillion LLP from July 2014 through July 2016, where he was responsible for executing the company's unique co-development partnership strategy. Since September 2013, Mr. Longcor has been the president of SBC Consulting, a corporate development consulting firm focused on developing strategic plans, raising capital, identifying, leading and closing partnership negotiations, market assessments, managing due diligence and managing operations in the biotech industry. From June 2007 through September 2013, he was Vice President of Corporate Development for Rib-X Pharmaceuticals, Inc. (now Melinta Therapeutics) where he was responsible for identifying and concluding several critical collaborations for that company. Prior thereto, Mr. Longcor held key positions in several small to midsized biotech companies where he was responsible for business development, strategic planning and operations. Mr. Longcor holds a B.S. from Dickinson College, an M.S. from Boston University School of Medicine and an M.B.A. from Saint Joseph's University's Haub School of Business.

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

At the close of business on October 17, 2016, there were 5,368,235 shares of our common stock outstanding. The following table provides information regarding beneficial ownership of our common stock as of October 17, 2016 including shares and warrants on that date:

- Each person known by us to be the beneficial owner of more than five percent of our common stock;
- Each of our directors;
- Each executive officer named in the summary compensation table; and
- All of our current directors and executive officers as a group.

The address of each executive officer and director is c/o Collectar Biosciences, Inc., 3301 Agriculture Drive, Madison, WI 53716. The persons named in this table have sole voting and investment power with respect to the shares listed, except as otherwise indicated. In these cases, the information with respect to voting and investment power has been provided to us by the security holder. The identification of natural persons having voting or investment power over securities held by a beneficial owner listed in the table below does not constitute an admission of beneficial ownership of any such natural person. Shares included in the “Right to Acquire” column consist of shares that may be purchased through the exercise of options or warrants that are exercisable within 60 days of October 17, 2016.

Name and Address of Beneficial Owner	Outstanding	Right to Acquire	Total	Percentage
Wisconsin Alumni Research Foundation <sup>(1)</sup> 614 Walnut Street, 14 <sup>th</sup> Floor Madison Wisconsin 53726	469,484	469,484	938,968	16.08%
Greenway Properties Inc. <sup>(2)</sup> 4954 N. Shore Drive Egg Harbor, Wisconsin 54209	362,599	164,199	526,798	9.52%
Venture Investors LLC <sup>(3)</sup> University Technology Park 505 S. Rosa Road; Suite 201 Madison, Wisconsin 53719	297,984	51,012	348,996	6.44%
Hertzberg Family Trust <sup>(4)</sup> 2637 Longboat Cove Del Mar, CA 92014	301,000	41,915	342,915	6.34%
James V. Caruso	47,548	89,656	137,204	2.51%
Chad Kolean	—	10,000	10,000	*
Stephen A. Hill	9,920	12,373	22,293	*
Stefan Loren	—	416	416	*
John Neis <sup>(4)</sup>	297,984	51,012	348,996	6.44%
Jarrold Longcor	—	6,250	6,250	*
All directors and officers as a group (6 persons)	355,452	169,707	525,159	9.48%

\* Less than 1%.

(1) Based on information contained in a report on Schedule 13D filed with the Securities and Exchange Commission on April 25, 2016.

(2) Based on information contained in a report on Schedule 13G filed with the Securities and Exchange Commission on July 25, 2016 and other information provided by the stockholder. Shares in the “Outstanding” column include shares held by Jeffrey Straubel. Mr. Straubel is the President and principal owner of Greenway Properties, Inc. and has sole dispositive and voting power over shares held by Greenway Properties, Inc. Shares in the “Right to Acquire” column consist of shares of common stock issuable upon the exercise of warrants at exercise prices ranging from \$2.13 to \$250.00 per share expiring between December 6, 2016 and October 20, 2021. Certain warrants held by the stockholder provide that the number of shares of common stock to be obtained by each of the holders upon exercise cannot exceed the number of shares that, when combined with all other shares of our common stock and securities beneficially owned by them, would result in them owning more than 4.99% of our outstanding common stock; provided, however that this limitation may be increased to 9.99% by the stockholder upon 61 days prior notice to us. Due to this limitation all such warrants to purchase shares of common stock have been omitted from the “Right to Acquire” column of this table.

