

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended: December 31, 2015

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number 333-119366

**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 No.)

**3301 Agriculture Drive**  
**Madison, WI 53716**  
(Address of principal executive offices and zip code)

Registrant's telephone number: (608) 441-8120

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	Name of each exchange on which registered
Common stock, par value \$0.00001	NASDAQ Capital Market
Warrant to purchase common stock, expiring August 20, 2019	NASDAQ Capital Market

Securities Registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  
Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of June 30, 2015, was \$12,894,808.

As of March 7, 2016, there were 858,013 shares of the registrant's \$0.00001 par value common stock outstanding.

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**CELLECTAR BIOSCIENCES, INC.**  
**FORM 10-K**

**TABLE OF CONTENTS**

<b>PART I</b>		<b>2</b>
Item 1.	<a href="#">Business</a>	2
Item 1A.	<a href="#">Risk Factors</a>	16
Item 2.	<a href="#">Properties</a>	27
Item 3.	<a href="#">Legal Proceedings</a>	27
Item 4.	<a href="#">Mine Safety Disclosures</a>	28
<b>PART II</b>		<b>28</b>
Item 5.	<a href="#">Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</a>	28
Item 6.	<a href="#">Selected Financial Data</a>	29
Item 7.	<a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	29
Item 7A.	<a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	35
Item 8.	<a href="#">Financial Statements</a>	36
Item 9.	<a href="#">Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</a>	58
Item 9A.	<a href="#">Controls and Procedures</a>	58
Item 9B.	<a href="#">Other Information</a>	60
<b>PART III</b>		<b>60</b>
Item 10.	<a href="#">Directors, Executive Officers, and Corporate Governance</a>	60
Item 11.	<a href="#">Executive Compensation</a>	60
Item 12.	<a href="#">Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a>	63
Item 13.	<a href="#">Certain Relationships and Related Transactions, and Director Independence</a>	64
Item 14.	<a href="#">Principal Accounting Fees and Services</a>	64
<b>PART IV</b>		<b>65</b>
Item 15.	<a href="#">Exhibits</a>	65

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*This annual report on Form 10-K of Collectar Biosciences, Inc. (“the Company”, “Collectar Bio”, “we”, “us”, “our”) contains forward-looking statements, which involve risks and uncertainties, such as our plans, objectives, expectations and intentions. You can identify these statements by our use of words such as “may,” “expect,” “believe,” “anticipate,” “intend,” “could,” “estimate,” “continue,” “plans,” or their negatives or cognates. Some of these statements include discussions regarding our future business strategy and our ability to generate revenue, income and cash flow. We wish to caution the reader that all forward-looking statements contained in this annual report on Form 10-K are only estimates and predictions. Our actual results could differ materially from those anticipated as a result of risks facing us or actual events differing from the assumptions underlying such forward-looking statements. Readers are cautioned not to place undue reliance on any forward-looking statements contained in this annual report on Form 10-K. We will not update these forward-looking statements unless the securities laws and regulations require us to do so.*

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

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

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## PART I

### Item 1. Business.

#### Business Overview

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

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

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

Our PDC platform is based on our cancer-targeting and delivery technology which provides selective delivery of a diverse range of oncologic payloads to cancer cells and cancer stem cells. By linking various drug payloads to our proprietary phospholipid ether cancer-targeting vehicle, we believe we can 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 drug payloads, enhancing or maintaining efficacy while reducing adverse events by minimizing drug delivery to healthy cells, increasing delivery to cancer cells and a broad range of cancerous tumors. The PDC product portfolio includes:

- CLR 131 is a small-molecule, broad-spectrum, cancer-targeting radiotherapeutic PDC that is designed to deliver cytotoxic (cell-killing) radiation directly and selectively to cancer cells and cancer stem cells. CLR 131 is our lead 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 announced performance results from the first patient cohort in January of 2016. The study's Data Monitoring Committee (DMC), unanimously agreed to advance CLR 131 into the second cohort. Patient enrollment is currently ongoing and the company plans to provide a study update in the third quarter of 2016. The primary goals of the Phase 1 study are to assess the compound's safety, identify the optimal Phase 2 dose, and possibly obtain an early evaluation of low dose drug 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, CLR 1602-PTX and CLR 1603-PTX; all are small-molecule, broad-spectrum, cancer-targeting chemotherapeutics in pre-clinical research. These PDCs are designed to selectively deliver paclitaxel, a chemotherapeutic payload to cancer cells and cancer stem cells to increase the therapeutic index of paclitaxel as a monotherapy. Each of our paclitaxel PDC's have been evaluated *in vitro* to demonstrate formulation stability and CLR 1602-PTX is currently being studied *in vivo* to further explore the PDC's cancer targeting selectivity. In December of 2015, the company entered into a research collaboration for our PDC technology with Pierre Fabre laboratories, the third largest French pharmaceutical company. The objective of the research collaboration is to co-design a library of PDC's employing Pierre Fabre's natural product derived chemotherapeutics in combination with our proprietary cancer targeting delivery vehicle. The newly developed PDC's may provide enhanced therapeutic indices to otherwise highly potent, non-targeted payloads through the targeted delivery to cancer cells provided by our cancer targeted delivery vehicle.

- CLR 125 is a broad-spectrum, cancer-targeting radiotherapeutic currently under pre-clinical investigation for the treatment of micrometastatic disease. In October, 2015, the company was awarded a national Cancer Institute Fast-Track Small Business Innovation Research (SBIR) grant to further advance its PDC delivery platform through CLR 125 preclinical and clinical research. The collaboration is designed to further explore the targeted delivery of radioisotopes for improved cancer therapy outcomes. The grant is awarded in two installments with up to \$2.3 million in funding. 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. Ongoing pre-clinical research includes: 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 working to identify the optimal clinical development and value optimizing strategic pathway. Based on our assessment, the Company believes that product will be similarly treated post marketing approval regardless of the regulatory pathway.

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

### ***Technology Overview***

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

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

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

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

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

Our core technology platform is based on research conducted by Collectar, Inc.'s founder and 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 — remains the focus of new therapies as well. We believe our isotope delivery technology is poised to achieve these goals. Because, to date, CLR 131 has been shown to reliably and near-universally accumulate in cancer cells, including cancer stem cells, and because the therapeutic properties of iodine-131 are well known, we believe the risk of non-efficacy in human clinical trials is less than that of other cancer therapies at this stage of development, although no assurance can be given.

In view of CLR 131's selective uptake and retention in a wide range of solid tumors and in cancer stem cells, its single-agent efficacy in animal models and its non-specific mechanism of cancer-killing (radiation), we are initially developing CLR 131 as a monotherapy for cancer indications with significant unmet medical need. While a number of indications were evaluated as the initial target treatment, multiple myeloma was selected principally because it is an incurable hematologic disease that is highly radiosensitive with significant unmet medical need in the relapse or refractory clinical setting, and is designated as an orphan disease. All of which may provide an accelerated regulatory pathway due to CLR 131 unique benefits versus existing therapeutic treatment options such as a novel mechanism of action and single dose treatment. The Investigational New Drug (IND) application was accepted by the FDA in September 2014. In December 2014, the FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma. We initiated our Phase 1 Study of CLR 131 for the treatment of Relapsed or Refractory multiple myeloma in April 2015, and provided a performance update on the first patient cohort and initiated the second study cohort in January 2016. CLR 131 is anticipated to be used as monotherapy through phase 1 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, CLR 1602-PTX and CLR 1603-PTX; both all are small-molecule, broad-spectrum, cancer-targeting chemotherapeutics in pre-clinical research. These PDCs are designed to selectively deliver paclitaxel, a chemotherapeutic payload to cancer cells and cancer stem cells increasing the therapeutic index of paclitaxel as a monotherapy. Each of our paclitaxel PDC's are being evaluated in vitro to demonstrate formulation stability and CLR 1602-PTX is currently being studied in vivo to demonstrate formulation stability and further explore the PDC's cancer targeting selectivity. In December of 2015, the company entered into a research collaboration for our PDC technology with Pierre Fabre laboratories, the third largest French pharmaceutical company. The objective of the research collaboration is to co-design a library of PDC's employing Pierre Fabre's natural product derived chemotherapeutics in combination with our proprietary cancer targeting delivery vehicle. The newly developed PDC's may provide enhanced therapeutic indices to otherwise highly potent, non-targeted payloads through the targeted delivery to cancer cells provided by our cancer targeted delivery vehicle.

### ***CLR 125***

CLR 125 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 program was initiated on October 1, 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) octadacyl phosphocholine, acting as a cancer-targeting delivery and retention vehicle, covalently labeled with iodine-124, a PET imaging radioisotope with a radiation half-life of four days. PET imaging used in conjunction with CT scanning has now become the imaging method of choice in much of oncology. In pre-clinical studies to date, CLR 124 selectively illuminated malignant tumors in over 60 animal models of different cancer types, demonstrating broad-spectrum, cancer-selective uptake and retention. Investigator-sponsored Phase 1/2 clinical trials of CLR 124 as a PET imaging agent are ongoing across multiple solid tumor indications. These trials have demonstrated positive initial imaging results in multiple tumor types. Based on positive initial CLR 124 imaging results in 29 primary and metastatic brain cancer patients, we believe CLR 124 has potential to address a significant unmet medical need for post-treatment efficacy assessment and differentiating tumor growth from pseudo-progression. In brain cancer, this has the potential to avoid unnecessary surgeries, biopsies and inappropriate treatment, resulting in better patient management and lower healthcare costs. We expect glioblastoma to be our lead indication for CLR 124 with additional development opportunities that could include brain metastases and other primary brain tumors.



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

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

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

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

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

### **CLR 1502**

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

## Market Overview

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

According to the National Cancer Institute SEER data base, multiple myeloma is the 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. A Market Research Engine report from December 2015 indicated the global cancer diagnostics market is expected to grow at a compound annual growth rate of 7.6% during 2015 to 2022.

