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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)*

**Copies to:**

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

**Joseph A. Smith, Esq.**  
**Ellenoff Grossman & Schole LLP**  
**1345 Avenue of the Americas**  
**New York, NY 10105-0302**  
**(212) 370-1300**

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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, par value \$0.00001 per share	10,869,565	\$ 0.92	\$ 10,000,000	\$ 1,007.00
Warrants to purchase Common Stock		\$ —	\$ —	\$ —
Common Stock issuable upon exercise of Warrants	10,869,565	\$ 0.92	\$ 10,000,000	\$ 1,007.00
Total			<u>\$ 20,000,000</u>	<u>\$ 2,014.00</u>

- (1) Pursuant to Rule 416 under the Securities Act of 1933 (the "Securities Act"), the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.
- (2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the Securities Act, based upon 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 December 14, 2015.

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

**PROSPECTUS**

**SUBJECT TO COMPLETION, DATED DECEMBER 18, 2015**

**Up to \$10,000,000 in Shares of Common Stock and  
Warrants to Purchase Shares of Common Stock**



We are offering up to \_\_\_\_\_ shares of common stock, together with warrants to purchase [●] shares of common stock at a purchase price of \_\_\_\_\_ (and the shares issuable from time to time upon exercise of the warrants) pursuant to this prospectus. The shares and warrants will be separately issued, but the shares and warrants will be issued and sold to purchasers in the ratio of \_\_\_\_\_ to \_\_\_\_\_. Each warrant will have an exercise price of \_\_\_\_\_ per share, will be exercisable upon issuance and will expire five years from the date of issuance. The warrants will be issued in book-entry form pursuant to a warrant agency agreement between us and American Stock Transfer and Trust Company, as warrant agent, respectively.

Our common stock is listed on the NASDAQ Capital Market under the symbol "CLRB." On December 14, 2015, the last reported sale price of our common stock on the NASDAQ Capital Market was \$0.92 per share.

**Investing in the offered securities involves a high degree of risk. See "Risk Factors" beginning on page 8 of this prospectus for a discussion of information that you should consider before investing in our securities.**

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

	<b>Per Share and Warrant</b>	<b>Total</b>
Public offering price	\$ _____	\$ _____
Underwriting discount (1)	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

We have granted a 45-day option to the underwriter, to purchase up to an additional \_\_\_\_\_ shares and/or warrants from us solely to cover over-allotments, if any. The shares and/or warrants issuable upon exercise of the underwriter option are identical to those offered by this prospectus and have been registered under the registration statement of which this prospectus forms a part. If the underwriters exercise the option in full, the total discount and commission will be \$ \_\_\_\_\_ and the total net proceeds, before expenses, to us will be \$ \_\_\_\_\_.

The underwriter expects to deliver the shares and warrants to purchasers in the offering on or about \_\_\_\_\_, 2015.

**LADENBURG THALMANN**

**The date of this prospectus is \_\_\_\_\_, 2015.**

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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.

We have not authorized anyone to provide you with different information. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the securities offered by this prospectus. No offers will be made to, nor accepted from, any person that does not meet the definition of an “institutional investor” under the blue sky laws of its state of domicile unless otherwise specified in the “Underwriting” section below. Neither the delivery of this prospectus nor any sale made in connection with this prospectus shall, under any circumstances, create any implication that there has been no change in our affairs since the date of this prospectus or that the information contained by reference to this prospectus is correct as of any time after its date.

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.

## 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 53 of this prospectus for definitions of certain technical and scientific terms used throughout this prospectus.**

### Overview

Collectar Biosciences, Inc. (the Company) is a biopharmaceutical company developing phospholipid ether-drug conjugates (PDCs) for the treatment and diagnostic imaging of cancer. 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.

The Company’s development program is based on its proprietary PDC delivery platform and its resources are focused on its radiotherapeutic and chemotherapeutic product candidates. The company also possesses diagnostic and optical imaging agents. 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 PDC radiotherapeutic product candidate and is currently being evaluated in a Phase 1 study for the treatment of relapse or refractory multiple myeloma. Multiple myeloma is an incurable cancer of plasma cells. This cancer type was selected for both clinical 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 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 anticipate evaluating our first cohort and initiating the second cohort in January 2016. The primary goals of the Phase 1 study are to assess the compound’s safety, identify a Phase 2 dose, and possibly obtain an early evaluation of low dose activity.
- 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 and CLR 1603-PTX; both 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. Both of our paclitaxel PDC’s are being evaluated *in vitro* and *in vivo* to demonstrate formulation stability and PDC cancer targeting selectivity.
- 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. Pre-clinical research will include: chemistry, manufacturing and controls of CLR 125; biodistribution and toxicity studies of CLR 125 in pre-clinical models; and efficacy and dose-response 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 NIR-fluorophore optical imaging PDC for intraoperative tumor and tumor margin illumination. This past June, 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. As a result, Collectar is identifying the optimal clinical development pathway. Based on our assessment, the Company believes that product will be similarly treated by third-party payors and end users post marketing approval regardless of 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 diagnostic 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 received a notice from NASDAQ of non-compliance with its continuing listing rules;
- 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;
- Eight of our stockholders beneficially own in the aggregate in excess of 60% 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 8 of this prospectus.

## Recent Developments

On December 14, 2015, Celectar Biosciences, Inc. (the "Company") entered into a Material Transfer Agreement (the "MTA") with Institut de Recherche Pierre Fabre ("IRPF"). Under the MTA, IRPF will provide a selection of its proprietary cytotoxics (the "IRPF Materials") 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 the 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 the MTA, 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 within twenty-four months of entry into the MTA, 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.

On October 1, 2015, pursuant to a securities purchase agreement, we issued Series A warrants to purchase an aggregate of 1,500,000 shares of common stock at an exercise price of \$2.83 per share in a private placement, which warrants become exercisable on April 1, 2016 and expire on April 1, 2021. We concurrently sold 1,017,272 shares of our common stock and Series B pre-funded warrants to purchase an aggregate of 482,728 shares of common stock at an offering price of \$2.20 per share, under a shelf registration statement on Form S-3. The gross proceeds of the Offerings was \$3,300,000 before expenses, estimated to be approximately \$417,500. Pursuant to the terms of a



placement agency agreement, we paid Ladenburg Thalmann & Co. Inc. (“Ladenburg Thalmann”) a fee equal to 7.5% on aggregate gross proceeds, excluding the proceeds, if any, from the exercise of the Series A Warrants, and issued to Ladenburg Thalmann a warrant to purchase up to 37,500 shares of our common stock at an adjusted exercise price of \$2.83 per share.

### **Corporate Information**

Our headquarters and manufacturing operation is located at 3301 Agriculture Drive, Madison, Wisconsin 53716. We maintain a website at [www.cellectarbiosciences.com](http://www.cellectarbiosciences.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>Securities offered by us:</i>	Up to      shares of our common stock and      warrants to purchase up to      shares of common stock.
<i>Description of Warrants:</i>	[The shares and warrants will be separately transferable immediately upon issuance, but the shares and warrants will be issued and sold to purchasers in the ratio of to      . Each warrant will have an exercise price of      per share, will be exercisable upon issuance and will expire five years from the date of issuance.]
<i>Common Stock to be outstanding after this offering:</i>	shares (1)
<i>Use of Proceeds:</i>	We expect to use the net proceeds received from this offering to fund our research and development activities and for general corporate purposes. For a more complete description of our anticipated use of proceeds from this offering, see “Use of Proceeds.”
<i>Risk Factors:</i>	See “Risk Factors” beginning on page 8 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

(1) The number of shares of our common stock outstanding before and after this offering is based on 8,581,405 shares of common stock outstanding as of December 11, 2015 and excludes, as of that date:

- an aggregate of 723,933 shares of common stock issuable upon the exercise of outstanding stock options issued to employees, directors and consultants;
- an aggregate of 1,050,997 additional shares of common stock reserved for future issuance under our 2015 Stock Incentive Plan;
- an aggregate of 482,728 additional shares of common stock issuable upon the exercise of Series B pre-funded warrants issued on October 1, 2015; and
- an aggregate of 8,134,983 additional shares of common stock reserved for issuance under outstanding warrants having expiration dates between December 31, 2015 and April 1, 2021, and exercise prices ranging from \$2.20 per share to \$2,019.60 per share.