- (3) Consists of shares of common stock held by Venture Investors Early Stage Fund IV Limited Partnership and Advantage Capital Wisconsin Partners I, Limited Partnership. VIESF IV GP LLC is the general partner of Venture Investors Early Stage Fund IV Limited Partnership and Venture Investors LLC is the submanager and special limited partner of Advantage Capital Wisconsin Partners I, Limited Partnership. The investment decisions of VIESF IV GP LLC and Venture Investors LLC are made collectively by seven managers, including Mr. Neis. Each such manager and Mr. Neis disclaim such beneficial ownership except to the extent of his pecuniary interest therein. The address of Mr. Neis is c/o Venture Investors LLC, 505 South Rosa Road, #201, Madison, Wisconsin 53719. Shares in the “Right to Acquire” column consist of 283,964 shares of common stock issuable upon the exercise of warrants held by Venture Investors Early Stage Fund IV Limited and Advantage Capital Wisconsin Partners I, Limited Partnership and common stock issuable upon options to purchase 1,624 shares of common stock issued to Mr. Neis in his capacity as director. Shares in the “Right to Acquire” column consist of shares of common stock issuable upon the exercise of warrants at exercise prices ranging from \$2.13 to \$250.00 per share expiring between December 6, 2016 and April 20, 2021. Certain warrants held by the stockholder provide that the number of shares of common stock to be obtained by each of the holders upon exercise cannot exceed the number of shares that, when combined with all other shares of our common stock and securities beneficially owned by them, would result in them owning more than 4.99% of our outstanding common stock; provided, however that this limitation may be increased to 9.99% by the stockholder upon 61 days prior notice to us. Due to this limitation all such warrants to purchase shares of common stock have been omitted from the “Right to Acquire” column of this table.
- (4) Based on information contained in a report on Schedule 13G/A, filed with the Securities and Exchange Commission on June 15, 2016. Shares in the “Right to Acquire” column consist of shares common stock issuable upon the exercise of warrants at exercise prices ranging from \$3.04 to \$120.00 per share, expiring between December 6, 2016 and April 20, 2021. Richard H. Hertzberg is the trustee of Hertzberg Family Trust and has sole dispositive and voting power for the shares held. Certain warrants held by the stockholder provide that the number of shares of common stock to be obtained by each of the holders upon exercise cannot exceed the number of shares that, when combined with all other shares of our common stock and securities beneficially owned by them, would result in them owning more than 4.99% of our outstanding common stock; provided, however that this limitation may be increased to 9.99% by the stockholder upon 61 days prior notice to us. Due to this limitation all such warrants to purchase shares of common stock have been omitted from the “Right to Acquire” column of this table.

## **CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

We do not have a written policy for the review, approval or ratification of transactions with related parties or conflicted transactions. When such transactions arise, they are referred to the Audit Committee for consideration or referred to the Board of Directors for its consideration.

One of our directors, John Neis, is a managing director of Venture Investors LLC, which beneficially owns approximately 6.4% of our outstanding common stock.

The Company's former Chief Scientific Officer and principal founder of Collectar, who resigned after the end of the second quarter of 2016, continues to be a shareholder of the Company, and is a faculty member at our research partner the University of Wisconsin - Madison ("UW"). During the six months ended June 30, 2016, the Company incurred approximately \$159,000 in expenses from UW for costs associated with clinical trial agreements. The Company had accrued liabilities to UW of approximately \$84,000 as of June 30, 2016.

## DESCRIPTION OF SECURITIES

*The following summary description of our common stock is based on the provisions of our Second Amended and Restated Certificate of Incorporation, as amended, which we refer to as our certificate of incorporation or charter, our by-laws, and the applicable provisions of the Delaware General Corporation Law, which we refer to as the DGCL. This description may not contain all of the information that is important to you and is subject to, and is qualified in its entirety by reference to our certificate of incorporation, our by-laws and the applicable provisions of the DGCL. For information on how to obtain copies of our certificate of incorporation and by-laws, see "Where You Can Find More Information."*

### Authorized and Outstanding Capital Stock

Our authorized capital stock consists of 40,000,000 shares of common stock, \$0.00001 par value per share and 7,000 shares of preferred stock, \$0.00001 par value per share. Our certificate of incorporation authorizes us to issue shares of our preferred stock from time to time in one or more series without stockholder approval, each such series to have rights and preferences, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences as our board of directors may determine. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of holders of any preferred stock that we may issue in the future. The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for others to acquire, or of discouraging others from attempting to acquire, a majority of our outstanding voting stock.

As of October 17, 2016, we had 5,368,235 shares of common stock outstanding and no shares of preferred stock outstanding. All outstanding shares of our common stock are duly authorized, validly issued, fully paid and non-assessable.

### Common Stock

*Voting.* Holders of our common stock are entitled to one vote per share held of record on all matters to be voted upon by our stockholders. Our common stock does not have cumulative voting rights. Persons who hold a majority of the outstanding common stock entitled to vote on the election of directors can elect all of the directors who are eligible for election.

*Dividends.* Subject to preferences that may be applicable to the holders of any outstanding shares of our preferred stock, the holders of our common stock are entitled to receive such lawful dividends as may be declared by our board of directors.

*Liquidation and Dissolution.* In the event of our liquidation, dissolution or winding up, and subject to the rights of the holders of any outstanding shares of our preferred stock, the holders of shares of our common stock will be entitled to receive pro rata all of our remaining assets available for distribution to our stockholders.