## Manufacturing

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

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

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

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

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

## Sales and Marketing

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

## Competition for Our Clinical-Stage Compounds

### *CLR 131*

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

### *CLR 124*

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

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

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

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

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

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

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

## **Intellectual Property**

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

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

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

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

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

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

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

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

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

### **Licenses / Collaborations**

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

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

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

## **Research and Development**

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

## **Regulation**

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

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

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

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

- pre-clinical laboratory and animal tests performed under the FDA's Good Laboratory Practices regulations, referred to herein as GLP;
- submission to the FDA of an IND application, which must become effective before human clinical trials may commence;
- human clinical studies performed under the FDA's Good Clinical Practices regulations, to evaluate the drug's safety and effectiveness for its intended uses;
- FDA review of whether the facility in which the drug is manufactured, processed, packed, or held meets standards designed to assure the product's continued quality; and
- submission of a marketing application to the FDA, and approval of the application by the FDA.

### *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.

### **Employees**

As of December 31, 2015, we had 19 full-time employees.

### **Corporate Information**

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

Our principal executive offices are located at 3301 Agriculture Drive, Madison, Wisconsin 53716 and our telephone number is (608) 441-8120. Our corporate website address is [www.collectarbiosciences.com](http://www.collectarbiosciences.com). Information contained on or accessible through our website is not a part of this annual report.

## **Item 1A. 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 December 31, 2015, our consolidated cash balance was approximately \$3,858,000. We believe our cash balance at December 31, 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 have received notices from NASDAQ of non-compliance with its continuing listing rules.**

On August 14, 2015 we received a notice from NASDAQ of non-compliance with its continuing listing rules, namely that our stockholders' equity at June 30, 2015 of \$2,373,371, as reported in our Form 10-Q for the quarter then ended, was less than \$2,500,000 minimum. The failure to meet continuing compliance standards subjects our common stock to delisting. We previously reported in our Form 8-K, filed on August 19, 2015, the receipt of notice from Nasdaq of non-compliance with Rule 5550(b)(1), and the Company's intention to submit a plan to Nasdaq to regain compliance. That plan was submitted and approved by Nasdaq, and required a number of actions to be completed by February 10, 2016, including the filing of a registration statement with the SEC for a underwritten public offering of equity and the closing of that offering. The registration statement was timely filed, however the Company did not complete the offering by that date. The Company believes that there are sound reasons to obtain a reversal of the Nasdaq Staff determination and a hearing has been scheduled for March 31, 2016 for the Company to present its position. There can be no assurance that we will be able to receive a further extension to attain compliance. In the event our common stock is delisted from NASDAQ, it may be more difficult for us to raise capital on favorable terms in the future.

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

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

We are a clinical-stage company and have incurred net losses and negative cash flows since inception. We currently have no product revenues, and may not succeed in developing or commercializing any products that will generate product or licensing revenues. We do not expect to have any products on the market for several years. Our primary activity to date has been research and development. In addition, development of our product candidates requires a process of pre-clinical and clinical testing, during which our product candidates could fail. We may not be able to enter into agreements with one or more companies experienced in the manufacturing and marketing of therapeutic drugs and, to the extent that we are unable to do so, we may not be able to market our product candidates. Whether we achieve profitability or not will depend on our success in developing, manufacturing, and marketing our product candidates. We have 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 December 31, 2015, we had working capital of approximately \$(1,522,000) and stockholders' equity of approximately \$1,650,000. For the period from Collectar, Inc.'s inception in November 2002 until the business combination with Novelos Therapeutics, Inc. on April 8, 2011, and thereafter through December 31, 2015, the Company incurred aggregated net losses of approximately \$64,607,000. The net loss for the twelve months ended December 31, 2015 was approximately \$5,495,000. 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, 2015 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2015 financial statements, in their report, included an explanatory paragraph referring to our recurring losses since inception and expressing substantial doubt in our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our ability to continue as a going concern depends on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

At the present time, we have limited research, development or manufacturing capabilities within our facilities. Our manufacturing facility in Madison, Wisconsin has capacity to supply drug product for Phase 2 studies of CLR 131. The company would need to expand internal capacity for a Phase 3 study, or engage a third party 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**

**Six of our stockholders beneficially own approximately 51 % of our outstanding common stock, which limits the influence of other stockholders.**

As of March 7, 2016, approximately 51 % of our outstanding common stock is beneficially owned by six stockholders. The interests of these stockholders may differ from those of other stockholders. These stockholders will likely continue to have the ability to significantly affect the outcome of all corporate actions requiring stockholder approval, including the following actions:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Item 2. Properties.**

We lease office, laboratory and manufacturing space in Madison, Wisconsin. The space consists of approximately 19,500 square feet and is rented for approximately \$13,400 per month under an agreement that expires on September 14, 2016. The lease may be renewed for two-year periods through 2024 with an increase of 3% in annual rent. We believe that our present facilities are adequate to meet our current needs. If new or additional production space is required, we believe that adequate facilities are available at competitive prices, but may require significant investment in leasehold improvements.

**Item 3. Legal Proceedings.**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.****MARKET FOR COMMON EQUITY****Market Information**

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

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

<b>Fiscal Year 2015</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 32.90	\$ 21.50
Second Quarter	34.90	25.00
Third Quarter	38.90	18.00
Fourth Quarter	22.30	6.20

  

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

On March 7, 2016 there were 359 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.

**Equity compensation plans**

During 2015, we issued 37,500 options to our Chief Executive Officer that were not issued pursuant to our 2015 Stock Incentive Plan. These options vest annually over four years and expire ten years after the date of grant. For all option issuances, the option price per share is not less than the fair market value of our common stock on the date of grant.

The following table provides information as of December 31, 2015 regarding shares authorized for issuance under our equity compensation plans, including individual compensation arrangements.

### Equity compensation plan information

Plan category	Number of shares to be issued upon exercise of outstanding options, warrants and rights (#)	Weighted-average exercise price of outstanding options, warrants and rights (\$)	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a)) (#)
	(a)	(b)	(c)
Equity compensation plans approved by stockholders	33,416	\$ 139.80	106,577
Equity compensation plans not approved by stockholders	37,500	\$ 26.40	—
<b>Total</b>	<b>70,916</b>	<b>\$ 79.80</b>	<b>106,577</b>

#### Item 6. Selected Financial Data.

Not applicable.

#### Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

##### Forward-Looking Statements

This annual report on Form 10-K includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those disclosed in the forward-looking statements we make. These important factors include our significant accounting estimates and the risk factors set forth above under the caption "Risk Factors". Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this annual report.

##### 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 announced performance results from the first patient cohort in January 2016, and we initiated 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 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.



## Results of Operations

**Research and development expense.** Research and development expense consists of costs incurred in identifying, developing and testing, and manufacturing product candidates, which primarily include salaries and related expenses for personnel, costs of our research and manufacturing facility, cost of manufacturing materials and contract manufacturing fees paid to contract research organizations, fees paid to medical institutions for clinical trials, and costs to secure intellectual property. The Company analyzes its research and development expenses based on four categories as follows: clinical projects, preclinical projects, chemistry and manufacturing costs, and general fixed and overhead costs that are not allocated to the functional project costs, including personnel costs, facility costs, related overhead costs and patent costs.

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

### *Twelve Months Ended December 31, 2015 and 2014*

**Research and Development.** Research and development expense for the year ended December 31, 2015 was approximately \$5,159,000 (composed of approximately \$1,109,000 in clinical project costs, \$26,000 of preclinical project costs, \$540,000 of manufacturing and related costs and \$3,484,000 in general unallocated research and development costs) compared to approximately \$5,964,000 (composed of approximately \$1,162,000 in clinical project costs, \$291,000 of preclinical project costs, \$735,000 of manufacturing and related costs and \$3,776,000 in general unallocated research and development costs) for 2014. The overall decrease in research and development of approximately \$806,000, or 14% was primarily related to reductions in lab supplies expense and contract research related to the closure of the glioma trial of approximately \$612,000; reduced IND-enabling expenditures of approximately \$94,000 in 2015 as compared to 2014; and a reduction in costs related to the SBIR reimbursement of approximately \$71,000.

**General and Administrative.** General and administrative expense for the year ended December 31, 2015 was approximately \$3,395,000 compared to approximately \$3,705,000 in 2014. The \$309,000, or 8%, decrease in general and administrative costs was primarily related to reductions in salaries and stock-based compensation as a result of the restructuring in the third quarter of approximately \$425,000, partially offset by employee relocation expenses of approximately \$100,000.

**Restructuring Costs.** The Company recorded approximately \$204,000 for restructuring costs in 2015, as compared to \$222,000 in 2014. These expenses related primarily to the elimination of certain personnel positions.

**Gain on Derivative Warrants.** We recorded a gain on derivative warrants of approximately \$3,668,000 in 2015 and \$2,285,000 in 2014. These amounts represent the change in fair value (resulting primarily from changes in the Company's stock price as well as a reduction in term), during the respective period, of outstanding warrants which are classified as liabilities because they contain a certain type of cash settlement provision or a "down-round" anti-dilution provision whereby the number of shares for which the warrants are exercisable and/or the exercise price of the warrants is subject to change in the event of certain issuances of stock at prices below the then-effective exercise prices of the warrants.

**Loss on Issuance of Derivative Warrants.** A charge of approximately \$404,000 was recorded in the year ended December 31, 2015, which represents the amount by which the initial fair value of warrants issued in connection with the October 2015 Public Offering (see Note 8 to the financial statements) exceeded the net proceeds received from the offering. These warrants are classified as derivative liabilities because they include "down-round" anti-dilution protection. We had no such expense in the year ended December 31, 2014.

**Interest expense, net.** Interest expense, net, for the year ended December 31, 2015 was approximately \$1,000, as compared to approximately \$446,000 for the year ended December 31, 2014. The decrease in 2015 was due to the approximately \$254,000 of non-cash interest expense related to the accretion of the discount on convertible debentures in 2014, approximately \$172,000 of interest expense related to the convertible debentures issued in February 2014, and approximately \$3,000 related to the August 2014 bridge notes. In 2015 the Company had approximately \$4,000 of interest related to the Company's outstanding debt owed to the Wisconsin Department of Commerce, as compared to \$17,000 in 2014. In 2015, this interest expense was largely offset by interest income from the Company's cash equivalents.

## Liquidity and Capital Resources

We have financed our operations since inception primarily through the sale of equity securities and securities convertible into equity securities. As of December 31, 2015, we had approximately \$3,858,000 in cash and cash equivalents. On October 1, 2015, the Company completed a registered direct offering of 101,727 shares of our common stock and Series B pre-funded warrants to purchase an aggregate of 48,273 shares of our common stock at an offering price of \$22.00 per share (collectively, the “2015 Registered Offering”).