Unless we specifically state otherwise, the share information in this prospectus is as of December 11, 2015 and reflects or assumes no exercise of outstanding options or warrants to purchase shares of our common stock.

## Summary Historical Financial Information

The following table summarizes our financial data. We derived the following summary of our statements of operations data for the nine months ended September 30, 2015 and 2014 and the summary of our balance sheet data as of September 30, 2015 from our unaudited consolidated financial statements which have been incorporated by reference in this prospectus. We have derived the following summary of our statements of operations data for the years ended December 31, 2014 and 2013 and the summary of our balance sheet data as of December 31, 2014 and 2013 from our audited consolidated financial statements, for the applicable periods, which have been incorporated by reference in this prospectus. The following 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>Nine Months Ended September 30,</b>		<b>Year Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2014</b>	<b>2013</b>
<b>Statement of Operations Data:</b>			(Restated)	
Costs and expenses:				
Research and development	\$ 4,194,727	\$ 4,566,403	\$ 5,964,453	\$ 6,860,163
General and administrative	2,595,979	2,849,714	3,704,676	4,444,767
Restructuring costs	180,348	221,815	221,816	1,096,874
Total costs and expenses	<u>6,971,054</u>	<u>7,637,932</u>	<u>9,890,945</u>	<u>12,401,804</u>
Loss from operations	<u>(6,971,054)</u>	<u>(7,637,932)</u>	<u>(9,890,945)</u>	<u>(12,401,804)</u>
Other income:				
Gain on revaluation of derivative warrants	526,024	3,368,977	2,285,157	2,373,941
Loss on issuance of derivative warrants	—	—	—	(744,957)
Interest income (expense), net	(913)	(436,272)	(446,314)	(9,348)
Total other income, net	<u>525,111</u>	<u>2,932,705</u>	<u>1,838,843</u>	<u>1,619,636</u>
Net loss	<u>\$ (6,445,943)</u>	<u>\$ (4,705,227)</u>	<u>\$ (8,052,102)</u>	<u>\$ (10,782,168)</u>
Basic and diluted net loss per common share	<u>\$ (.85)</u>	<u>\$ (1.31)</u>	<u>\$ (1.75)</u>	<u>\$ (3.86)</u>
Shares used in computing basic and diluted net loss per common share	<u>7,563,078</u>	<u>3,591,742</u>	<u>4,592,657</u>	<u>2,794,557</u>
		<b>September 30,</b>	<b>December 31,</b>	
		<b>2015</b>	<b>2014</b>	<b>2013</b>
<b>Balance Sheet Data:</b>				
Current assets		\$ 2,972,808	\$ 9,698,238	\$ 2,768,071
Working capital		(2,502,768)	3,465,232	(1,755,084)
Total assets		6,461,507	13,419,516	6,815,939
Long term debt, including current portion		390,299	450,000	450,000
Total stockholders' equity		680,151	6,697,533	1,699,550

## 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 significant operating losses for the foreseeable future. At September 30, 2015, our consolidated cash balance was approximately \$2,473,000. We believe our cash balance at September 30, 2015, when aggregated with the approximately \$2,868,000 of cash generated from the financing completed on October 1, 2015, is adequate to fund operations into the second quarter of 2016. We will require additional funds to conduct research and development, establish and conduct clinical and pre-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 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 pre-clinical 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 pre-clinical 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 received a notice 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. We have requested, and the NASDAQ Staff has granted, an extension of time to effect transactions to allow us to regain compliance and to report the same in our annual report on Form 10-K for the year ended December 31, 2015. There can be no assurance that we will be able to effect such transactions on a timely basis or at all. The delisting of our common stock from NASDAQ may make it more difficult for us to raise capital on favorable terms in the future.

**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 experienced net losses and negative cash flows from operating activities since inception and we expect such losses and negative cash flows to continue for the foreseeable future. As of September 30, 2015, we had working capital of almost \$(2,503,000) and stockholders' equity of approximately \$680,000. For the period from Collectar, Inc.'s inception in November 2002 until the business combination with Novelos on April 8, 2011, and thereafter through September 30, 2015, the Company incurred aggregated net losses of over \$65,557,000. The net loss for the nine months ended September 30, 2015 was approximately \$6,446,000. We may never achieve profitability.

**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, 2014 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2014 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 their 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 GMP manufacturing vendor. GMP 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.

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

#### **Eight of our stockholders beneficially own approximately 61 % of our outstanding common stock, which limits the influence of other stockholders.**

As of December 11, 2015, approximately 61 % of our outstanding common stock is beneficially owned by eight 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 amended restated 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 restated certificate of incorporation and restated 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.

## Risks Related to this Offering

**Our management team will have immediate and broad discretion over the use of the net proceeds from this offering and we may use the net proceeds in ways with which you disagree.**

The net proceeds from this offering will be immediately available to our management to use at their discretion. We currently intend to use the net proceeds from this offering to fund our research and development activities, for general corporate purposes, and possibly for acquisitions of other companies, products or technologies, though no such acquisitions are currently contemplated. See “Use of Proceeds.” We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us or our stockholders. The failure of our management to use such funds effectively could have a material adverse effect on our business, prospects, financial condition, and results of operation.

**You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.**

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of up to \$     in securities offered in this offering, at an assumed public offering price of \$     per share and warrant, and after deducting the underwriters discounts and commissions and other estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of \$     per share, or     %, at the assumed public offering price, assuming no exercise of the warrants. In addition, in the past, we issued options and warrants to acquire shares of common stock. To the extent these options are ultimately exercised, you will sustain future dilution. We may also acquire or license other technologies or finance strategic alliances by issuing equity, which may result in additional dilution to our stockholders.

## 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

Based on an assumed public offering price of \$ per share of common stock and warrant, we estimate that the net proceeds to us from the sale of the securities that we are offering, assuming gross proceeds of \$ million and no exercise of the overallotment option, will be approximately \$ million, after deducting underwriting discounts and commissions and estimated offering expenses. In addition, if all of the warrants offered pursuant to this prospectus are exercised in full for cash, we will receive approximately an additional \$ million in cash. However, the warrants contain a cashless exercise provision that permit exercise of warrants on a cashless basis at any time where there is no effective registration statement under the Securities Act of 1933, as amended, covering the issuance of the underlying shares.

We expect to use any proceeds received from this offering as follows:

- to fund our research and development activities, including the further development of CLR 131, and the research advancement of our CTX Program, including product candidates, CLR 1601-PTX and CLR 1603-PTX.
- for general corporate purposes, such as human resource acquisition to support organizational priorities, general and administrative expenses, capital expenditures, working capital, repayment of debt, prosecution and maintenance of our intellectual property, and the potential investment in technologies, products or collaborations that complement our business.

Even if we sell all of the securities subject to this offering, we will still need to obtain additional financing in the future in order to fully fund these product candidates through the regulatory approval process. We may seek such additional financing through public or private equity or debt offerings or other sources, including collaborative or other arrangements with corporate partners, and through government grants and contracts. There can be no assurance we will be able to obtain such additional financing. Although we currently anticipate that we will use the net proceeds of this offering as described above, there may be circumstances where a reallocation of funds may be necessary. The amounts and timing of our actual expenditures will depend upon numerous factors, including the progress of our development and commercialization efforts, the progress of our clinical studies, whether or not we enter into strategic collaborations or partnerships and our operating costs and expenditures. Accordingly, our management will have significant flexibility in applying the net proceeds of this offering.