*Other Rights and Restrictions.* Our charter prohibits us from granting preemptive rights to any of our stockholders.

### Anti-Takeover Effect of Certain Charter and By-Law Provisions

Provisions of our charter and our by-laws could make it more difficult to acquire us by means of a merger, tender offer, proxy contest, open market purchases, removal of incumbent directors and otherwise. These provisions, which are summarized below, are expected to discourage types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of us to first negotiate with us. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because negotiation of these proposals could result in an improvement of their terms.

*Authorized but Unissued Stock.* We have shares of common stock and preferred stock available for future issuance, in some cases, without stockholder approval. We may issue these additional shares for a variety of corporate purposes, including public offerings to raise additional capital, corporate acquisitions, stock dividends on our capital stock or equity compensation plans. The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us, thereby protecting the continuity of our management. In addition, if we issue preferred stock, the issuance could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation.

*Amendments to By-laws.* Our certificate of incorporation and by-laws authorize the Board to amend, repeal, alter or rescind the by-laws at any time without stockholder approval. Allowing the Board to amend our by-laws without stockholder approval enhances Board control over our by-laws.

*Classification of Board; Removal of Directors; Vacancies.* Our certificate of incorporation provide for the division of the Board into three classes as nearly equal in size as possible with staggered three-year terms; that directors may be removed only for cause by the affirmative vote of the holders of two-thirds of our shares of capital stock entitled to vote; and that any vacancy on the Board, however occurring, including a vacancy resulting from an enlargement of the board, may be filled only by the vote of a majority of the directors then in office. The limitations on the removal of directors and the filling of vacancies could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from acquiring, control of us. Our certificate of incorporation requires the affirmative vote of the holders of at least 75% of our shares of capital stock issued and outstanding and entitled to vote to amend or repeal any of these provisions.

*Notice Periods for Stockholder Meetings.* Our by-laws provide that for business to be brought by a stockholder before an annual meeting of stockholders, the stockholder must give written notice to the corporation not less than 90 nor more than 120 days prior to the one year anniversary of the date of the annual meeting of stockholders of the previous year; provided, however, that in the event that the annual meeting of stockholders is called for a date that is not within 30 days before or after such anniversary date, notice by the stockholder must be received not later than the close of business on the tenth day following the day on which the corporation's notice of the date of the meeting is first given or made to the stockholders or disclosed to the general public, whichever occurs first.

*Stockholder Action; Special Meetings.* Our certificate of incorporation provides that stockholder action may not be taken by written action in lieu of a meeting and provides special meetings of the stockholders may only be called by our president or by our Board. These provisions could have the effect of delaying until the next stockholders' meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions may also discourage another person or entity from making a tender offer for our common stock, because that person or entity, even if it acquired a majority of our outstanding voting securities, would be able to take action as a stockholder only at a duly called stockholders' meeting, and not by written consent. Our certificate of incorporation requires the affirmative vote of the holders of at least 75% of our shares of capital stock issued and outstanding and entitled to vote to amend or repeal the provisions relating to prohibition on action by written consent and the calling of a special meeting of stockholders.

*Nominations.* Our by-laws provide that nominations for election of directors may be made only by (i) the Board or a committee appointed by the Board; or (ii) a stockholder entitled to vote on director election, if the stockholder provides notice to the Secretary of the Corporation presented not less than 90 days nor more than 120 days prior to the anniversary of the last annual meeting (subject to the limited exceptions set forth in the bylaws). These provisions may deter takeovers by requiring that any stockholder wishing to conduct a proxy contest have its position solidified well in advance of the meeting at which directors are to be elected and by providing the incumbent Board with sufficient notice to allow them to put an election strategy in place.

## **Nasdaq Capital Market Listing**

Our common stock is listed for trading and quotation on the Nasdaq Capital Market under the trading symbol "CLRB." Certain warrants to purchase shares of our common stock expiring on August 20, 2019 are listed on the Nasdaq Capital Market under the trading symbol "CLRBW," and certain warrants to purchase shares of our common stock expiring on April 20, 2021 are listed on the Nasdaq Capital Market under the trading symbol "CLRBZ."

On August 14, 2015 we received a notice from Nasdaq of non-compliance with its continuing listing rules, namely that our stockholders' equity at June 30, 2015 of \$2,373,371, as reported in our Form 10-Q for the quarter then ended, was less than \$2,500,000 minimum. We did not satisfy the terms of a compliance plan approved by Nasdaq. On February 11, 2016, Nasdaq issued a second notice of noncompliance. The failure to meet continuing compliance standards subjects our common stock to delisting. At a hearing on March 31, 2016, the Company requested, and NASDAQ subsequently granted, an extension of time to effect transactions to allow us to regain compliance and to report the same. On April 20, 2016, we closed the 2016 Underwritten Offering, and on May 16, 2016, Nasdaq issued a determination that the Company had evidenced compliance with all requirements for continued listing on The Nasdaq Capital Market and, accordingly, the listing qualifications matter had been closed.