In a concurrent private placement (the “2015 Private Placement” and, together with the 2015 Registered Offering, the “2015 Offerings”), the Company issued a Series A warrant (the “Series A Warrants” and, together with the Shares and the Pre-Funded Warrants, the “Securities”) to purchase one share of our common stock for each share of common stock purchased or pre-funded in the 2015 Registered Offering. The Series A Warrants cover, in the aggregate, 150,000 shares of common stock and become exercisable six months following the date of issuance at an exercise price of \$28.30 per share and expire five years from the date they become exercisable. The 2015 Offerings resulted in gross proceeds of \$3,300,000 and net proceeds of approximately \$2,868,000 after deducting transaction costs. Additionally, the placement agent received a warrant to purchase up to 3,750 shares of our common stock at \$28.30 per share, the fair value of which was approximately \$61,000 at issuance and had no effect on stockholders’ equity. To date, including funds raised by Collectar, Inc., we have raised capital aggregating approximately \$146 million.

Under the terms of the Pre-Funded Warrants, if the Company issues shares of common stock or common stock equivalents at a purchase price (a “Dilutive Price”) less than the then-effective warrant share purchase price for the Pre-Funded Warrants, which is initially \$22.00 per share, the number of shares of Common Stock issuable upon the exercise of the Pre-Funded Warrants will be increased to equal (i) the product of the then-effective warrant share purchase price multiplied by the number of shares of Common Stock for which the Pre-Funded Warrants may be exercised, divided by (ii) the Dilutive Price. Following any such adjustment, the warrant share purchase price shall be adjusted to equal the Dilutive Price. Similarly, until the Company completes an equity financing with gross proceeds of at least \$10.0 million, if the Company issues shares of common stock or common stock equivalents for a purchase price less than the then-effective exercise price for the Series A Warrants, the exercise price of the Series A Warrants will be lowered to equal that lower price.

In connection with the entry into the purchase agreement, the Company and the purchasers entered into a registration rights agreement (the “Registration Rights Agreement”), which required the Company to file a registration statement on Form S-3 to provide for the resale of the shares of Common Stock issuable upon the exercise of the Series A Warrants. The Company will also be required to file one or more registration statements from time to time to register the issuance or resale of any additional shares of Common Stock that may become issuable as a result of the Offerings. The Company will be obligated to use its commercially reasonable efforts to keep any registration statement effective until the earlier of (i) the date on which the shares of Common Stock subject to the registration statement may be sold without registration pursuant to Rule 144 under the Securities Act, or (ii) the date on which all of the shares of Common Stock subject to the registration statement have been sold under the registration statement or pursuant to Rule 144 under the Securities Act or any other rule of similar effect.

Due to the issuance of common stock at \$22.00 per share as part of this Registered Offering, the remaining outstanding warrants issued as part of the February 2013 Public Offering (see Notes 3 and 8) were adjusted to reflect the revised exercise price of \$22.00 each.

On February 6, 2014, we completed a private placement of convertible debentures and warrants for gross proceeds of \$4,000,000 (February 2014 Private Placement). On August 20, 2014, we completed an underwritten public offering of common stock and warrants to purchase common shares for gross proceeds of approximately \$13,500,000 (August 2014 Underwritten Offering); additionally, all holders of the debentures and warrants issued in the February 2014 private placement elected to participate in the August 2014 Underwritten Offering, resulting in the extinguishment of the February 2014 debentures and warrants in exchange for 110,969 shares of our common stock and warrants to purchase 110,969 shares of common stock at \$46.80 per share.

During the year ended December 31, 2015, approximately \$8,213,000 in cash was used in operations. During this period we reported a net loss of approximately 5,495,000. However, this loss included the following non-cash items: approximately \$447,000 in stock-based compensation, approximately \$404,000 for loss on issuance of derivative warrants, approximately \$363,000 in depreciation and amortization expense and approximately \$1,000 for loss on disposal of equipment; offset by a gain of approximately \$3,668,000 related to warrants that are classified as derivative instruments. After adjustment for these non-cash items, changes in working capital used cash of \$266,000, which was the result of \$258,000 from the timing of payments of accounts payable and accrued expenses and a reduction in prepaid expenses of approximately \$9,000.

During the year ended December 31, 2015, we purchased approximately \$58,000 in fixed assets.

The accompanying consolidated financial statements have been prepared on a basis that assumes that we will continue as a going concern and that contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. We have incurred losses since inception in devoting substantially all of our efforts toward research and development and have an accumulated deficit of approximately \$65,000,000 at December 31, 2015. During the year ended December 31, 2015, we generated a net loss of approximately \$5,495,000 and we expect that we will continue to generate operating losses for the foreseeable future. At December 31, 2015, our consolidated cash balance was approximately \$3,858,000. We believe this cash balance is adequate to fund budgeted operations into second quarter 2016. Our ability to execute our operating plan beyond that time depends on our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. We have, in the past, successfully completed multiple rounds of financings, but, due to market conditions and other factors, including our development stage, the proceeds we have been able to secure have been less than the amounts we sought to obtain. We plan to actively pursue all available financing alternatives; however, we have not entered into negotiations for any such transactions and there can be no assurance that we will obtain the necessary funding. Other than the uncertainties regarding our ability to obtain additional funding and the repayment of convertible debt obligations, there are currently no known trends, demands, commitments, events or uncertainties that are likely to materially affect our liquidity.

### **Critical Accounting Policies and Estimates**

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States, or GAAP, requires management to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, as well as the reported amounts of revenues and expenses during the periods presented. Management bases its estimates and judgments on historical experience, knowledge of current conditions and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates. We review these estimates and assumptions periodically and reflect the effects of revisions in the period that they are determined to be necessary.

We believe that the following accounting policies reflect our more significant judgments and estimates used in the preparation of our financial statements.

*Accrued Liabilities.* As part of the process of preparing financial statements, we are required to estimate accrued liabilities. This process involves identifying services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated expenses for which we accrue include: contract service fees such as amounts paid to clinical research organizations and investigators in conjunction with clinical trials; fees paid to vendors in conjunction with the manufacturing of clinical materials; and professional service fees, such as for lawyers and accountants. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred, or we over- or underestimate the level of services performed or the costs of such services, our reported expenses for such period would be too high or too low. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often determined based on subjective judgments. We make these judgments based on the facts and circumstances known to us, in accordance with GAAP.

*Goodwill.* As of December 31, 2015 and 2014 there was approximately \$1,675,000 of goodwill recorded on the balance sheet. We are required to evaluate goodwill for impairment annually, or whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. The Company evaluates goodwill for impairment annually in the fourth fiscal quarter and additionally on an interim basis if an event occurs or circumstances change such as a decline in the Company's stock price, or a material adverse change in the business climate, which would more likely than not reduce the fair value of the reporting unit below its carrying amount.

*Long-Lived Assets.* With the exception of goodwill, our only long-lived assets are property and equipment. The Company periodically evaluates long-lived assets for potential impairment. Whenever events or circumstances change, an assessment is made as to whether there has been impairment to the value of long-lived assets by determining whether projected undiscounted cash flows generated by the applicable asset exceed its net book value as of the assessment date.

*Stock-based Compensation.* We account for stock-based compensation by measuring the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award, using the Black-Scholes option-pricing model. The cost of non-performance based awards is recognized over the period during which an employee is required to provide service in exchange for the award, the requisite service period (usually the vesting period). For stock options with performance-based vesting provisions, recognition of compensation expense commences if and when the achievement of the performance criteria is deemed probable and is recognized over the relevant performance period. We account for transactions in which services are received from non-employees in exchange for equity instruments based on the fair value of such services received or of the equity instruments issued (using the Black-Scholes option-pricing model) whichever is more reliably measured. The measurement of stock-based compensation for non-employees is subject to periodic adjustments as the options vest, and the expense is recognized over the period during which a non-employee is required to provide services for the award (usually the vesting period).

Accounting for equity instruments granted or sold by us under accounting guidance requires fair-value estimates of the equity instrument granted or sold. If our estimates of the fair value of these equity instruments are too high or too low, our expenses may be over- or understated. For equity instruments granted or sold in exchange for the receipt of goods or services, we estimate the fair value of the equity instruments based on consideration of factors that we deem to be relevant at that time.

*Derivative Warrants.* Certain warrants to purchase common stock that do not meet the requirements for classification as equity, in accordance with the Derivatives and Hedging Topic of the FASB ASC, are classified as liabilities on our balance sheet. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. These warrants are considered derivative instruments as the agreements allow cash settlement in certain circumstances or contain either "down-round" provisions whereby the number of shares for which the warrants are exercisable and/or the exercise price of the warrants is subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. The primary underlying risk exposure pertaining to the warrants is the change in fair value of the underlying common stock. Such financial instruments are initially recorded at fair value, or relative fair value when issued with other instruments, with subsequent changes in fair value recorded as a component of gain or loss on derivatives in each reporting period.

The fair value of the outstanding derivative warrants is estimated as of a reporting date. Where an active market for the warrant exists, fair value is based on the market value. Where no active market exists, the Company principally uses a modified option-pricing model together with assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rates, volatility, contractual term of the warrants, projected future financings and dividend rates in estimating fair value for the warrants considered to be derivative instruments. We estimate volatility based on an average of our historical volatility and volatility estimates of publicly held drug development companies with similar market capitalizations. If our estimates of the fair value of these derivative warrants are too high or too low, our expenses may be over- or understated.

*Fair value measurements.* We account for certain financial assets at fair value, defined as the price that would be received to sell an asset or pay to transfer a liability (i.e., exit price) in the principal, most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. As such, fair value is a market-based measurement that is determined based on assumptions that a market participant would use in pricing an asset or liability. If management made different assumptions or judgments, material differences in measurements of fair value could occur.