The costs and timing of drug development and regulatory approval, particularly conducting clinical studies, are highly uncertain, are subject to substantial risks and can often change. Accordingly, we may change the allocation of use of these proceeds as a result of contingencies such as the progress and results of our clinical studies and other development activities, the establishment of collaborations, our manufacturing requirements and regulatory or competitive developments.

Pending the application of the net proceeds as described above or otherwise, we may invest the proceeds in short-term, investment-grade, interest-bearing securities or guaranteed obligations of the U.S. government or other securities.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization, each as of September 30, 2015 on:

- an actual basis;
- a pro forma basis to give effect to the sale of shares of common stock, Series A warrants and Series B pre-funded warrants on October 1, 2015; and
- a pro forma as adjusted basis to give 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 September 30, 2015 (Unaudited)</b>		
	<b>Actual</b>	<b>Pro Forma <sup>(1)</sup></b>	<b>Pro Forma as Adjusted <sup>(2)</sup></b>
Cash and cash equivalents	\$ 2,472,527	\$ 5,355,027	\$
Notes payable to the Wisconsin Department of Commerce	390,299	390,299	390,299
Deferred rent	149,249	149,249	149,249
Capital lease obligations	10,996	10,996	10,996
Total debt obligations	<u>550,544</u>	<u>550,544</u>	<u>550,544</u>
Stockholders' equity:			
Common stock, par value \$0.00001 per share: 40,000,000 shares authorized; 7,564,133 actual; 8,581,405 <i>pro forma</i> ; [●] <i>pro forma as adjusted</i>	76	76	
Additional paid in capital	66,237,688	66,237,688	
Accumulated deficit	<u>(65,557,613)</u>	<u>(65,557,613)</u>	<u>(65,557,613)</u>
Total stockholders' equity	680,151	680,151	
Total capitalization	<u>\$ 1,230,695</u>	<u>\$ 1,230,695</u>	<u>\$</u>

- (1) Assumes that the financing completed on October 1, 2015 does not increase equity due to the derivative treatment of warrants issued (final calculation of derivative impact is pending).
- (2) Assumes that \$ of securities are sold in this offering at an assumed offering price of \$ per share and warrant and that the net proceeds thereof are approximately \$ after underwriter's discounts and commissions and estimated offering expenses.

## MARKET FOR COMMON EQUITY

Our common stock was quoted on the OTC Bulletin Board under the symbol NVLT from June 14, 2005 until February 16, 2012, after which it was quoted on the OTCQX platform. On February 12, 2014, 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 bid prices for our common stock. These over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

<b>Fiscal Year 2015</b>	High	Low
First Quarter	\$ 3.29	\$ 2.15
Second Quarter	3.49	2.50
Third Quarter	3.89	1.80
Fourth Quarter (through December 14, 2015)	2.23	0.85

  

<b>Fiscal Year 2014</b>	High	Low
First Quarter	\$ 9.00	\$ 7.00
Second Quarter	9.20	6.00
Third Quarter	7.20	2.09
Fourth Quarter	3.70	1.76

  

<b>Fiscal Year 2013</b>	High	Low
First Quarter	\$ 15.80	\$ 9.20
Second Quarter	9.40	7.20
Third Quarter	9.40	6.40
Fourth Quarter	8.20	5.00

On December 14, 2015 there were 349 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.

## DILUTION

Our net tangible book value as of September 30, 2015, as adjusted to give effect to the sale of shares of common stock, Series B pre-funded warrants and Series A warrants on October 1, 2015, was approximately \$6.5 million, or \$0.76 per share of common stock, based upon 8,581,405 shares outstanding. Net tangible book value per share is determined by dividing such number of outstanding shares of common stock into our net tangible book value, which is our total tangible assets, less total liabilities, excluding the derivative liability of \$4,651,000 at that date.

After giving effect to the sale of the securities in this offering at the public offering price of \$ per share of common stock, [together with a warrant to purchase one share of common stock,] excluding the exercise of the underwriter's over-allotment option and after deducting underwriting discounts and commission and other estimated offering expenses payable by us, our adjusted net tangible book value at September 30, 2015 would have been approximately \$ million, or \$ per share. This represents an immediate increase in net tangible book value of approximately \$ per share to our existing stockholders, and an immediate dilution of \$ per share to investors purchasing securities in the offering.

The following table illustrates the per share dilution to investors purchasing securities in the offering:

Assumed public offering price per share of common stock, [together with a warrant to purchase one share of common stock]		\$
Net tangible book value per share as of September 30, 2015 (adjusted)	\$	[0.76]
Increase per share attributable to sale of securities to investors	\$	
Adjusted net tangible book value per share after the offering		\$
Dilution per share to investors		\$

The foregoing illustration does not reflect the potential dilution from the exercise of outstanding options or warrants to purchase shares of our common stock. The foregoing illustration also does not reflect the dilution that would result from the exercise of the warrants sold in the offering.

## BUSINESS

### Business Overview

Collectar Biosciences, Inc. (the Company) is a biopharmaceutical company developing phospholipid ether-drug conjugates (PDCs) for the treatment and diagnostic imaging of cancer. The Company's development program is based on its proprietary PDC delivery platform and its resources are focused on its radiotherapeutic and chemotherapeutic product candidates. The Company also possesses diagnostic and optical imaging assets.

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 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. 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 PDC radiotherapeutic product candidate and is currently being evaluated in a Phase 1 study for the treatment of relapse or refractory multiple myeloma. Multiple myeloma is an incurable cancer of plasma cells. This cancer type was selected for both clinical 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 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 anticipate evaluating our first cohort and initiating the second cohort in the first half of 2016. The primary goals of the Phase 1 study are to assess the compound's safety, identify a Phase 2 dose, and possibly obtain an early evaluation of low dose activity.
- 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 and CLR 1603-PTX; both 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. Both of our paclitaxel PDC's are being evaluated *in vitro* and *in vivo* to demonstrate formulation stability and PDC cancer targeting selectivity.
- 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. Pre-clinical research will include: chemistry, manufacturing and controls of CLR 125; biodistribution and toxicity studies of CLR 125 in pre-clinical models; and efficacy and dose-response 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 NIR-fluorophore optical imaging PDC for intraoperative tumor and tumor margin illumination. This past June, 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. As a result, Collectar is identifying the optimal clinical development pathway. Based on our assessment, the Company believes that product will be similarly treated by third-party payors and end users post marketing approval regardless of 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 diagnostic 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 (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. Due to 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 carrier molecule was deliberately designed to be coupled to 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. Because of their chemical identity, CLR 124 also represents an ideal imaging agent that may be used to predict tumor sensitivity of CLR 131 and, potentially, establish an efficacious and safe dose in individual patients. Other non-radioactive molecules can also be attached to the PLE carrier. 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. 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 and CLR 1603-PTX; both 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 cytotoxic payload as a monotherapy.

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 Chief Scientific Officer, Dr. Jamey Weichert, beginning in 1994 at the University of Michigan (U. Mich.), where phospholipid ether analogs were initially designed, synthesized, radiolabeled, and evaluated in the laboratory of Dr. Raymond Counsell. Since 1998, Dr. Weichert has continued his research at the University of Wisconsin (U. Wisc.) and subsequently founded 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 — remain goals 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 highly radiosensitive, has clear unmet medical need in the relapse or refractory setting and is considered an orphan drug designation and may provide regulatory pathway benefits due to clear unmet medical need and the unique benefits such as a novel mechanism of action and single dose treatment CLR 131 may provide versus existing therapeutic options. 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 of 2015 and anticipate a performance update on the first patient cohort in January of 2016. CLR 131 is anticipated to be used as monotherapy through proof-of-concept clinical trials, with subsequent exploration of CLR 131 in combination with chemotherapeutic agents (a number of which are known to be radiosensitizers and thus have the potential to enhance the efficacy of CLR 131) and in combination with external beam radiotherapy.