On January 21, 2016 we received a notice from Nasdaq of non-compliance with its listing rules regarding the requirement that the listed securities maintain a minimum bid price of \$1 per share. On March 4, 2016, the Company effected a reverse stock split at a ratio of 1-for-10, and on March 21, 2016, Nasdaq notified the Company that we had regained compliance with the minimum bid price requirement.

## **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is American Stock Transfer and Trust Company.

## **DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

Our charter contains provisions to indemnify our directors and officers to the maximum extent permitted by Delaware law. We believe that indemnification under our charter covers at least negligence on the part of an indemnified person. Our charter permits us to advance expenses incurred by an indemnified person in connection with the defense of any action or proceeding arising out of the person's status or service as our director, officer, employee or other agent upon an undertaking by the person to repay those advances if it is ultimately determined that the person is not entitled to indemnification.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable.

## **WHERE YOU CAN FIND MORE INFORMATION**

We are a reporting company and file annual, quarterly and special reports, and other information with the Securities and Exchange Commission. Copies of the reports and other information may be read and copied at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. You can request copies of such documents by writing to the SEC and paying a fee for the copying cost. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a web site at <http://www.sec.gov> that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC.

This prospectus is part of a registration statement on Form S-1 that we filed with the SEC. Certain information in the registration statement has been omitted from this prospectus in accordance with the rules and regulations of the SEC. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus. For further information you may:

- read a copy of the registration statement, including the exhibits and schedules, without charge at the SEC's Public Reference Room; or
- obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

## **LEGAL MATTERS**

The validity of the securities being offered by this prospectus has been passed upon for us by Foley Hoag LLP, Boston, Massachusetts.

## **EXPERTS**

The audited financial statements incorporated by reference in this prospectus and elsewhere in the registration statement have been so incorporated by reference in reliance upon the report of Baker Tilly Virchow Krause LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

## **INCORPORATION OF DOCUMENTS BY REFERENCE**

The Securities and Exchange Commission allows us to "incorporate by reference" information into this prospectus. This means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is considered to be a part of this prospectus, except for any information that is superseded by other information that is included in this prospectus.

We incorporate by reference into this prospectus the following document, which we have previously filed with the SEC:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, filed with the SEC on March 11, 2016;
- our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2015, filed with the SEC on July 1, 2016;
- our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2015, filed with the SEC on October 20, 2016;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the SEC on May 12, 2016;
- our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 11, 2016;
- our Definitive Proxy Statement on Schedule 14A for a special meeting of stockholders, filed with the SEC on January 7, 2016;



- our Definitive Proxy Statement on Schedule 14A for our special meeting in lieu of our 2016 annual meeting of stockholders, filed with the SEC on June 1, 2016;
- our Current Report on Form 8-K dated January 21, 2016, filed with the SEC on January 26, 2016;
- our Current Report on Form 8-K dated February 8, 2016, filed with the SEC on February 11, 2016;
- our Current Report on Form 8-K dated February 11, 2016, filed with the SEC on February 17, 2016;
- our Current Report on Form 8-K dated March 4, 2016, filed with the SEC on March 4, 2016;
- our Current Report on Form 8-K dated March 11, 2016, filed with the SEC on March 17, 2016;
- our Current Report on Form 8-K dated April 14, 2016, filed with the SEC on April 14, 2016;
- our Current Report on Form 8-K dated April 15, 2016, filed with the SEC on April 21, 2016;
- our Current Report on Form 8-K dated May 2, 2016, filed with the SEC on May 3, 2016;
- our Current Report on Form 8-K dated May 16, 2016, filed with the SEC on May 19, 2016;
- our Current Report on Form 8-K dated May 12, 2016, filed with the SEC on May 20, 2016;
- our Current Report on Form 8-K dated June 29, 2016, filed with the SEC on June 30, 2016;
- our Current Report on Form 8-K dated July 8, 2016, filed with the SEC on July 14, 2016;
- our Current Report on Form 8-K dated July 14, 2016, filed with the SEC on July 14, 2016;
- our Current Report on Form 8-K dated July 15, 2016, filed with the SEC on July 20, 2016;
- our Current Report on Form 8-K dated July 25, 2016, filed with the SEC on July 27, 2016; and
- the description of our securities contained in our Registration Statement on Form 8-A filed on August 14, 2014, including any amendment or report filed for the purpose of updating such description.

In addition, all documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, prior to the termination of the offering shall be deemed to be incorporated by reference into this prospectus.