*Contingencies.* From time to time, we may become involved in legal disputes regarding our products in development, intellectual property rights, stockholder claims or other matters. We assess each matter to determine if a contingent liability should be recorded. In making this assessment, we may consult, depending on the nature of the matter, with external legal counsel and technical experts. Based on the information we obtain, combined with our judgment regarding all the facts and circumstances of each matter, we determine whether it is probable that a contingent loss may be incurred and whether the amount of such loss can be reasonably estimated. Should a loss be probable and reasonably estimable, we record a loss. In determining the amount of the loss, we consider advice received from experts in the specific matter, current status of legal proceedings, if any, prior case history and other factors. Should the judgments and estimates made by us be incorrect, we may need to record additional contingent losses that could materially adversely impact the results of operations and financial conditions.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

Not applicable.

**Item 8. Financial Statements.**

**FINANCIAL STATEMENTS**

**INDEX TO FINANCIAL STATEMENTS FOR COLLECTAR BIOSCIENCES, INC.**

	<u>Page</u>
<a href="#"><u>Report of Independent Registered Public Accounting Firm</u></a>	37
<a href="#"><u>Consolidated Balance Sheets at December 31, 2015 and 2014</u></a>	38
<a href="#"><u>Consolidated Statements of Operations for the Years Ended December 31, 2015 and 2014</u></a>	39
<a href="#"><u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2015 and 2014</u></a>	40
<a href="#"><u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2015 and 2014</u></a>	41
<a href="#"><u>Notes to Consolidated Financial Statements</u></a>	42

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders  
Cellecstar Biosciences, Inc.

We have audited the accompanying consolidated balance sheets of Cellecstar Biosciences, Inc. (a Delaware corporation) and subsidiary (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cellecstar Biosciences, Inc. and subsidiary as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred losses since its inception and, as of December 31, 2015 has an accumulated deficit of \$64,606,700. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ GRANT THORNTON LLP

Appleton, Wisconsin  
March 11, 2016

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

	<u>December 31, 2015</u>	<u>December 31, 2014</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 3,857,791	\$ 9,422,627
Restricted cash	55,000	55,000
Prepaid expenses and other current assets	267,783	220,611
Total current assets	<u>4,180,574</u>	<u>9,698,238</u>
<b>FIXED ASSETS, NET</b>	1,728,471	2,033,944
<b>GOODWILL</b>	1,675,462	1,675,462
<b>OTHER ASSETS</b>	11,872	11,872
<b>TOTAL ASSETS</b>	<u>\$ 7,596,379</u>	<u>\$ 13,419,516</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Current maturities of notes payable	\$ 243,590	\$ 119,923
Accounts payable and accrued liabilities	675,924	933,988
Derivative liability	4,781,082	5,176,915
Capital lease obligations, current portion	2,449	2,180
Total current liabilities	<u>5,703,045</u>	<u>6,233,006</u>
<b>LONG-TERM LIABILITIES:</b>		
Notes payable, less current maturities	86,632	330,077
Deferred rent	148,924	147,774
Capital lease obligations, less current portion	7,975	11,126
Total long-term liabilities	<u>243,531</u>	<u>488,977</u>
Total liabilities	<u>5,946,576</u>	<u>6,721,983</u>
<b>COMMITMENTS AND CONTINGENCIES (Notes 12 and 13)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock, \$0.00001 par value; 7,000 shares authorized; none issued and outstanding as of December 31, 2015 and 2014	—	—
Common stock, \$0.00001 par value; 40,000,000 shares authorized; 858,140 and 756,276 shares issued and outstanding at December 31, 2015 and 2014, respectively	9	8
Additional paid-in capital	66,256,494	65,809,195
Accumulated deficit	(64,606,700)	(59,111,670)
Total stockholders' equity	<u>1,649,803</u>	<u>6,697,533</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 7,596,379</u>	<u>\$ 13,419,516</u>

*See report of independent registered public accounting firm and accompanying notes to the consolidated financial statements.*



**CELLECTAR BIOSCIENCES, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>Year Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>COSTS AND EXPENSES:</b>		
Research and development	\$ 5,158,874	\$ 5,964,453
General and administrative	3,395,360	3,704,676
Restructuring costs	203,631	221,816
Total costs and expenses	8,757,865	9,890,945
<b>LOSS FROM OPERATIONS</b>	<b>(8,757,865)</b>	<b>(9,890,945)</b>
<b>OTHER INCOME (EXPENSE):</b>		
Gain on revaluation of derivative warrants	3,667,826	2,285,157
Loss on issuance of derivative warrants	(404,150)	—
Interest expense, net	(841)	(446,314)
Total other income, net	3,262,835	1,838,843
<b>NET LOSS</b>	<b>\$ (5,495,030)</b>	<b>\$ (8,052,102)</b>
<b>BASIC AND DILUTED NET LOSS PER COMMON SHARE</b>	<b>\$ (7.03)</b>	<b>\$ (17.53)</b>
<b>SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS PER COMMON SHARE</b>	<b>781,975</b>	<b>459,266</b>

*See report of independent registered public accounting firm and accompanying notes to the consolidated financial statements.*

**CELLECTAR BIOSCIENCES, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Amount			
BALANCE AT DECEMBER 31, 2013	286,974	\$ 3	\$ 52,759,115	\$ (51,059,568)	\$ 1,699,550
Issuance of common stock and warrants, net of issuance costs	358,333	4	11,877,139	—	11,877,143
Fair value of warrants issued in connection with sale of common stock and recorded as a derivative liability	—	—	(4,102,709)	—	(4,102,709)
Issuance of common stock and warrants to extinguish convertible debentures and accrued interest	110,969	1	4,172,434	—	4,172,435
Stock-based compensation	—	—	850,350	—	850,350
Relative fair value of warrants issued with debentures	—	—	254,024	—	254,024
Cash paid in lieu of fractional shares in reverse stock split	—	—	(1,158)	—	(1,158)
Net loss	—	—	—	(8,052,102)	(8,052,102)
<b>BALANCE AT DECEMBER 31, 2014</b>	<b>756,276</b>	<b>8</b>	<b>65,809,195</b>	<b>(59,111,670)</b>	<b>6,697,533</b>
Issuance of common stock and warrants, net of issuance costs	101,727	1	2,867,999	—	2,868,000
Fair value of warrants issued in connection with sale of common stock and recorded as a derivative liability, net of loss on issuance	—	—	(2,868,000)	—	(2,868,000)
Stock-based compensation	—	—	447,300	—	447,300
Cashless option exercise	137	—	—	—	—
Net loss	—	—	—	(5,495,030)	(5,495,030)
<b>BALANCE AT DECEMBER 31, 2015</b>	<b>858,140</b>	<b>\$ 9</b>	<b>\$ 66,256,494</b>	<b>\$ (64,606,700)</b>	<b>\$ 1,649,803</b>

*See report of independent registered public accounting firm and accompanying notes to the consolidated financial statements.*

**CELLECTAR BIOSCIENCES, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Year Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (5,495,030)	\$ (8,052,102)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	362,502	367,197
Stock-based compensation	447,300	850,350
Non-cash interest expense related to convertible debt	—	426,458
Loss on disposal of fixed assets	1,441	2,269
Gain on revaluation of derivative warrants	(3,667,826)	(2,285,157)
Loss on issuance of derivative warrants	404,150	—
Changes in:		
Prepaid expenses and other current assets	(8,603)	74,076
Accounts payable and accrued liabilities	(258,064)	(228,110)
Deferred rent	1,150	4,540
Cash used in operating activities	(8,212,980)	(8,840,479)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(58,470)	(29,569)
Cash used in investing activities	(58,470)	(29,569)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of convertible notes	—	4,000,000
Proceeds from issuance of notes payable	—	617,500
Payment of notes payable	—	(617,500)
Payments on capital lease obligations	(2,882)	(1,694)
Reverse stock split fractional shares	—	(1,158)
Proceeds from issuance of common stock and warrants	3,300,000	12,395,965
Cash paid for issuance costs	(432,157)	(518,822)
Payments on long-term obligations	(119,778)	—
Deferred financing costs	(38,569)	—
Cash provided by financing activities	2,706,614	15,874,291
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>(5,564,836)</b>	<b>7,004,243</b>
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<b>9,422,627</b>	<b>2,418,384</b>
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 3,857,791</b>	<b>\$ 9,422,627</b>
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION</b>		
Exchange of debentures and accrued interest for common stock	\$ —	\$ 4,172,435
Fair value of warrants issued	\$ 3,272,000	\$ 4,102,709
Relative fair value of warrants issued with debentures	\$ —	\$ 254,024
Asset acquired by the issuance of a capital lease	\$ —	\$ 13,306
Cash paid for interest expense	\$ 45,542	\$ 3,156

*See report of independent registered public accounting firm and accompanying notes to the consolidated financial statements.*

**CELLECTAR BIOSCIENCES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. NATURE OF BUSINESS, ORGANIZATION AND GOING CONCERN**

The Company is a biopharmaceutical company developing compounds for the treatment and imaging of cancer. Prior to February 11, 2014, the name of the Company was Novelos Therapeutics, Inc. (“Novelos”). On April 8, 2011, Novelos entered into a business combination (the “Acquisition”) with Collectar, Inc., a privately held Wisconsin corporation that designed and developed products to detect, treat and monitor a wide variety of human cancers.

References in these financial statements and notes to “Collectar, Inc.” relate to the activities and financial information of Collectar, Inc. prior to the Acquisition, references to “Novelos” relate to the activities and financial information of Novelos prior to the Acquisition and references to “Collectar Bio” or “the Company” or “we” or “us” or “our” relate to the activities and obligations of the combined Company following the Acquisition.

The Company’s headquarters are located in Madison, Wisconsin.

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

The accompanying financial statements have been prepared on a basis that assumes that the Company will continue as a going concern and that contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has incurred losses since inception in devoting substantially all of its efforts toward research and development and has an accumulated deficit of approximately \$65,000,000 at December 31, 2015. During the year ended December 31, 2015, the Company generated a net loss of approximately \$5,495,000 and the Company expects that it will continue to generate operating losses for the foreseeable future.

The Company believes that its cash balance at December 31, 2015 is adequate to fund operations at budgeted levels into second quarter 2016. The Company’s ability to execute its operating plan beyond second quarter 2016 depends on its ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. The Company plans to continue to actively pursue financing alternatives, but there can be no assurance that it will obtain the necessary funding. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The accompanying consolidated financial statements reflect the application of certain accounting policies, as described in this note and elsewhere in the accompanying notes to the consolidated financial statements. The consolidated financial statements as of and for the twelve months ended December 31, 2015 are presented on a consolidated basis.