### ***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 and CLR 1603-PTX; both 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. Both of our paclitaxel PDC's are being evaluated *in vitro* and *in vivo* to demonstrate formulation stability and PDC cancer-targeting selectivity

### ***CLR 125***

CLR 125 research is fully funded through an NCI Small Business Research Grant ("SBIR"). 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. Ultimately, this would yield a superior therapeutic ratio for CLR 125. The feasibility and safety of CLR 125 is currently being investigated for the treatment of triple-negative breast cancer (TNBC) in the (neo) adjuvant setting. This project was initiated on September 30, 2015. This Phase 1 is part of a larger Phase 1/2 SBIR Fast-Track grant that was awarded Collectar in September 2015. Upon successful completion of the preclinical work in Phase 1, an additional grant in the amount of \$2.0 million may be awarded by the NCI for the Phase 2 option period. Based upon pre-clinical performance and a thorough analysis of the clinical and commercial potential of CLR 125, Collectar will determine whether to advance or cease additional research. Deliverables of the pre-clinical research conducted during Phase 1 will include: chemistry, manufacturing and controls (CMC) of CLR 125; biodistribution and toxicity studies of CLR 125 in pre-clinical models of TNBC; and efficacy and dose-response studies. The anticipated completion date for the Phase 1 efforts is June 30, 2016.



## 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) octadecyl 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 provide funding for the trial and the data is shared with us while the study progresses and at the conclusion of the study. A total of 11 patients have been 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 continue exploration of dose and imaging time points in an effort to optimize dosing and results. Enrollment began in May 2014 for the evaluation of a 10 mCi/m<sup>2</sup> dose in up to 16 patients.

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. Dr. Lance Hall at the UWCCC is the principal investigator for this trial. This trial is being 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. Dr. Lance Hall at the UWCCC is the principal investigator for this clinical trial. Dr. Jamey Weichert is the primary principal investigator for the \$1.2 million grant from the National Cancer Institute, which funds the trial. Total enrollment of 23 patients is targeted and 19 patients have been enrolled as of the end of February 2015.

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. Dr. Glenn Liu at UWCCC is the principal investigator for this trial. We provide funding for the trial and the data is shared with us. Up to twelve patients per tumor type will be enrolled across dose levels ranging from 3 mCi/m<sup>2</sup> to 10 mCi/m<sup>2</sup> in this Phase 1/2 trial. Twelve patients have been enrolled as of the end of February 2015, 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 in man (e.g., melanoma, head & neck, colon, esophageal). An IND for CLR 1502 was submitted to the FDA in February 2015. We anticipate initiating a multi-site Phase 1 study with CLR 1502 in breast cancer patients undergoing lumpectomy in the second half of 2015. The trial is intended to confirm the safety and tolerability of CLR 1502 while demonstrating its utility in the real-time identification of malignant tissue.

### **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 would be diagnosed in the U.S. in 2014 and the majority of cancer patients will have some type of surgery. According to the Society, about 6 million people worldwide would die of cancer in 2013, including approximately 580,000 in the U.S.

According to Cowen Therapeutic Categories Outlook (February 2013), cancer was the largest global pharmaceutical category with worldwide sales of \$74 billion in 2011. Cowen estimates that targeted therapies are changing the landscape of cancer treatment and will likely be used in most cancer patients in 5 to 10 years. Furthermore, the worldwide sales of targeted cancer therapies could exceed \$61 billion by 2017. The National Institutes of Health (NIH) estimates the direct medical cost for treating cancer in 2010 (the latest figure available under the NIH's new methodology) was \$124.6 billion in the U.S., and projects that by 2020, the cost will have risen to at least \$158 billion.

According to the National Cancer Institute SEER data base, multiple myeloma is the 2<sup>nd</sup> 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. According to a BCC Research report from August 2014, the total market for next-generation cancer diagnostics was \$1.6 billion in 2013, was growing at a compound annual growth rate of 42.6%, and was forecasted to reach a market size of \$10 billion in 2019.

### **Manufacturing**

We maintain a 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 during the next several years.

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 should be 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 for any Phase 2 trials and the potential for larger scale build-out for larger Phase 3 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 (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 existing approved agents, some of which are radiosensitive and maintain exclusive adverse event profiles.

### *CLR 124*

FDG is the current gold standard for cancer PET imaging. According to Bio-Tech Systems (November 2010), sales of FDG in the U.S. in 2009 were approximately \$300 million and projected to grow to approximately \$880 million in 2017. 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 demarcate structural changes in tissue, it is not cancer-selective. This imaging can result in a diagnostic dilemma for clinicians, particularly with respect to glioma, which is 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. A key goal of Company sponsored Phase 2 trials of CLR 124 in glioma patients will be to employ pathology confirmation to demonstrate that CLR 124 provides a more accurate assessment of malignant vs. non-malignant tissue, including in cases of suspected pseudo-progression. Pathology confirmation will also be applied in primary glioma patients to assess the accuracy and completeness of tumor resection. The available market for addressing unmet medical need with respect to pseudo-progression alone is approximately 40,000 patients annually (U.S. and Europe). The opportunity for robust pricing while still reducing current SOC healthcare costs is substantial. Current National Comprehensive Cancer Network® (NCCN®) guidelines provide for up to 18 MRIs over three years for post-treatment assessment of glioma progression. The cost of each MRI is approximately \$2,500 to \$5,000. The opportunity for CLR 124 to become the SOC for assessment of post-treatment progression of glioma results from the potential for better patient management (avoid unnecessary surgeries, biopsies, and treatments) and better patient outcomes (detect progression earlier, avoid tumor spread to critical structures) while reducing current SOC healthcare system costs.

Following the first commercial opportunity for CLR 124 addressing the unmet need for better assessment of post-treatment progression in glioma, brain metastases may represent the next commercial opportunity. Metastatic cancer patients with brain metastases are commonly followed with both FDG PET and brain MRI due to the inability of FDG PET to image for intracranial disease. CLR 124 may supplant this dual modality imaging surveillance paradigm due to its ability to image both intracranial and extra cranial disease. Initial data from Phase 1/2 imaging trials at the UWCCC demonstrates avid uptake in brain metastases. The available market for addressing this unmet need in brain metastases is considerably larger than glioma. In 2014, the National Cancer Institute estimated that there are between 98,000 and 170,000 new cases in the U.S. each year.

#### *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. In December, 2013, Blaze Biosciences announced the initiation of the first Phase 1 clinical study of the first Tumor Paint™ product candidate, BLZ-100. The study, titled "A Phase I Dose Escalation/Expansion Study of BLZ-100 Administered by Intravenous Injection in Adult Subjects with Skin Cancer", is ongoing in Australia. Additionally, Avelas Biosciences, based in San Diego, CA, is developing a fluorescence peptide based compound named AVB-620 for fluorescence image-guided cancer surgery. Avelas disclosed the intention to initiate human clinical trials with AVB-620 in 2014.

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 CLR 131, CLR 124 and CLR 1502.

Our proprietary rights 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 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 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.

In particular, CLR 124 is covered by the Michigan patents 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 and one of which is directed to its use for *in vitro* diagnostics. Each of these is expected to expire in 2025. CLR 124 is also covered by an issued European patent, and pending U.S. and Japanese patent applications. Any patents issued from these applications would be expected to expire in 2025. Separate from these patents, we have been granted orphan status for CLR 124 as a diagnostic for the management of glioma by the US FDA. Orphan status provides for seven years of marketing exclusivity following US approval of CLR 124 as a diagnostic for the management of gliomas.

CLR 131 is covered by an additional series of our patents and applications aside from the Michigan patents. 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. Separate from these patents, we have also been granted orphan status for CLR 131 for the treatment of multiple myeloma. Orphan status provides for seven years of marketing exclusivity following US approval of CLR 131 for treatment of multiple myeloma.