You should rely only on the information contained in this prospectus, as updated and supplemented by any prospectus supplement, or that information to which this prospectus or any prospectus supplement has referred you by reference. We have not authorized anyone to provide you with any additional information.

Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request and obtain a copy of any of the filings incorporated herein by reference, at no cost, by writing or telephoning us at the following address or phone number:

Collectar Biosciences, Inc., 3301 Agriculture Drive, Madison, WI 53716, Attention: Chief Financial Officer (608) 441-8120.

## GLOSSARY OF CERTAIN SCIENTIFIC TERMS

**Cytotoxic** — Cytotoxicity is the quality of being toxic to cells (i.e. cell-killing). Many cancer chemotherapeutic drugs are cytotoxic to cancer cells (and, to some extent, normal cells) thus resulting in unwanted side-effects e.g. nausea/vomiting, hair loss, suppression of the immune system.

**Dosimetry** — Radiation dosimetry is the calculation of absorbed dose and optimization of dose delivery in radiation therapy.

**Lipid Rafts** — Specialized regions of the membrane phospholipid bilayer that contain high concentrations of cholesterol and sphingolipids and serve to organize cell surface and intracellular signaling molecules (e.g. growth factor and cytokine receptors, the phosphatidylinositol 3-kinase (P13K)/Akt survival pathway).

**Radiolabeled** — Refers to a molecule containing a radioisotope as a part of its structure.

**Radioisotope** — Also referred to as radioactive isotopes or radionuclides. These are variants of atoms of particular chemical elements (e.g. iodine) with an unstable nucleus that can undergo radioactive decay during which ionizing radiation (e.g. gamma rays, subatomic particles) is emitted.

**Uptake** — An act of taking in or absorbing, especially into a living organism, tissue or cell.

**Xenograft** — Tissue, organs or cells from an individual of one species transplanted into or grafted onto an individual of another species.

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**PROSPECTUS**

**SUBJECT TO COMPLETION, DATED OCTOBER 21, 2016**



**300,006 SHARES OF COMMON STOCK**

**OFFERED BY SELLING STOCKHOLDER**

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**PART II**

**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 16. Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>	<b>Filed with this Form S-1</b>	<b>Incorporated by Reference</b>		
			<b>Form</b>	<b>Filing Date</b>	<b>Exhibit No.</b>
2.1	Agreement and Plan of Merger by and among Novelos Therapeutics, Inc., Cell Acquisition Corp. and Collectar, Inc. dated April 8, 2011		8-K	April 11, 2011	2.1
3.1	Second Amended and Restated Certificate of Incorporation		8-K	April 11, 2011	3.1
3.2	Certificate of Ownership and Merger of Collectar Biosciences, Inc. with and into Novelos Therapeutics, Inc.		8-K	February 11, 2014	3.1
3.3	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation		8-K	June 13, 2014	3.1
3.4	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation		8-K	June 19, 2015	3.2
3.5	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation		8-K	March 4, 2016	3.1
3.6	Amended and Restated By-laws		8-K	June 1, 2011	3.1
4.1	Form of common stock certificate		S-1/A	November 9, 2011	4.1
5.1	Legal Opinion of Foley Hoag LLP	X			5.1
10.1	Form of non-plan non-qualified stock option used from February to May 2005 *		SB-2	November 16, 2005	10.4
10.2	Form of non-plan non-qualified stock option used after May 2005 *		SB-2	November 16, 2005	10.5
10.3	2006 Stock Incentive Plan, as amended *		8-K	December 18, 2013	10.1
10.4	Form of Incentive Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan*		8-K	December 15, 2006	10.1
10.5	Form of Non-Statutory Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan*		8-K	December 15, 2006	10.2
10.6	Common Stock Purchase Warrant dated February 11, 2009		8-K	February 18, 2009	4.2
10.7	Form of Common Stock Purchase Warrant issued pursuant to the Consent and Waiver of Holders of Series C Convertible Preferred Stock and Series E Convertible Preferred Stock dated July 6, 2010		S-1A	July 7, 2010	10.53
10.8	Form of Common Stock Purchase Warrant dated April 8, 2011		8-K	April 11, 2011	4.3
10.9	Securities Purchase Agreement dated April 8, 2011		8-K	April 11, 2011	10.1
10.10	License Agreement between Collectar, LLC and the Regents of the University of Michigan dated September 14, 2003, as amended through June 2010		S-1	July 1, 2011	10.31
10.11	Lease Agreement between Collectar, LLC and McAllen Properties LLC, as amended and extended		S-1	July 1, 2011	10.32
10.12	Loan Agreement between the Wisconsin Department of Commerce and Collectar, Inc. dated September 15, 2010		S-1	July 1, 2011	10.33
10.13	General Business Security Agreement dated September 15, 2010		S-1	July 1, 2011	10.34
10.14	Form of Warrant dated December 6, 2011		S-1/A	November 9, 2011	4.2
10.15	Placement Agent Agreement dated April 9, 2012 between the Company and Rodman and Renshaw, LLC		S-1	April 9, 2012	10.31
10.16	Securities Purchase Agreement dated June 7, 2012		8-K	June 11, 2012	10.1