**Principles of Consolidation** — The consolidated financial statements include the accounts of the Company and the accounts of its wholly-owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

**Use of Estimates** — The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenue and expenses and disclosure of contingent assets and liabilities. On an on-going basis, management evaluates its estimates including those related to unbilled vendor amounts, share-based compensation and derivative liability valuation. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from those estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

**Cash and Cash Equivalents** — All short-term investments purchased with original maturities of three months or less are considered to be cash equivalents.

**Restricted Cash** — The Company accounts for cash and claims to cash that are committed for other than current operations as restricted cash. Restricted cash at December 31, 2015 and 2014 consists of a certificate of deposit of \$55,000 required under the Company's lease agreement for its Madison, Wisconsin facility (see Note 12).

**Fixed Assets** — Property and equipment are stated at cost. Depreciation on property and equipment is provided using the straight-line method over the estimated useful lives of the assets (5 to 10 years). Due to the significant value of leasehold improvements purchased during the initial 3-year lease term and the economic penalty for not extending the building lease, leasehold improvements are depreciated over 17 years (their estimated useful life), which represents the full term of the lease, including all extensions. With the exception of goodwill, our only long-lived assets are property and equipment. The Company periodically evaluates long-lived assets for potential impairment. Whenever events or circumstances change, an assessment is made as to whether there has been impairment to the value of long-lived assets by determining whether projected undiscounted cash flows generated by the applicable asset exceed its net book value as of the assessment date. (see Note 5).

**Goodwill** — Intangible assets at December 31, 2015 and 2014 consist of goodwill. Goodwill is not amortized, but is required to be evaluated for impairment annually or whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. The Company evaluates goodwill for impairment annually in the fourth fiscal quarter and additionally on an interim basis if an event occurs or there is a change in circumstances, such as a decline in the Company's stock price or a material adverse change in the business climate, which would more likely than not reduce the fair value of the reporting unit below its carrying amount (see Note 4).

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

**Research and Development** — Research and development costs are expensed as incurred.

**Income Taxes** — Income taxes are accounted for using the liability method of accounting. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement basis and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some portion of the deferred tax assets will not be realized. Management has provided a full valuation allowance against the Company's gross deferred tax asset. Tax positions taken or expected to be taken in the course of preparing tax returns are required to be evaluated to determine whether the tax positions are "more likely than not" to be sustained by the applicable tax authority. Tax positions deemed not to meet a more-likely-than-not threshold would be recorded as tax expense in the current year. There were no uncertain tax positions that require accrual to or disclosure in the financial statements as of December 31, 2015 and 2014.

**Comprehensive Loss** — There were no components of comprehensive loss other than net loss in all of the periods presented.

**Fair Value of Financial Instruments** — The guidance under FASB ASC Topic 825, *Financial Instruments*, requires disclosure of the fair value of certain financial instruments. Financial instruments in the accompanying financial statements consist of cash equivalents, accounts payable and long-term obligations. The carrying amount of cash equivalents, and accounts payable approximate their fair value due to their short-term nature. The carrying value of long-term obligations, including the current portion, approximates fair value because the fixed interest rate approximates current market rates of interest available in the market.

**Derivative Instruments** — The Company generally does not use derivative instruments to hedge exposures to cash flow or market risks; however, certain warrants to purchase common stock that do not meet the requirements for classification as equity, in accordance with the Derivatives and Hedging Topic of the FASB ASC, are classified as liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. These warrants are considered derivative instruments because the agreements contain a certain type of cash settlement feature, contain “down-round” provisions whereby the number of shares for which the warrants are exercisable, and/or the exercise price of the warrants are subject to change in the event of certain issuances of stock at prices below the then-effective exercise price of the warrants. The number of shares issuable under such warrants was 7,475,751 and 5,494,388 at December 31, 2015 and 2014, respectively. The primary underlying risk exposures pertaining to the warrants and their related fair value is the change in fair value of the underlying common stock, the market price of traded warrants, and estimated timing and probability of future financings. Such financial instruments are initially recorded at fair value with subsequent changes in fair value recorded as a component of gain or loss on derivatives on the consolidated statements of operations in each reporting period. If these instruments subsequently meet the requirements for equity classification, the Company reclassifies the fair value to equity. At December 31, 2015 and 2014, these warrants represented the only outstanding derivative instruments issued or held by the Company.

**Concentration of Credit Risk** — Financial instruments that subject the Company to credit risk consist of cash and equivalents on deposit with financial institutions. The Company’s excess cash as of December 31, 2015 and 2014 is on deposit in an interest-bearing transaction account with a well-established financial institution. At times, such amounts may exceed the FDIC insurance limits. As of December 31, 2015, uninsured cash balances totaled approximately \$3,358,000.

**Development Stage Entity** — In June 2014, the FASB published an Accounting Standards Update 2014-10 (ASU 2014-10) that removed the development stage entity guidance under ASC 915 Development Stage Entities, thereby eliminating the financial reporting distinction between development stage entities and other reporting entities.

In addition, ASU 2014-10 eliminates the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows, and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage.

Presentation and disclosure requirements under ASC 915 are no longer required for the first annual period beginning after December 15, 2014, including interim periods therein. Earlier adoption of the new guidance for ASC 915 is permitted for any annual or interim period for which financial statements have not yet been issued for public business entities. Accordingly, the Company elected to adopt these changes effective with the filing of its second quarter Form 10-Q on August 4, 2014.

**Going Concern** — In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties About an Entity’s Ability to Continue as a Going Concern*. The standard requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date the financial statements are issued and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements.

ASU 2014-15 applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. The Company does not expect that the adoption of this standard will have a material effect on its financial statements.

**Leases** — In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) which supersedes FASB ASC Topic 840, Leases (Topic 840) and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company is currently evaluating the method of adoption and the impact of adopting ASU 2016-02 on its results of operations, cash flows and financial position.

### 3. FAIR VALUE

In accordance with Fair Value Measurements and Disclosures Topic of the FASB ASC 820, the Company groups its financial assets and financial liabilities generally measured at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value.

- Level 1: Input prices quoted in an active market for identical financial assets or liabilities.
- Level 2: Inputs other than prices quoted in Level 1, such as prices quoted for similar financial assets and liabilities in active markets, prices for identical assets and liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data.
- Level 3: Input prices quoted that are significant to the fair value of the financial assets or liabilities which are not observable or supported by an active market.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company issued warrants to purchase an aggregate of 82,500 common shares in a February 2013 public offering (the "February 2013 Public Offering Warrants"). On February 20, 2014, 27,500 of the February 2013 Public Offering Warrants expired. The remaining 55,000 warrants are classified within the Level 3 hierarchy. The 494,302 August 2014 Warrants are listed on the NASDAQ Capital Market under the symbol "CLRBW," however, there are certain periods where trading volume is low; therefore, they are classified within the Level 2 hierarchy.

As is discussed further in Note 8, on October 1, 2015, the Company issued Series A warrants to purchase an aggregate of 150,000 shares of our common stock at an exercise price of \$28.30 per share, and Series B pre-funded warrants to purchase an aggregate of 48,273 shares of our common stock at an offering price of \$22.00 per share. These warrants are classified within the Level 3 hierarchy.

The following tables set forth the Company's financial instruments carried at fair value using the lowest level of input applicable to each financial instrument as of December 31, 2015 and 2014:

	<b>December 31, 2015</b>			<b>Fair Value</b>
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	
<b>Liabilities:</b>				
February 2013 Public Offering Warrants	\$ —	\$ —	\$ 209,000	\$ 209,000
August 2014 Warrants	—	2,714,000	—	2,714,000
October 2015 Warrants	—	—	1,858,000	1,858,000
<b>Total</b>	<b>\$ —</b>	<b>\$ 2,714,000</b>	<b>\$ 2,067,000</b>	<b>\$ 4,781,000</b>
<b>December 31, 2014</b>				
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Fair Value</b>
<b>Liabilities:</b>				
Legacy Warrants	\$ —	\$ 999	\$ —	\$ 999
February 2013 Public Offering Warrants	—	—	1,127,500	1,127,500
August 2014 Warrants	—	4,048,416	—	4,048,416
<b>Total</b>	<b>\$ —</b>	<b>\$ 4,049,415</b>	<b>\$ 1,127,500</b>	<b>\$ 5,176,915</b>

In order to estimate the value of the February 2013 Public Offering Warrants considered to be derivative instruments, the Company uses a modified option-pricing model together with assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rates, volatility, the contractual term of the warrants, future financing requirements and dividend rates. The future financing estimates are based on the Company's estimates of anticipated cash requirements over the term of the warrants as well as the frequency of required financings based on its assessment of its historical financing trends and anticipated future events. Due to the nature of these inputs and the valuation technique utilized, these warrants are classified within the Level 3 hierarchy.

The following table summarizes the modified option-pricing assumptions used:

	<b>Year Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
Volatility	87.3-90.0%	100.0-115.0%
Risk-free interest rate	0.82-1.10%	1.07-2.63%
Expected life (years)	2.14-2.89	3.14-3.89
Dividend	0%	0%

In order to estimate the value of the October 2015 Warrants considered to be derivative instruments, the Company uses a modified option-pricing model together with assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, the contractual term of the warrants, future financing requirements and dividend rates. The future financing estimates are based on the Company's estimates of anticipated cash requirements over the term of the warrants as well as the frequency of required financings based on its assessment of its historical financing trends and anticipated future events. Due to the nature of these inputs and the valuation technique utilized, these warrants are also classified within the Level 3 hierarchy.

The following table summarizes the modified option-pricing assumptions used:

	<b>Year Ended</b>
	<b>December 31,</b>
	<b>2015</b>
Volatility	97.57%
Risk-free interest rate	1.70%
Expected life (years)	4.75
Dividend	0%

The following table summarizes the modified option-pricing assumptions used at the issuance date:

	<b>October 1, 2015</b>	
	<b>Series A</b>	<b>Series B</b>
Volatility	94.33%	97.57%
Risk-free interest rate	1.76%	1.76%
Expected life (years)	5.00	5.00
Dividend	0%	0%



The following table summarizes the changes in the fair market value of the Company's warrants which are classified within the Level 3 fair value hierarchy.