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 2029. 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.

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 124 and CLR 1502, we own other patents/applications directed to different forms of phospholipid ethers and methods of manufacturing of phospholipid ethers.

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.

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

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 at varying dates in 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.

## 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.

### *Pre-clinical Testing*

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.

### **Legal Proceedings**

We are not a party to any pending legal proceedings.

## MANAGEMENT

Our executive officers and directors as of December 18, 2015 are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Paul L. Berns (1)	48	Chairman of the Board and Director
James Caruso	56	President, Chief Executive Officer and Director
Jamey P. Weichert, Ph.D.	58	Chief Scientific Officer and Director
Kevin Kozak, M.D., Ph.D.	44	Chief Medical Officer
Chad J. Kolean	50	Vice President, Chief Financial Officer and Treasurer
J. Patrick Genn	58	Vice President of Business Development
Stephen A. Hill, B.M. B.Ch., M.A., F.R.C.S. (1)(2)(3)	57	Director
John Neis (1)(2)(3)	59	Director
Stefan D. Loren, Ph.D. (2)(3)	51	Director

- (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.

**Paul L. Berns.** Mr. Berns was appointed a director in November 2013 and was elected Chairman of the Board in July 2015. He was appointed as President and Chief Executive Officer of Anacor Pharmaceuticals in March 2014 and has been a director of Anacor since June 2012. Mr. Berns has served as a member of the Board of Directors of Jazz Pharmaceuticals, Inc. since June 2010 and has been a director of XenoPort, Inc. since 2005. From March 2006 to September 2012, Mr. Berns served as President and Chief Executive Officer, and as a member of the Board of Directors of Allos Therapeutics, Inc., a pharmaceutical company acquired by Spectrum Pharmaceuticals, Inc. From July 2005 to March 2006, Mr. Berns was a self-employed consultant to the pharmaceutical industry. From June 2002 to July 2005, Mr. Berns was President, Chief Executive Officer and a director of Bone Care International, Inc., a specialty pharmaceutical company that was acquired by Genzyme Corporation in 2005. From 2001 to 2002, Mr. Berns served as Vice President and General Manager of the Immunology, Oncology and Pain Therapeutics business unit of Abbott Laboratories. From 2000 to 2001, he served as Vice President, Marketing of BASF Pharmaceuticals/Knoll and from 1990 to 2000, Mr. Berns held various positions, including senior management roles, at Bristol-Myers Squibb Company. Mr. Berns received a B.S. in Economics from the University of Wisconsin. Mr. Berns' experience leading and advising drug development companies make him highly qualified to serve on our 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 Company 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.

**Jamey P. Weichert.** Dr. Weichert was the primary founder of Collectar and has served as Collectar's Chief Scientific Officer since 2002. Dr. Weichert is an Associate Professor of the Departments of Radiology, Medical Physics, Pharmaceutics and member of the Carbone Cancer Center at the University of Wisconsin-Madison. He has a bachelor's degree in Chemistry from the University of Minnesota and a doctorate in Medicinal Chemistry from the University of Michigan. His research has focused on the design, synthesis and evaluation of biomimetic CT and MRI imaging agents and dipeptide radiopharmaceuticals. He has been involved in molecularly targeted imaging agent development his entire professional career and has developed or co-developed several imaging agents nearing clinical trial status. Dr. Weichert serves or has served on the editorial boards of numerous scientific journals and has authored more than 40 peer reviewed publications and 150 abstracts. He also has 20 issued or pending patents related to drug delivery, imaging and contrast agent development. Dr. Weichert's experience founding and managing the development of Collectar's product candidates and his knowledge of radiation technology are strong qualifications to serve on our Board of Directors.

**Kevin Kozak.** Dr. Kozak, as a consultant, began serving as Chief Medical Officer on August 1, 2013. Dr. Kozak is the Director of Radiation Oncology at Mercy Regional Cancer Center. Between 2008 and 2013, he served as Assistant Professor of Human Oncology and Medical Physics, staff radiation oncologist and basic scientist at the University of Wisconsin Carbone Cancer Center. Dr. Kozak earned his medical and doctoral degrees from Vanderbilt University School of Medicine in 2003 then completed his residency and post-doctoral research at the Harvard Radiation Oncology Program in 2008. He has received research funding from multiple cancer research organizations including the National Institutes of Health, the Susan G. Komen Foundation, and the Damon Runyon Cancer Research Foundation. Additionally, Dr. Kozak is co-founder of Co-D Therapeutics, a company developing novel nanomedicines for cancer therapy. Dr. Kozak has numerous peer-reviewed publications, patents, book-chapters, and invited lectures to his credit.

**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.

**J. Patrick Genn.** Mr. Genn was appointed Vice President of Business Development in October 2013. Previously he served as Vice President of Investor Relations, beginning in April 2011. He has 28 years of senior management experience in finance, banking and investment management. Mr. Genn was previously President of Continuum Investment Holdings, Inc., from 2006 through mid-2010 while serving on the Board of Directors of several biotech and technology companies including Collectar, Inc. From 2001 through 2005, he was an advisor and consultant to several companies including Carmel Valley Ventures and Continuum Investment Partners. Mr. Genn held several senior management positions at Wells Fargo between 1987 and 2001. He was a member of the senior management team that launched the Mortgage Lending division in 1987 and the Premier Banking division in 1993. He was also a member of the core M&A integration team and managed private client services in San Diego, CA. Mr. Genn received a B.B.A. in Marketing and a Master of Science in Product Management from the University of Wisconsin-Madison.

**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 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 30 years of 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., Delphinus Medical Technologies, Inc., and Great Lakes Pharmaceuticals, 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 serves on the Board of the Wisconsin Technology Council, and 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.

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

At the close of business on December 14, 2015, there were 8,581,405 shares of our common stock outstanding. The following table provides information regarding beneficial ownership of our common stock as of December 14, 2015 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 December 14, 2015.

Name and Address of Beneficial Owner	Outstanding	Right to Acquire	Total	Percentage
Greenway Properties Inc. <sup>(1)</sup> 4954 N. Shore Drive Egg Harbor, Wisconsin 54209	1,278,579	1,187,430	2,466,009	25.24%
Austin W. Marx/David M. Greenhouse/Adam C. Stettner <sup>(2)</sup> 527 Madison Avenue, Suite 2600 New York, New York 10022	702,562	1,066,000	1,768,562	18.33%
Venture Investors LLC <sup>(3)</sup> University Technology Park 505 S. Rosa Road; Suite 201 Madison, Wisconsin 53719	632,426	506,063	1,138,489	12.53%
Cormorant Asset Management <sup>(4)</sup> 100 High Street, Suite 1105 Boston, MA 02110	530,000	530,000	1,060,000	11.63%
Sabby Management, LLC <sup>(6)</sup> 10 Mountainview Road, Suite 205 Upper Saddle River, NJ 07458	777,000	1,534,241	2,311,241	9.99%
Hertzberg Family Trust <sup>(5)</sup> 2637 Longboat Cove Del Mar, CA 92014	419,158	419,158	838,316	9.31%
Enso Ventures 2 Limited <sup>(7)</sup> Suite C1, Hirzel Court St. Peter Port, Guernsey GY12NH	288,058	276,264	564,322	6.37%
Pine River Capital Management LP 601 Carlson Parkway Suite 330 Minnetonka, MN 55305	500,000	—	500,000	5.83%
James Caruso	6,000	—	6,000	*
Patrick Genn	3,532	77,498	81,030	*
Chad Kolean	—	10,000	10,000	*
Jamey Weichert <sup>(8)</sup>	235,336	24,783	260,119	3.02%
Paul L. Berns	—	7,082	7,082	*
Stephen A. Hill	5,300	26,371	31,671	*
Stefan Loren	—	1,666	1,666	*
John Neis <sup>(3)</sup>	632,426	506,793	1,139,219	12.54%
All directors and officers as a group (8 persons)	882,594	654,193	1,536,787	16.64%