10.17	Amendment Agreement dated May 11, 2012 between the Company and Rodman and Renshaw, LLC	S-1/A	May 14, 2012	10.33
10.18	Form of Common Stock Purchase Warrant dated June 13, 2012	8-K	June 11, 2012	4.1
10.19	Securities Purchase Agreement between the Company and Renova Industries Ltd.	10-Q	November 6, 2012	10.2
10.20	Form of Securities Purchase Agreement	8-K	February 14, 2013	10.1
10.21	Form of Common Stock Purchase Warrant	8-K	February 14, 2013	4.1
10.22	Amendment and restated Placement Agent Agreement dated January 8, 2013 between the Company and Burrill LLC	S-1/A	January 31, 2013	10.37
10.23	Retention Agreement between the Company and Christopher Pazoles dated July 26, 2013*	10-Q	November 13, 2013	10.2
10.24	Retention Agreement between the Company and Joanne M. Protano dated July 26, 2013*	10-Q	November 13, 2013	10.3
10.25	Consulting Agreement between the Company and Simon Pedder dated October 4, 2013*	10-Q	November 13, 2013	10.4
10.26	Employment Agreement between the Company and Simon Pedder dated October 4, 2013*	10-Q	November 13, 2013	10.5
10.27	Waiver Agreement between the Company and Renova Assets Ltd. dated October 9, 2013	8-K	October 10, 2013	10.1
10.28	Securities Purchase Agreement dated February 5, 2014	8-K	February 10, 2014	10.1
10.29	Form of Convertible Debenture	8-K	February 10, 2014	4.1
10.30	Form of Common Stock Purchase Warrant	8-K	February 10, 2014	4.2
10.31	Form of Warrant Agreement between Cellectar Biosciences, Inc. and American Stock Transfer and Trust Company	S-1/A	July 7, 2014	10.31
10.32	Form of Underwriting Agreement	S-1/A	July 7, 2014	1.1
10.33	Form of Note Purchase and Security Agreement	10-Q	August 4, 2014	10.1
10.34	Form of 8% Secured Promissory Note	10-Q	August 4, 2014	10.2
10.35	Form of Consent Agreement with Debenture Holders	10-Q	August 4, 2014	10.3
10.36	2015 Stock Incentive Plan	10-Q	August 12, 2015	10.1
10.37	Employment Agreement between the Company and James Caruso, dated June 15, 2015	10-Q	August 12, 2015	10.2
10.38	Placement Agency Agreement dated September 28, 2015 between the Company and Ladenburg Thalmann & Co. Inc.	8-K	September 30, 2015	1.1
10.39	Form of Series B Pre-Funded Warrant	8-K	September 30, 2015	4.1
10.40	Form of Series A Warrant	8-K	September 30, 2015	4.2
10.41	Securities Purchase Agreement dated September 28, 2015	8-K	September 30, 2015	10.1
10.42	Registration Rights Agreement dated September 28, 2015	8-K	September 30, 2015	10.2
10.43	Amendment and Exchange Agreement dated April 13, 2016	S-1/A	April 14, 2016	10.43
10.44	Form of Underwriting Agreement	S-1/A	April 14, 2016	1.1
10.45	Form of Series A Warrant	S-1/A	April 14, 2016	4.2
10.46	Form of Series B Pre-Funded Warrant	S-1/A	April 14, 2016	4.3
10.47	Form of Warrant Agency Agreement	S-1/A	April 14, 2016	4.4
21.1	List of Subsidiaries	10-K	March 11, 2016	21.1
23.1	Consent of Foley Hoag LLP (included in Exhibit 5.1)			X 23.1
23.2	Consent of Baker Tilly Virchow Krause, LLP			X 23.2
24.1	Powers of Attorney (included on signature page)			X 24.1

\* Compensation-related agreement.

## Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.
2. That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
4. That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to the offering shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
5. That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
  - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
  - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
  - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this amendment to the registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Madison, State of Wisconsin, on October 21, 2016.