	<u>Year Ended December 31,</u>	
	<u>2015</u>	<u>2014</u>
Beginning fair value of warrants	\$ 1,127,500	\$ 3,355,000
Fair value of warrants issued in connection with the October 2015 offering	3,272,000	—
Gain on derivatives resulting from change in fair value	<u>(2,332,500)</u>	<u>(2,227,500)</u>
Ending fair value of warrants	<u>\$ 2,067,000</u>	<u>\$ 1,127,500</u>

To estimate the fair value of the August 2014 Warrants, the Company calculated the weighted average closing price for the trailing 10 trading day period that ended on the balance sheet date.

#### 4. GOODWILL

The Company has recorded goodwill of \$1,675,462 as described in Note 2. Goodwill represents the excess of the purchase price of an acquired business over the fair value of the underlying net tangible and intangible assets. There were no changes in goodwill during the years ended December 31, 2015 or 2014.

The Company is required to perform an annual impairment test related to goodwill which is performed in the fourth quarter of each year, or sooner if changes in circumstances suggest that the carrying value of an asset may not be recoverable. Due to the decline in our stock price during the fourth quarter, we experienced a significant decrease in the excess market capitalization over carrying value of the Company. As a result, we performed certain procedures to ensure that the quoted value of our stock was representative of the fair value. We reviewed the recent volume of trading, who was trading, price trends of industry peers, actual industry control premiums, and other factors. Through this analysis we concluded that the quoted value was reflective of the fair value of our stock and that the market capitalization was reliable for purposes of this test. Our analysis concluded that as of December 31, 2015, goodwill was not impaired.

#### 5. FIXED ASSETS

Fixed assets consisted of the following at December 31:

	<u>2015</u>	<u>2014</u>
Office and laboratory equipment	\$ 3,345,353	\$ 3,317,386
Computer software	4,000	4,000
Leasehold improvements	<u>2,324,672</u>	<u>2,324,672</u>
Total fixed assets	5,674,025	5,646,058
Less— accumulated depreciation and amortization	<u>(3,945,554)</u>	<u>(3,612,114)</u>
Fixed assets, net	<u>\$ 1,728,471</u>	<u>\$ 2,033,944</u>

For the years ended December 31, 2015 and 2014, the Company incurred approximately \$363,000 and \$367,000 of depreciation and amortization expense, respectively.

The decline in our stock price during the fourth quarter and continuing losses resulted in a triggering event that required an impairment review of non-current assets. We performed a step 1 impairment assessment of our non-current assets by preparing a probability weighted cash flow forecast. Such an analysis is highly subjective given, the risk associated with the development, approval and marketing of our products, and the extended time required to bring our products to market. As a result, we utilized low probability weighted assumptions to reflect the risk and extended time period before which positive cash flows will be generated. This analysis indicated that the un-discounted cash flows exceeded the carrying amount and no impairment was evident.

## 6. AGREEMENTS

### *2003 License Agreement with the University of Michigan*

In September 2003, Collectar, Inc. entered into an exclusive license agreement (the “U. Mich. License”) with the Regents of the University of Michigan, (“U. Mich.”) for the development, manufacture and marketing of products under several composition-of-matter patents in North America that expire in December 2016. The U. Mich. License expires upon the expiration of the last covered patent. The Company is responsible for an annual license fee of \$10,000 and is required to pay costs associated with the maintenance of the patents covered by the U. Mich. License. Additionally, the Company is required to make milestone payments of \$50,000 upon the filing of a New Drug Application (“NDA”) with the U.S. Food and Drug Administration (“FDA”) for a licensed product intended for use in a therapeutic or diagnostic application (such milestone fees may be deferred and paid within 12 months of the first commercial sale of such products) 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, provided that 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 the Company pay a royalty equal to 3% of net sales of any licensed products sold by the Company or its sub licensees for such licensed products, provided however if the sublicense fee payable to the Company 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 the Company is required to pay royalties to any third parties related to the sale of the licensed products. If the Company receives any revenue in consideration of rights to the licensed technology that is not based on net sales, excluding any funded research and development, the Company is required to pay U. Mich. 10% of amounts received. U. Mich. may terminate the license agreement if the Company ceases operations, fails to make any required payment under the license agreement, or otherwise materially breaches the U. Mich. License agreement, subject to the applicable notice and cure periods. To date, the Company has made all payments as they have become due, there have been no defaults under the U. Mich. License, nor has the Company been notified of a default by U. Mich. The Company may terminate the 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 either been completed or have been 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 Company incurred expenses of approximately \$500 for the reimbursement of patent maintenance fees to U. Mich. during the years ended December 31, 2015 and 2014. As of December 31, 2015 and 2014, all annual license fees have been paid in a timely manner.

### *2015 Material Transfer Arrangement with Pierre Fabre*

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

## 7. LONG-TERM NOTES PAYABLE

On September 15, 2010, Collectar, Inc. entered into certain loan agreements with the Wisconsin Department of Commerce (the “WDOC Notes”) to borrow a total of \$450,000. The WDOC Notes bear interest at 2% per annum beginning on the date of disbursement and allow for the deferral of interest and principal payments until April 30, 2015. In the event of default of payment, interest on the delinquent payment is payable at a rate equal to 12% per annum. Monthly payments of \$20,665 for principal and interest commenced on May 1, 2015 and continue for 23 equal installments with the final installment of any remaining unpaid principal and interest due on April 1, 2017.

As of December 31, 2015, notes payable mature as follows:

Years ending December 31,	
2016	\$ 243,590
2017	86,632
	<u>\$ 330,222</u>

The Company recorded interest expense related to these notes of approximately \$4,000 and \$17,000 for the years ended December 31, 2015 and 2014, respectively.

On February 6, 2014, the Company sold \$4,000,000 in aggregate principal of convertible debentures and warrants to purchase 400,000 shares of its common stock for an aggregate purchase price of \$4,000,000. The debentures and warrants were extinguished through the holders' participation in the public offering completed by the Company in August 2014 (see Note 8).

## 8. STOCKHOLDERS' EQUITY

### *October 2015 Registered Direct Offering*

On October 1, 2015, the Company completed a registered direct offering of 101,727 shares of our common stock and Series B pre-funded warrants to purchase an aggregate of 48,273 shares of our common stock at an offering price of \$22.00 per share (collectively, the "2015 Registered Offering").

In a concurrent private placement (the "2015 Private Placement" and, together with the 2015 Registered Offering, the "2015 Offerings"), the Company issued a Series A warrant (the "Series A Warrants" and, together with the Shares and the Pre-Funded Warrants, the "Securities") to purchase one share of our common stock for each share of common stock purchased or pre-funded in the Registered Offering. The Series A Warrants cover, in the aggregate, 150,000 shares of common stock and become exercisable six months following the date of issuance at an exercise price of \$28.30 per share and expire five years from the date they become exercisable. The Offerings resulted in gross proceeds of \$3,300,000 and net proceeds of approximately \$2,868,000. A charge of approximately \$404,000 was recorded in the year ended December 31, 2015 and represents the amount by which the initial fair value of warrants issued in connection with the October 2015 Public Offering exceeded the net proceeds received from the offering. The net proceeds of the offering were allocated first to the warrants based on their fair value with the residual to common stock. The actual net proceeds were less than the combined fair value of the warrants at the closing date. As a result the company recorded a loss on issuance of derivative warrants of \$404,150. Additionally, the placement agent received a warrant to purchase up to 3,750 shares of our common stock at \$28.30 per share, the fair value of which was approximately \$61,000 at issuance and had no effect on stockholders' equity.

Under the terms of the Pre-Funded Warrants, if the Company issues shares of common stock or common stock equivalents at a purchase price (a "Dilutive Price") less than the then-effective warrant share purchase price for the Pre-Funded Warrants, which is initially \$22.00 per share, the number of shares of Common Stock issuable upon the exercise of the Pre-Funded Warrants will be increased to equal (i) the product of the then-effective warrant share purchase price multiplied by the number of shares of Common Stock for which the Pre-Funded Warrants may be exercised, divided by (ii) the Dilutive Price. Following any such adjustment, the warrant share purchase price shall be adjusted to equal the Dilutive Price. Similarly, until the Company completes an equity financing with gross proceeds of at least \$10.0 million, if the Company issues shares of common stock or common stock equivalents for a purchase price less than the then-effective exercise price for the Series A Warrants, the exercise price of the Series A Warrants will be lowered to equal that lower price.

In connection with the entry into the purchase agreement, the Company and the purchasers entered into a registration rights agreement, which required the Company to file a registration statement on Form S-3 to provide for the resale of the shares of Common Stock issuable upon the exercise of the Series A Warrants. The Company will also be required to file one or more registration statements from time to time to register the issuance or resale of any additional shares of Common Stock that may become issuable as a result of the Offerings. The Company will be obligated to use its commercially reasonable efforts to keep any registration statement effective until the earlier of (i) the date on which the shares of Common Stock subject to the registration statement may be sold without registration pursuant to Rule 144 under the Securities Act, or (ii) the date on which all of the shares of Common Stock subject to the registration statement have been sold under the registration statement or pursuant to Rule 144 under the Securities Act or any other rule of similar effect.

#### ***2014 Reverse Stock Split and Recapitalization***

At the annual meeting of stockholders held on May 22, 2014, the Company's stockholders approved an amendment to our certificate of incorporation to effect a reverse split of the Company's common stock at a ratio between 1:10 to 1:20 in order to satisfy requirements for the listing of the Company's common stock on the NASDAQ Capital Market. In addition, the proposal approved by the stockholders provided that if the reverse split was effected, the number of shares of common stock that the Company is authorized to issue would be reduced from 150,000,000 to the greater of (A) 20,000,000 and (B) the number of shares equal to three (3) times the sum of the number of all shares of common stock outstanding and the number of shares of common stock issuable upon exercise or conversion of all outstanding options, warrants and convertible debt. The Company's stockholders further authorized the board of directors to determine the ratio at which the reverse split would be effected and the corresponding reduction in authorized shares of common stock by filing an appropriate amendment to the Company's certificate of incorporation. The board of directors authorized the ratio of the reverse split and corresponding reduction in authorized shares on June 6, 2014, and effective at the close of business on June 13, 2014, the certificate of incorporation was amended to effect a 1-for-20 reverse split of the Company's common stock (the "Listing Reverse Split") and reduce the number of authorized shares of common stock to 20,000,000 from 150,000,000. All share and per share numbers included in these consolidated financial statements give effect to the Listing Reverse Split.