- (1) 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 \$2.83 to \$25.00 per share expiring between March 1, 2016 and April 1, 2021.
- (2) Based on information contained in a report on Schedule 13G, filed with the Securities and Exchange Commission on January 29, 2015 and a Form 4 filed with the Securities and Exchange Commission on December 8, 2015. Shares in the “Outstanding” column include 110,526 shares of common stock owned by Special Situations Cayman Fund, L.P., 331,776 shares owned by Special Situations Fund III QP, L.P., and 260,260 shares owned by Special Situations Life Sciences Fund, L.P. Shares in the “Right to Acquire” column include 179,000 shares of common stock issuable upon the exercise of warrants owned by Special Situations Cayman Fund, L.P., 537,000 shares of common stock issuable upon the exercise of warrants owned by Special Situations Fund III QP, L.P., and 350,000 shares of common stock issuable upon the exercise of warrants owned by Special Situations Life Sciences Fund, L.P. Austin W. Marxe, David M. Greenhouse and Adam C. Stettner are members of SSCayman LLC, the general partner of Special Situations Cayman Fund, L.P., controlling principals of AWM Investment Company, Inc., the general partner of MGP Advisers Limited Partnership, the general partner of Special Situations Fund III QP, L.P., and members of LS Advisers LILAC., the general partner of Special Situations Life Sciences Fund, L.P. AWM Investment Company, Inc. serves as the investment adviser to of Special Situations Cayman Fund, L.P., Special Situations Fund III QP, L.P. and Special Situations Life Sciences Fund, L.P. Messrs. Marxe, Greenhouse and Stettner share sole voting and investment power of the shares of common stock beneficially owned by Special Situations Cayman Fund, L.P., Special Situations Fund III QP, L.P. and Special Situations Life Sciences Fund, L.P.
- (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 sub-manager 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 492,141 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 14,582 shares of common stock issued to Mr. Neis in his capacity as director.
- (4) Based on information contained in a report on Schedule 13G, filed with the Securities and Exchange Commission on September 2, 2014. Shares in the “Outstanding” column include 530,000 shares of common stock held by Cormorant Global Healthcare Master Fund, LP. Shares in the “Right to Acquire” column consist of 530,000 shares of common stock issuable upon the exercise of warrants held by Cormorant Global Healthcare Master Fund, LP. Cormorant Global Healthcare GP, LLC serves as the general partner of Cormorant Global Healthcare Master Fund, LP, and Cormorant Asset Management, LLC serves as the investment manager of Cormorant Global Healthcare Master Fund, LP. Bihua Chen serves as the managing member of Cormorant Global Healthcare GP, LLC and Cormorant Asset Management, LLC. Cormorant Global Healthcare Master Fund, LP, Cormorant Global Healthcare GP, LLC, Cormorant Asset Management, LLC, and Ms. Chen share dispositive and voting power of the shares of common stock beneficially owned by Cormorant Global Healthcare Master Fund, LP.
- (5) Shares in the “Right to Acquire” column consist of shares common stock issuable upon the exercise of warrants at exercise prices ranging from \$4.68 to \$12.00 per share, expiring between December 6, 2016 and August 20, 2019. Richard H. Hertzberg is the trustee of Hertzberg Family Trust and has sole dispositive and voting power for the shares held.

- (6) Based on information contained in a report on Schedule 13G, filed with the Securities and Exchange Commission on January 12, 2015 and our current report on Form 8-K filed with the Securities and Exchange Commission on September 30, 2015. Consists of shares held by Sabby Healthcare Volatility Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd. Sabby Management, LLC shares voting and investment power with respect to these shares on behalf of this stockholder. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of this stockholder. Each of Sabby Management, LLC and Hal Mintz disclaim beneficial ownership over the securities owned except to the extent of their pecuniary interest therein. Sabby Management LLC beneficially owns warrants to purchase 878,712 shares of common stock at exercise prices ranging from \$2.20 per share to \$25.00 per share expiring between June 13, 2017 and August 20, 2019. Also includes (i) 263,333 shares of our common stock, Series A Warrants to purchase 424,242 shares of common stock exercisable within 60 days of October 1, 2015, and Series B Pre - Funded Warrants to purchase 160,909 shares of our common stock exercisable within 60 days of October 1, 2015 purchased by Sabby Healthcare Master Fund, Ltd., in our October 2015 offering, and (ii) 131,667 shares of our common stock, Series A Warrants to purchase 212,122 shares of our common stock exercisable within 60 days of October 1, 2015, and Series B Pre-Funded Warrants to purchase 80,455 shares of our common stock exercisable within 60 days of October 1, 2015 purchased by Sabby Volatility Warrant Master Fund, Ltd. in our October 2015 offering. The warrants (other than the warrants issued in the October 2015 offering) 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 9.99% of our outstanding common stock, provided, however that this limitation may be revoked by the stockholder upon 61 days prior notice to us. The warrants issued in the October 2015 offering have a 4.99% limitation, which may be increased to 9.99% upon a 61 day prior notice to us by the stockholder. Due to these limitations all such warrants to purchase shares of common stock have been included in the "Right to Acquire" column of this table, but excluded from the beneficial ownership percentage.

## **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 for referral 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 7.4% of our outstanding common stock.

Jamey Weichert, our Chief Scientific Officer and principal founder of Collectar, Inc., and a director and stockholder of the Company, is a faculty member at the University of Wisconsin-Madison (U. Wisc.). During the year ended December 31, 2014, the Company paid \$508,000 to UW for costs associated with clinical trial and other research agreements. During the year ended December 31, 2013, the Company made contributions to UW totaling \$187,500 for use towards unrestricted research activities and paid \$380,625 to UW for costs associated with clinical trial and other research agreements.



## UNDERWRITING

We have entered into an underwriting agreement dated [●], with Ladenburg Thalmann & Co. Inc., as the representative of the underwriters (the “representative”) named below and the sole book-running manager of this offering. Subject to the terms and conditions of the underwriting agreement, the underwriters have agreed to purchase the number of our securities set forth opposite its name below.

<b>Underwriter</b>	<b>SHARES</b>	<b>WARRANTS</b>
Ladenburg Thalmann & Co. Inc.	[●]	[●]
[●]	[●]	[●]
[●]	[●]	[●]
Total	<u>[●]</u>	<u>[●]</u>

A copy of the underwriting agreement has been filed as an exhibit to the registration statement of which this prospectus is part.

We have been advised by the underwriters that they propose to offer the shares and warrants directly to the public at the public offering price set forth on the cover page of this prospectus. Any securities sold by the underwriters to securities dealers will be sold at the public offering price less a selling concession not in excess of \$[●] of fixed combination of shares and \_\_\_ warrants per unit. The underwriters may allow, and these selected dealers may re-allow, a concession of not more than \$[●] per fixed combination to other brokers and dealers.

The underwriting agreement provides that the underwriters’ obligation to purchase the securities we are offering is subject to conditions contained in the underwriting agreement.

No action has been taken by us or the underwriters that would permit a public offering of the shares and warrants to in any jurisdiction where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offering hereby be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the shares and warrants in any jurisdiction where that would not be permitted or legal.

The underwriters have advised us that they do not intend to confirm sales to any accounts over which they exercise discretionary authority.

## Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriters by us.

	<u>Per Share</u>	<u>Per Warrant</u>	<u>Total</u>
Public offering price	\$		
Underwriting discount to be paid to the underwriters by us (7.5%)			
Proceeds to us (before expenses)			

We estimate the total expenses payable by us for this offering to be approximately \$\_\_\_\_\_, which amount includes (i) the underwriting discount of \$\_\_\_\_\_ (\$\_\_\_\_\_ if the underwriters' over-allotment option is exercised in full), (ii) reimbursement of the accountable expenses of the representative equal to \$65,000, including the legal fees of the representative being paid by us, and (iii) other estimated company expenses of approximately \$\_\_\_\_\_ which includes legal, accounting, printing costs and various fees associated with the registration and listing of our shares. In no event will the aggregated expenses of the representative reimbursed exceed \$65,000.