### CELLECTAR BIOSCIENCES, INC.

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

We, the undersigned officers and directors of Cellectar Biosciences, Inc., hereby severally constitute and appoint James Caruso and Chad J. Kolean, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign for us and in our names in the capacities indicated below any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this amendment to the registration statement has been signed by the following persons in the indicated capacities as of October 21, 2016.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ James Caruso</u> James Caruso	Chief Executive Officer and Director ( <i>principal executive officer</i> )	October 21, 2016
<u>/s/ Chad J. Kolean</u> Chad J. Kolean	Chief Financial Officer ( <i>principal financial officer and principal accounting officer</i> )	October 21, 2016
<u>/s/ Stephen A. Hill</u> Stephen A. Hill	Director	October 21, 2016
<u>/s/ Stefan Loren</u> Stefan Loren	Director	October 21, 2016
<u>/s/ John Neis</u> John Neis	Director	October 21, 2016

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>	<b>Filed with this Form S-1</b>	<b>Incorporated by Reference</b>		<b>Exhibit No.</b>
			<b>Form</b>	<b>Filing Date</b>	
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3.6	Amended and Restated By-laws		8-K	June 1, 2011	3.1
4.1	Form of common stock certificate		S-1/A	November 9, 2011	4.1
5.1	Legal Opinion of Foley Hoag LLP	X			5.1
10.1	Form of non-plan non-qualified stock option used from February to May 2005 *		SB-2	November 16, 2005	10.4
10.2	Form of non-plan non-qualified stock option used after May 2005 *		SB-2	November 16, 2005	10.5
10.3	2006 Stock Incentive Plan, as amended *		8-K	December 18, 2013	10.1
10.4	Form of Incentive Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan*		8-K	December 15, 2006	10.1
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10.7	Form of Common Stock Purchase Warrant issued pursuant to the Consent and Waiver of Holders of Series C Convertible Preferred Stock and Series E Convertible Preferred Stock dated July 6, 2010		S-1A	July 7, 2010	10.53
10.8	Form of Common Stock Purchase Warrant dated April 8, 2011		8-K	April 11, 2011	4.3
10.9	Securities Purchase Agreement dated April 8, 2011		8-K	April 11, 2011	10.1
10.10	License Agreement between Collectar, LLC and the Regents of the University of Michigan dated September 14, 2003, as amended through June 2010		S-1	July 1, 2011	10.31
10.11	Lease Agreement between Collectar, LLC and McAllen Properties LLC, as amended and extended		S-1	July 1, 2011	10.32
10.12	Loan Agreement between the Wisconsin Department of Commerce and Collectar, Inc. dated September 15, 2010		S-1	July 1, 2011	10.33
10.13	General Business Security Agreement dated September 15, 2010		S-1	July 1, 2011	10.34
10.14	Form of Warrant dated December 6, 2011		S-1/A	November 9, 2011	4.2
10.15	Placement Agent Agreement dated April 9, 2012 between the Company and Rodman and Renshaw, LLC		S-1	April 9, 2012	10.31
10.16	Securities Purchase Agreement dated June 7, 2012		8-K	June 11, 2012	10.1
10.17	Amendment Agreement dated May 11, 2012 between the Company and Rodman and Renshaw, LLC		S-1/A	May 14, 2012	10.33
10.18	Form of Common Stock Purchase Warrant dated June 13, 2012		8-K	June 11, 2012	4.1
10.19	Securities Purchase Agreement between the Company and Renova Industries Ltd.		10-Q	November 6, 2012	10.2



10.20	Form of Securities Purchase Agreement		8-K	February 14, 2013	10.1
10.21	Form of Common Stock Purchase Warrant		8-K	February 14, 2013	4.1
10.22	Amendment and restated Placement Agent Agreement dated January 8, 2013 between the Company and Burrill LLC		S-1/A	January 31, 2013	10.37
10.23	Retention Agreement between the Company and Christopher Pazoles dated July 26, 2013*		10-Q	November 13, 2013	10.2
10.24	Retention Agreement between the Company and Joanne M. Protano dated July 26, 2013*		10-Q	November 13, 2013	10.3
10.25	Consulting Agreement between the Company and Simon Pedder dated October 4, 2013*		10-Q	November 13, 2013	10.4
10.26	Employment Agreement between the Company and Simon Pedder dated October 4, 2013*		10-Q	November 13, 2013	10.5
10.27	Waiver Agreement between the Company and Renova Assets Ltd. dated October 9, 2013		8-K	October 10, 2013	10.1
10.28	Securities Purchase Agreement dated February 5, 2014		8-K	February 10, 2014	10.1
10.29	Form of Convertible Debenture		8-K	February 10, 2014	4.1
10.30	Form of Common Stock Purchase Warrant		8-K	February 10, 2014	4.2
10.31	Form of Warrant Agreement between Collectar Biosciences, Inc. and American Stock Transfer and Trust Company		S-1/A	July 7, 2014	10.31
10.32	Form of Underwriting Agreement		S-1/A	July 7, 2014	1.1
10.33	Form of Note Purchase and Security Agreement		10-Q	August 4, 2014	10.1
10.34	Form of 8% Secured Promissory Note		10-Q	August 4, 2014	10.2
10.35	Form of Consent Agreement with Debenture Holders		10-Q	August 4, 2014	10.3
10.36	2015 Stock Incentive Plan		10-Q	August 12, 2015	10.1
10.37	Employment Agreement between the Company and James Caruso, dated June 15, 2015		10-Q	August 12, 2015	10.2
10.38	Placement Agency Agreement dated September 28, 2015 between the Company and Ladenburg Thalmann & Co. Inc.		8-K	September 30, 2015	1.1
10.39	Form of Series B Pre-Funded Warrant		8-K	September 30, 2015	4.1
10.40	Form of Series A Warrant		8-K	September 30, 2015	4.2
10.41	Securities Purchase Agreement dated September 28, 2015		8-K	September 30, 2015	10.1
10.42	Registration Rights Agreement dated September 28, 2015		8-K	September 30, 2015	10.2
10.43	Amendment and Exchange Agreement dated April 13, 2016		S-1/A	April 14, 2016	10.43
10.44	Form of Underwriting Agreement		S-1/A	April 14, 2016	1.1
10.45	Form of Series A Warrant		S-1/A	April 14, 2016	4.2
10.46	Form of Series B Pre-Funded Warrant		S-1/A	April 14, 2016	4.3
10.47	Form of Warrant Agency Agreement		S-1/A	April 14, 2016	4.4
21.1	List of Subsidiaries		10-K	March 11, 2016	21.1
23.1	Consent of Foley Hoag LLP (included in Exhibit 5.1)	X			23.1
23.2	Consent of Baker Tilly Virchow Krause, LLP	X			23.2
24.1	Powers of Attorney (included on signature page)	X			24.1