#### ***August 2014 Underwritten Offering***

On August 20, 2014, the Company completed an underwritten public offering of 358,333 shares of its common stock and warrants to purchase 383,333 shares of its common stock at an exercise price of \$46.80 per share, expiring on August 20, 2019. The offering price was \$37.50 per common share and \$.10 per warrant, which resulted in gross proceeds of \$13,475,832 and net proceeds of \$11,877,143 after deducting transaction costs. The underwriter received a weighted average discount of approximately 6.4 percent on the underwritten securities. The underwriting discount, along with other legal and accounting costs associated with the offering totaling \$1,598,689, including those previously included as deferred issuance costs, was recorded as a reduction of the gross proceeds received. The underwriter also received warrants to purchase 9,699 shares of common stock at an exercise price of \$46.88 as compensation pursuant to the underwriting agreement. The fair value of the underwriter warrants was approximately \$275,000 at issuance and had no impact on stockholders' equity. The Company used the Black-Scholes option pricing model to value the warrants issued to the underwriter and applied assumptions that consider, among other variables, the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants. Assumptions used are generally consistent with those disclosed for stock-based compensation (see Note 9).

The warrant exercise price for all warrants issued as part of the August 2014 Underwritten Offering and the common stock issuable pursuant to such warrants is subject to adjustment only for stock dividends, stock splits and similar capital reorganizations so that the rights of the warrant holders after such events will be equivalent to the rights of the warrant holders prior to such events. As discussed in Note 1A above, since the warrants have a certain type of cash settlement feature, the Company has determined that these warrants should be classified as a derivative liability.

Due to the issuance of common stock at \$37.50 per share as part August 2014 Underwritten Offering, the remaining outstanding warrants issued as part of the February 2013 Public Offering, as well as the Legacy Warrants (see Note 3) were adjusted to reflect the revised exercise price of \$37.50 each.

As a result of the August 2014 Underwritten Offering, the Company's common stock and the warrants issued in the offering were listed on the NASDAQ Capital Market under the ticker symbols CLRB and CLRBW, respectively.

### *August 2014 Debenture Tender and Exchange*

In conjunction with the August 2014 Underwritten Offering, all of the debenture holders elected to participate in the offering of common stock and warrants at the combined offering price of \$37.60 per share. As a result, the \$4,000,000 principal amount of debentures and accrued interest of \$172,435 was extinguished in exchange for 110,969 shares of the Company's common stock and warrants to purchase 110,969 shares of common stock at \$46.80 per share.

### *Registration Rights*

In connection with securities purchase agreements entered into on April 8, 2011 with certain accredited investors, the Company is subject to certain registration requirements. The Company filed a registration statement with the SEC on July 17, 2012 covering the resale of 20,000 shares of common stock pursuant to the registration requirements and this registration statement was declared effective on July 26, 2012. The Company is required to keep the registration statement continuously effective under the Securities Act of 1933, as amended (the "Securities Act"), until the earlier of the date when all the registrable securities covered by the registration statement have been sold or such time as all the registrable securities covered by the registration statement can be sold under Rule 144 without any volume limitations. The Company will be allowed to suspend the use of the registration statement for not more than 30 consecutive days on not more than two occasions in any 12-month period (the "Allowed Delay"). If the Company suspends the use of the registration for longer than the Allowed Delay, it may be required to pay to the purchasers liquidated damages equal to 1.5% per month (pro-rated on a daily basis for any period of less than a full month) of the aggregate purchase price of the units purchased until the use of the registration statement is no longer suspended, not to exceed 5% of the aggregate purchase price. As of December 31, 2015, and through the date of this filing, the Company has not concluded that it is probable that damages will become due; therefore, no accrual for damages has been recorded.

Additionally, in connection with registered offerings of common stock and warrants during 2013, the Company has entered into certain securities purchase agreements which require the Company to use commercially reasonable efforts to keep the applicable registration statements effective for the issuance of shares of common stock pursuant to the exercise of warrants issued in the offering as long as the warrants remain outstanding.

### *Common Stock Warrants*

The following table summarizes information with regard to outstanding warrants to purchase common stock as of December 31, 2015.

<b>Offering</b>	<b>Number of Shares Issuable Upon Exercise of Outstanding Warrants</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
October 2015 Registered Offering <sup>(1)</sup>	150,000	\$ 28.30	April 1, 2021
October 2015 Private Placement <sup>(1)</sup>	48,273	\$ 22.00	October 1, 2020
October 2015 Offering – Placement Agent	3,750	\$ 28.30	October 1, 2020
August 2014 Public Offering <sup>(1)</sup>	504,001	\$ 46.80	August 20, 2019
February 2013 Public Offering <sup>(1)</sup>	55,000	\$ 22.00 <sup>(2)</sup>	February 20, 2018
February 2013 Public Offering – Placement Agents	3,850	\$ 125.00	February 4, 2018
November 2012 Private Placement	5,000	\$ 250.00	November 2, 2017
June 2012 Public Offering	14,907	\$ 250.00	June 13, 2017
December 2011 Underwritten Offering	46,241	\$ 120.00	December 6, 2016
April 2011 Private Placement	30,292	\$ 150.00	March 31, 2016
<b>Total</b>	<b>861,314</b>		

- (1) These warrants have a certain type of cash settlement feature or their exercise prices or the number of shares for which the warrant may be exercised are subject to adjustment for “down-rounds” and the warrants have been accounted for as derivative instruments as described in Note 3, with the exception of 9,699 warrants issued in August 2014.
- (2) Due to the issuance of common stock at \$22.00 per share as part of the October 2015 Registered Offering, the remaining outstanding warrants issued as part of the February 2013 Public Offering were adjusted to reflect the revised exercise price of \$22.00 each.

### **Reserved Shares**

The following shares were reserved for future issuance upon exercise of stock options and warrants:

	<b>December 31,</b>	
	<b>2015</b>	<b>2014</b>
Warrants	861,314	660,410
Stock options	70,916	71,947
Total number of shares reserved for future issuance	<u>932,230</u>	<u>732,357</u>

## **9. STOCK-BASED COMPENSATION**

*2015 Stock Incentive Plan.* The 2015 Stock Incentive Plan (the “2015 Plan”) was approved for a total of 70,000 shares of common stock and are authorized for issuance under the plan for grants of incentive or nonqualified stock options, rights to purchase restricted and unrestricted shares of common stock, stock appreciation rights and performance share grants. A committee of the board of directors determines exercise prices, vesting periods and any performance requirements on the date of grant, subject to the provisions of the Plan. Options are granted at or above the fair market value of the common stock at the grant date and expire on the tenth anniversary of the grant date. Vesting periods are generally between one and four years. Options granted pursuant to the Plan generally will become fully vested upon a termination event occurring within one year following a change in control, as defined. A termination event is defined as either termination of employment or services other than for cause or constructive termination of employees or consultants resulting from a significant reduction in either the nature or scope of duties and responsibilities, a reduction in compensation or a required relocation. The 2015 Plan replaces our 2006 Stock Incentive Plan (the “2006 Plan”). Awards will no longer be granted under the 2006 Plan; however, all outstanding awards under the 2006 Plan will remain in effect according to the terms of the 2006 Plan and the respective agreements relating to such awards. In addition, any shares that are currently available under the 2006 Plan and any shares underlying awards under the 2006 Plan which are forfeited, cancelled, reacquired by the Company or otherwise terminated will instead be added to the number of shares available for grant under the 2015 Plan. The 2015 Plan was approved by stockholders at our 2015 Annual Meeting of Stockholders. As of December 31, 2015, there are an aggregate of 106,577 shares available for future grants under the Plan.

*2006 Stock Option Plan.* Prior to the approval of the 2015 Stock Incentive Plan, option grants to directors and employees were made under the 2006 Plan. A total of 70,000 shares of common stock were authorized for issuance under the Plan for grants of incentive or nonqualified stock options, rights to purchase restricted and unrestricted shares of common stock, stock appreciation rights and performance share grants. A committee of the board of directors determined exercise prices, vesting periods and any performance requirements on the date of grant, subject to the provisions of the Plan. Options were granted at or above the fair market value of the common stock at the grant date and expire on the tenth anniversary of the grant date. Vesting periods were generally between one and four years. Options granted pursuant to the Plan generally will become fully vested upon a termination event occurring within one year following a change in control, as defined. A termination event is defined as either termination of employment or services other than for cause or constructive termination of employees or consultants resulting from a significant reduction in either the nature or scope of duties and responsibilities, a reduction in compensation or a required relocation.

## Accounting for Stock-Based Compensation

The following table summarizes amounts charged to expense for stock-based compensation related to employee and director stock option grants and recorded in connection with stock options granted to non-employee consultants:

	<b>Year Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
Employee and director stock option grants:		
Research and development	\$ 130,901	\$ 174,666
General and administrative	317,257	621,563
Restructuring costs	—	47,853
	<u>448,158</u>	<u>844,082</u>
Non-employee consultant stock option grants:		
Research and development	(858)	6,268
General and administrative	—	—
	<u>(858)</u>	<u>6,268</u>
Total stock-based compensation	<u>\$ 447,300</u>	<u>\$ 850,350</u>

## Assumptions Used In Determining Fair Value

*Valuation and amortization method.* The fair value of each stock award is estimated on the grant date using the Black-Scholes option-pricing model. The estimated fair value of employee stock options is amortized to expense using the straight-line method over the required service period which is generally the vesting period. The estimated fair value of the non-employee options is amortized to expense over the period during which a non-employee is required to provide services for the award (usually the vesting period).

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

*Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption.

*Expected term.* The expected term of stock options granted is based on an estimate of when options will be exercised in the future. The Company applied the simplified method of estimating the expected term of the options, as described in the SEC's Staff Accounting Bulletins 107 and 110, as the historical experience is not indicative of the expected behavior in the future. The expected term, calculated under the simplified method, is applied to groups of stock options that have similar contractual terms. Using this method, the expected term is determined using the average of the vesting period and the contractual life of the stock options granted. The Company applied the simplified method to non-employees who have a truncation of term based on termination of service and utilizes the contractual life of the stock options granted for those non-employee grants which do not have a truncation of service.