In addition, pursuant to FINRA Rule 5110(g), no warrant shares issued upon exercise of the warrants shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security:

- by operation of law or by reason of our reorganization;
- to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction for the remainder of the time period;
- if the aggregate amount of our securities held by the holder of the warrants or related persons do not exceed 1% of the securities being offered;
- that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or
- the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction for the remainder of the time period.

The warrants are exercisable for cash or on a cashless basis. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of common stock at a price below the warrant exercise price.

The securities we are offering are being offered by the underwriters subject to certain conditions specified in the underwriting agreement.

### **Over-allotment Option**

We have granted to the underwriters an option, exercisable not later than 45 days after the date of this prospectus, to purchase up to a number of additional shares of common stock equal to 15% of the number of shares of common stock sold in the primary offering and/or up to a number of additional warrants to purchase shares of common stock equal to 15% of the number of warrants sold in the primary offering. Any shares so purchased shall be sold at a price per share equal to the public offering price, less the underwriting discount. Any warrants so purchased shall be sold at a price per warrant of \$0.0001, less the underwriting discount. The underwriters may exercise the option solely to cover over-allotments, if any, made in connection with this offering. If any additional shares of common stock and/or warrants are purchased pursuant to the over-allotment option, the underwriters will offer these shares of common stock and/or warrants on the same terms as those on which the other securities are being offered hereby. The over-allotment option may be used to purchase shares of common stock, or warrants, or any combination thereof, as determined by the representative.

### **Determination of Offering Price**

Our common stock is currently traded on the Nasdaq Capital Market under the symbol "CLRB." On December 14, 2015, the closing price of our common stock was \$0.92 per share. We do not intend to apply for listing of warrants on any securities exchange or other trading system.

The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriters. Among the factors considered in determining the public offering price of the shares were:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the units. That price is subject to change as a result of market conditions and other factors, and we cannot assure you that the units can be resold at or above the public offering price.

### **Lock-up Agreements**

Our officers and directors, and each of their respective affiliates and associated partners, have agreed with the representative to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for 90 days following the closing of this offering, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. The lock-up period is subject to an additional extension to accommodate for our reports of financial results or material news releases. The representative may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

### **Transfer Agent and Registrar**

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

### **Stabilization, Short Positions and Penalty Bids**

The underwriters may engage in syndicate covering transactions, stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock:

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.
- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.
- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriters also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transactions, once commenced, will not be discontinued without notice.

### **Indemnification**

We have agreed to indemnify the underwriters against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the underwriters may be required to make for these liabilities.

## 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. We currently have no plans to issue any shares of preferred stock.

As of December 11, 2015, we had 8,581,405 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.

### Warrants to be Issued as Part of this Offering

The warrants offered in this offering will be issued in a form filed as an exhibit to the registration statement of which this prospectus is a part. You should review a copy of the form of warrant for a complete description of the terms and conditions applicable to the warrants. The following is a brief summary of the warrants and is subject in all respects to the provisions contained in the form of warrant. Pursuant to a warrant agency agreement between us and American Stock Transfer and Trust Company, as warrant agent, the warrants will be issued in book-entry form and shall initially be represented by one or more book-entry certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Each warrant represents the right to purchase one share of common stock at an exercise price equal to \$ , subject to adjustment as described below. Each warrant may be exercised on or after the closing date of this offering through and including the close of business on the fifth anniversary of the date of issuance. Each warrant will have a cashless exercise right in the event that the shares of common stock underlying such warrants are not covered by an effective registration statement at the time of such exercise.

The exercise price and the number of shares underlying the warrants are subject to appropriate adjustment in the event of stock splits, stock dividends on our common stock, stock combinations or similar events affecting our common stock. In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchange for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding common shares, then following such event, the holders of the warrants will be entitled to receive upon exercise of the warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the warrants. Further, as more fully described in the warrants, in the event of certain fundamental transactions that are all cash or involve a going private transaction, the holders of the warrants will be entitled to receive an amount equal to the Black-Scholes value of the warrants as of the date of such transaction.

No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the market value of a share of common stock. A warrant may be transferred by a holder, upon surrender of the warrant, properly endorsed (by the holder executing an assignment in the form attached to the warrant).

The warrants are not exercisable by their holder to the extent (but only to the extent) that such holder or any of its affiliates would beneficially own in excess of 4.99% of our common stock.

Amendments and waivers of the terms of the warrants require the written consent of the holder of such warrant and us.

**THE HOLDER OF A WARRANT WILL NOT POSSESS ANY RIGHTS AS A STOCKHOLDER UNDER THAT WARRANT UNTIL THE HOLDER EXERCISES THE WARRANT. THE WARRANTS MAY BE TRANSFERRED INDEPENDENT OF THE COMMON STOCK WITH WHICH THEY WERE ISSUED, SUBJECT TO APPLICABLE LAWS.**

#### **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 also listed on the NASDAQ Capital market under the trading symbol "CLRBW." On August 14, 2015, the Company received notice from NASDAQ which indicated that under NASDAQ Listing Rule 5550(b)(1), the Company is required to maintain a minimum of \$2,500,000 in stockholders' equity for continued listing. In the Company's Form 10-Q for the period ended June 30, 2015, we reported stockholders' equity was \$2,373,371. The Company has requested, and the NASDAQ Staff has granted, an extension of time to effect transactions to allow the Company to regain compliance and to report the same in the Company's annual report on Form 10-K for the year ended December 31, 2015.

### **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. Ellenoff Grossman & Schole LLP, New York, New York, is acting as counsel to the underwriters in this offering.

### **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 Grant Thornton 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 documents, which we have previously filed with the SEC:

- our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2014 filed on May 20, 2015;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 filed on May 20, 2015;
- our Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 filed on August 12, 2015;
- our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 filed on November 12, 2015;
- our Definitive Proxy Statement on Schedule 14A for our 2015 annual meeting of stockholders, filed with the SEC on April 22, 2015;
- our Definitive Proxy Statement on Schedule 14A for a special meeting of stockholders, filed with the SEC on October 28, 2015;
- our Current Report on Form 8-K for the event date of May 14, 2015, filed with the SEC on May 18, 2015;
- our Current Report on Form 8-K for the event date of June 9, 2015 filed on June 11, 2015;
- our Current Report on Form 8-K for the event date of June 15, 2015 filed on June 16, 2015;
- our Current Report on Form 8-K for the event date of June 15, 2015 filed on June 19, 2015;
- our Current Report on Form 8-K for the event date of July 1, 2015 filed on July 8, 2015;
- our Current Report on Form 8-K for the event date of July 28, 2015 filed on July 31, 2015;
- our Current Report on Form 8-K for the event date of August 14, 2015 filed on August 19, 2015;
- our Current Report on Form 8-K for the event date of September 28, 2015, filed with the SEC on September 30, 2015; and
- our Current Report on Form 8-K for the event date of December 14, 2015, filed with the SEC on December 17, 2015.

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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**Up to \$10,000,000 in Shares of Common Stock and  
Warrants to Purchase Shares of Common Stock**

**PROSPECTUS**

**LADENBURG THALMANN**

Through and including \_\_\_\_\_, 2015 (the 25<sup>th</sup> day after the date of this offering), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

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## PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 13. Other Expenses of Issuance and Distribution.

The following table provides information regarding the various actual and anticipated expenses (other than underwriter fees and expenses) payable by us in connection with the issuance and distribution of the securities being registered hereby. All amounts shown are estimates except the Securities and Exchange Commission registration fee.