\* Compensation-related agreement.



Seaport West  
155 Seaport Boulevard  
Boston, MA 02210-2600

617 832 1000 *main*  
617 832 7000 *fax*

August 25, 2016

Collectar Biosciences, Inc.  
3301 Agriculture Drive  
Madison, WI 53716

Re: S-3 Registration Statement

Ladies and Gentlemen:

We have acted as counsel to Collectar Biosciences, Inc., a Delaware corporation (the "Company"), in connection with the registration statement on Form S-1 (the "Registration Statement") being filed by the Company with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), covering the resale by the selling stockholders identified therein (the "Selling Stockholders") of up to 300,006 shares (the "Shares") of the Company's common stock, \$0.00001 par value per share ("Common Stock"), issuable upon exercise of outstanding warrants to purchase Common Stock issued on April 20, 2016 (the "Warrants").

In rendering the opinion set forth below, we have assumed that (i) all information contained in all documents reviewed by us is true and correct; (ii) all signatures on all documents examined by us are genuine; (iii) all documents submitted to us as originals are authentic, and all documents submitted to us as copies conform to the originals of those documents; (iv) each natural person signing any document reviewed by us had the legal capacity to do so; and (v) the certificates or other documents representing the Shares will be duly executed and delivered. We have further assumed that the Company will have sufficient authorized, unissued and otherwise unreserved shares of Common Stock available for issuance at the time of each issuance of the Shares upon exercise of the Warrants.

We express no opinion as to the laws of any state or jurisdiction other than the General Corporation Law of the State of Delaware (including applicable provisions of the Delaware Constitution and reported judicial decisions interpreting such Law and such Constitution) and the federal laws of the United States of America.

We have examined the Registration Statement, including the exhibits thereto, and such other documents, corporate records, and instruments and have examined such laws and regulations as we have deemed necessary for purposes of rendering the opinion set forth herein.

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Collectar Biosciences, Inc.  
August 25, 2016  
Page 2

Based upon such examination and subject to the further provisions hereof, we are of the opinion that the Shares, if and when issued, paid for and delivered in compliance with the terms of the Warrants and in compliance with the terms of the Company's Certificate of Incorporation as in effect from time to time, will be validly issued, fully paid and non-assessable.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and the reference to us under the caption "Legal Matters" in the prospectus included in the Registration Statement. In giving this consent, we do not admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission promulgated thereunder.

This opinion letter is given to you solely for use in connection with the offer and sale by the Selling Stockholders of the Shares pursuant to the Registration Statement. Our opinion is expressly limited to the matters set forth above, and we render no opinion, whether by implication or otherwise, as to any other matters relating to the Company, the Shares or the Registration Statement.

Very truly yours,

FOLEY HOAG LLP

By: /s/ Paul Bork  
A Partner

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CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated October 20, 2016, with respect to the consolidated financial statements of Collectar Biosciences, Inc. and Subsidiary included in the Annual Report on Form 10-K/A for the year ended December 31, 2015, which is incorporated by reference in this Registration Statement. We consent to the incorporation by reference of the aforementioned report in this Registration Statement, and to the use of our name as it appears under the caption "Experts."

/s/ BAKER TILLY VIRCHOW KRAUSE, LLP

Madison, Wisconsin  
October 21, 2016

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