<b>Nature of Expense</b>	<b>Amount</b>
SEC registration fee	\$ 2,014
Accounting fees and expenses	25,000
Legal fees and expenses	75,000
Transfer agent fees and expenses	10,000
Miscellaneous	50,000
Total	<u>\$ 162,014</u>

#### Item 14. Indemnification of Directors and Officers.

Section 102(b)(7) of the Delaware General Corporation Law allows us to adopt a charter provision eliminating or limiting the personal liability of directors to us or our stockholders for breach of fiduciary duty as directors, but the provision may not eliminate or limit the liability of directors for (a) any breach of the director's duty of loyalty to us or our stockholders, (b) any acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (c) unlawful payments of dividends or unlawful stock repurchases or redemptions under Section 174 of the Delaware General Corporation Law or (d) any transaction from which the director derived an improper personal benefit. Article Seventh of our charter provides that none of our directors shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, subject to the limitations imposed by Section 102(b)(7). Article Seventh also provides that no amendment to or repeal of Article Seventh shall apply to or have any effect on the liability or the alleged liability of any director with respect to any acts or omissions of such director occurring prior to such amendment or repeal. A principal effect of Article Seventh is to eliminate or limit the potential liability of our directors for monetary damages arising from breaches of their duty of care, unless the breach involves one of the four exceptions described in (a) through (d) above.

Section 145 of the Delaware General Corporation Law provides, in general, that a corporation incorporated under the laws of the State of Delaware, such as us, may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than a derivative action by or in the right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. In the case of a derivative action, a Delaware corporation may indemnify any such person against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification will be made in respect of any claim, issue or matter as to which such person will have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery of the State of Delaware or any other court in which such action was brought determines such person is fairly and reasonably entitled to indemnity for such expenses.

Article Eighth of our amended and restated certificate of incorporation and Section 5.1 of our bylaws provide that we will indemnify our directors, officers, employees and agents to the extent and in the manner permitted by the provisions of the Delaware General Corporation Law, as amended from time to time, subject to any permissible expansion or limitation of such indemnification, as may be set forth in any shareholders' or directors' resolution or by contract.

## Item 15. Recent Sales of Unregistered Securities

In the last three years we have sold the following securities in reliance on, unless otherwise indicated, the exemption under Section 4(a)(2) of the Securities Act of 1933, as amended, as transactions not involving any public offering. All share and per share amounts have been adjusted to give effect to the 1-for-20 Listing Reverse Split.

On February 6, 2014, we sold \$4,000,000 in principal amount of convertible debentures and warrants to purchase 400,000 shares of our common stock for an aggregate purchase price of \$4,000,000. The debentures had a maturity date of February 6, 2016 and were convertible at any time at a conversion price of \$10.00 per share into an aggregate of 400,000 shares of common stock. The debentures accrued interest at an annual rate of 8%, payable upon redemption or conversion, in cash or shares of our common stock. The warrants had an additional exercise price of \$20.00 and, if unexercised, would expire on February 6, 2019. The warrants were exercisable only following the full or partial conversion of the associated debentures, and in the event of a partial conversion the warrant would become exercisable only for a proportionate number of the total shares subject to the warrant. In the event any debentures ceased to be outstanding prior to the associated warrants becoming exercisable, whether by reason of repayment, prepayment, redemption or otherwise, the associated warrants would automatically terminate. These debentures and all accrued interest were exchanged for 1,109,690 shares of common stock and warrants to purchase an equal number of shares of common stock concurrently with the closing in August 2014 of an underwritten registered offering of common stock and warrants.

On October 1, 2015, pursuant to a securities purchase agreement, we issued Series A warrants to purchase an aggregate of 1,500,000 shares of common stock at an exercise price of \$2.83 per share in a private placement, which warrants become exercisable on April 1, 2016 and expire on April 1, 2021. We concurrently sold 1,017,272 shares of our common stock at an offering price of \$2.20 per share and Series B pre-funded warrants to purchase an aggregate of 482,728 shares of common stock pursuant to a shelf registration statement on Form S-3. The gross proceeds of the offerings was \$3,300,000 before expenses of approximately \$417,500. Pursuant to the terms of a placement agency agreement, we paid Ladenburg Thalmann a fee equal to 7.5% on aggregate gross proceeds, excluding the proceeds, if any, from the exercise of the Series A warrants, and to issue to Ladenburg Thalmann a warrant to purchase up to 37,500 shares of our common stock at an adjusted exercise price of \$2.83 per share.

## Item 16. Exhibits.

Exhibit No.	Description	Filed with this Form S-1	Incorporated by Reference		Exhibit No.
			Form	Filing Date	
1.1	Form of Underwriting Agreement *				
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 the Second Amended and Restated Articles of Incorporation		8-K	June 13, 2014	3.1
3.4	Amendment of Second Amended and Restated Articles of Incorporation		8-K	June 19, 2015	3.2
3.5	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*				
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	Amended 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	2015 Stock Incentive Plan	10-Q	August 12, 2015	10.1
10.33	Employment Agreement between the Company and James Caruso, dated June 15, 2015	10-Q	August 12, 2015	10.2
10.34	Placement Agency Agreement dated September 28, 2015 between the Company and Ladenburg Thalmann & Co. Inc.	8-K	September 30, 2015	1.1
10.35	Form of Series B Pre-Funded Warrant	8-K	September 30, 2015	4.1
10.36	Form of Series A Warrant	8-K	September 30, 2015	4.2
10.37	Securities Purchase Agreement dated September 28, 2015	8-K	September 30, 2015	10.1
10.38	Registration Rights Agreement dated September 28, 2015	8-K	September 30, 2015	10.2
10.39	Form of Warrant Agreement between Collectar Biosciences, Inc. and American Stock Transfer and Trust Company*			
10.40	Form of Common Stock Purchase Warrant *			
10.41	Material Transfer Agreement between the Company and Institut de Recherche Pierre Fabre (IRPF) dated December 14, 2015*			
21.1	List of Subsidiaries	10-K	March 19, 2014	21.1
23.1	Consent of Foley Hoag LLP (included in Exhibit 5.1)			
23.2	Consent of Grant Thornton LLP	X		
24.1	Powers of Attorney (included on signature page)	X		

\* To be filed by amendment.

## 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) 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 registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Madison, State of Wisconsin, on December 18, 2015.

### CELLECTAR BIOSCIENCES, INC.

By: /s/ James Caruso

James Caruso  
President and Chief Executive Officer

### POWER OF ATTORNEY

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 re-substitution 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), 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 registration statement has been signed by the following persons in the capacities and on the date indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ James Caruso</u> James Caruso	Chief Executive Officer and Director ( <i>principal executive officer</i> )	December 18, 2015
<u>/s/ Chad J. Kolean</u> Chad J. Kolean	Chief Financial Officer ( <i>principal financial officer and principal accounting officer</i> )	December 18, 2015
<u>/s/ Paul L. Berns</u> Paul L. Berns	Chairman of the Board of Directors	December 18, 2015
<u>/s/ Stephen A. Hill</u> Stephen A. Hill	Director	December 18, 2015
<u>/s/ Stefan Loren</u> Stefan Loren	Director	December 18, 2015
<u>/s/ John Neis</u> John Neis	Director	December 18, 2015
<u>/s/ Jamey P. Weichert</u> Jamey P. Weichert	Director	December 18, 2015



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24.1	Powers of Attorney (included on signature page)			X

\* To be filed by amendment.

**Consent of Independent Registered Public Accounting Firm**

We have issued our report dated March 24, 2015 (except for the effects of the restatement described in Note 1A, as to which the date is May 20, 2015), with respect to the consolidated financial statements of Collectar Biosciences, Inc. included in the Annual Report on Form 10-K/A for the year ended December 31, 2014, 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/ Grant Thornton LLP

Appleton, Wisconsin  
December 18, 2015

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