*Forfeitures.* The Company records stock-based compensation expense only for those awards that are expected to vest. A forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from initial estimates. An annual forfeiture rate of 2% and 0% was applied to all unvested options for employees and directors, respectively, during the periods ended December 31, 2015 and 2014. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest.

The following table summarizes weighted-average values and assumptions used for options granted to employees, directors and consultants in the periods indicated:

	<b>Year Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
Volatility	106%-107%	107%-109%
Risk-free interest rate	1.70%-1.95%	1.76%-1.83%
Expected life (years)	6	6
Dividend	0%	0%
Weighted-average exercise price	\$ 26.50	\$ 36.90
Weighted-average grant-date fair value	\$ 21.60	\$ 30.10

### Stock Option Activity

A summary of stock option activity is as follows:

	<b>Number of Shares Issuable Upon Exercise of Outstanding Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contracted Term in Years</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2013	63,466	\$ 180.70		
Granted	12,030	\$ 36.90		
Expired	(1,844)	\$ 241.90		
Forfeited	(1,706)	\$ 145.80		
Outstanding at December 31, 2014	71,946	\$ 155.90		
Granted	46,520	\$ 26.50		
Exercised	(833)	\$ 27.40		
Expired	(18,340)	\$ 241.80		
Forfeited	(28,377)	\$ 82.20		
Outstanding at December 31, 2015	70,916	79.80		
Vested, December 31, 2015	23,683	\$ 180.70	5.70	\$ —
Unvested, December 31, 2015	47,233	\$ 29.20	9.35	\$ —
Exercisable at December 31, 2015	23,683	\$ 180.70	5.70	\$ —

Exercise prices for all grants made during the twelve months ended December 31, 2015 and 2014 were equal to or greater than the market value of the Company's common stock on the date of grant. The aggregate intrinsic value of options outstanding is calculated based on the positive difference between the estimated per-share fair value of common stock at the end of the respective period and the exercise price of the underlying options. There were 833 options exercised in 2015. Shares of common stock issued upon the exercise of options are from authorized but unissued shares.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2015 and 2014 was \$21.60 and \$30.10, respectively. The total fair value of shares vested during the years ended December 31, 2015 and 2014 was \$449,649 and \$936,310, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2015 was \$125.70 and \$23.90, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2014 was \$145.50 and \$46.70, respectively.

The weighted average grant date fair value of options expired during the years ended December 31, 2015 and December 31, 2014 was \$126.10 and \$196.21, respectively. The weighted average grant date fair value of options forfeited during the years ended December 31, 2015 and December 31, 2014 was \$47.09 and \$58.70, respectively. The number of options vested during the years ended December 31, 2015 and December 31, 2014 was 9,466 and 10,912, respectively. The number of options unvested at January 1, 2015 and January 1, 2014 was 38,555 and 39,144, respectively. The weighted average grant date fair value of options unvested at January 1, 2015 and January 1, 2014 was \$49.52 and \$65.99, respectively.



As of December 31, 2015, there was \$964,935 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, the Company expects to recognize \$376,553, \$292,060, \$206,132 and \$90,190 during 2016, 2017, 2018 and 2019 respectively. The Company expects options to purchase 46,404 shares to vest in the future.

## 10. INCOME TAXES

	<u>2015</u>	<u>2014</u>
Tax provision (benefit)		
Current		
Federal	\$ —	\$ —
State	—	—
Total current	<u>—</u>	<u>—</u>
Deferred		
Federal	(3,105,641)	(3,868,524)
State	42,562	810,914
Total deferred	<u>(3,063,079)</u>	<u>(3,057,610)</u>
Change in valuation allowance	3,063,079	3,057,610
Total	<u>\$ —</u>	<u>\$ —</u>

Deferred tax assets consisted of the following at December 31:

	<u>2015</u>	<u>2014</u>
Deferred tax assets		
Federal net operating loss	\$ 32,565,906	\$ 29,246,965
Federal research and development tax credit carryforwards	2,858,628	2,689,775
State net operating loss	1,812,722	1,813,954
State research and development tax credit carryforwards	806,568	753,818
Capitalized research and development expenses	9,883,932	10,609,942
Stock-based compensation expense	1,993,664	1,758,909
Charitable contributions carryforwards	340	—
Intangible assets	253,971	313,412
Charitable contribution carryforwards	—	—
Accrued liabilities	35,332	35,392
Total deferred tax assets	<u>50,211,063</u>	<u>47,222,167</u>
Deferred tax liabilities		
Depreciable assets	(171,602)	(245,785)
Total deferred tax liabilities	<u>(171,602)</u>	<u>(245,785)</u>
Net deferred tax assets	<u>50,039,461</u>	<u>46,976,382</u>
Less— valuation allowance	(50,039,461)	(46,976,382)
Total deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

A reconciliation of income taxes computed using the U.S. federal statutory rate to that reflected in operations is as follows:

	<b>Year ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
Income tax benefit using U.S. federal statutory rate	34.00%	34.00%
State income taxes	(0.50)%	(6.65)%
Permanent items	23.18%	9.62%
Change in valuation allowance	(55.76)%	(37.98)%
Other	(0.92)%	1.01%
Total	<u>—%</u>	<u>—%</u>

As of December 31, 2015, the Company had federal and state net operating loss carryforwards (“NOLs”) of approximately \$95,782,000 and \$34,530,000 respectively, which expire in 2018 through 2034 and in 2015 through 2034, respectively. In addition, the Company has federal and state research and development and investment tax credits of approximately \$2,859,000 and \$1,222,000, respectively which expire in 2018 through 2033 and in 2018 through 2028, respectively. The amount of NOLs and tax credit carryforwards which may be utilized annually in future periods will be limited pursuant to Section 382 of the Internal Revenue Code as a result of substantial changes in the Company’s ownership that have occurred or that may occur in the future. The Company has not quantified the amount of such limitations.

Because of the Company’s limited operating history, continuing losses and uncertainty associated with the utilization of the NOLs in the future, management has provided a full allowance against the gross deferred tax asset.

The Company did not have unrecognized tax benefits or accrued interest and penalties at any time during the years ended December 31, 2015 or 2014, and does not anticipate having unrecognized tax benefits over the next twelve months. The Company is subject to audit by the IRS and state taxing authorities for tax periods commencing January 1, 2009. Additionally, the Company may be subject to examination by the IRS for years beginning prior to January 1, 2009 as a result of its NOLs. However, any adjustment related to these periods would be limited to the amount of the NOL generated in the year(s) under examination.

#### **11. NET LOSS PER SHARE**

Basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing net loss, as adjusted, by the sum of the weighted average number of shares of common stock and the dilutive potential common stock equivalents then outstanding. Potential common stock equivalents consist of stock options and warrants. Since there is a net loss attributable to common stockholders for the years ended December 31, 2015 and 2014, the inclusion of common stock equivalents in the computation for those periods would be antidilutive. Accordingly, basic and diluted net loss per share is the same for all periods presented.

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

	<b>Year Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
Warrants	<u>861,314</u>	<u>660,410</u>
Stock options	<u>70,916</u>	<u>71,947</u>

## 12. COMMITMENTS

### *Real Property Leases*

On September 5, 2007, Collectar, Inc. entered into a 36-month lease for office and manufacturing space, commencing September 15, 2007. The lease provides for the option to extend the lease under its current terms for seven additional two-year terms. Rent was \$8,050 per month for the first year and then escalates by 3% per year for the duration of the term including any lease extension terms. The lease also requires the payment of monthly rent of \$1,140 for approximately 3,400 square feet of expansion space. The monthly rent for the expansion space is fixed until such time as the expansion space is occupied at which time the rent would increase to the current per square foot rate in effect under the original lease terms. The Company is responsible for certain building-related costs such as property taxes, insurance, and repairs and maintenance. Rent expense is recognized on a straight-line basis and accordingly the difference between the recorded rent expense and the actual cash payments has been recorded as deferred rent as of each balance sheet date. Due to the significant value of leasehold improvements purchased during the initial 3-year lease term and the economic penalty for not extending the building lease, straight-line rent expense and the associated deferred rent has been calculated over 17 years, which represents the full term of the lease, including all extensions.

The Company is required to remove certain alterations, additions and improvements upon termination of the lease that altered a portion of the rentable space. In no event shall the cost of such removal, at commercially reasonable rates, paid by the Company exceed \$55,000 (the "Capped Amount"). Any amount in excess of the Capped Amount shall be the obligation of the landlord. The Company is required to maintain a certificate of deposit equal to the Capped Amount during the term of the lease, which amount is shown as restricted cash on the accompanying balance sheets.

In February 2014, the Company exercised its option to extend the lease for an additional two-year term that commenced on September 15, 2014 and continues through September 14, 2016.

As of December 31, 2015, future minimum lease payments under this non-cancelable lease are approximately as follows:

Years ending December 31,	
2016	\$ 88,000
Thereafter	—
	<u>\$ 88,000</u>

Rent expense was approximately \$142,000 and \$180,000 for the years ended December 31, 2015 and 2014, respectively.

## 13. CONTINGENCIES

The Company is involved in legal matters and disputes in the ordinary course of business. We do not anticipate that the outcome of such matters and disputes will materially affect the Company's financial statements.

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 has granted, a hearing to be conducted in March 2016, at which the Company will request an extension of time to effect transactions to allow us to regain compliance and to report the same. There can be no assurance that NASDAQ will grant the extension we are seeking as a result of the hearing, or 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.

On January 21, 2016 we received a notice from NASDAQ of non-compliance with its listing rules regarding the requirement that the listed securities maintain a minimum bid price of \$1 per share. Based upon the closing bid price for the last 30 consecutive business days, the Company no longer meets this requirement. However, the Rules also provide the Company a compliance period of 180 calendar days in which to regain compliance (see Note 17).

## 14. EMPLOYEE RETIREMENT PLAN

The Company has a defined contribution plan under Section 401(k) of the Internal Revenue Code that allows eligible employees who meet minimum age requirements to contribute a portion of their annual compensation on a pre-tax basis. The Company has not made any matching contributions under this plan.

## 15. RELATED PARTY TRANSACTIONS

The Company's Chief Scientific Officer and principal founder of Collectar, Inc. and a director and shareholder of the Company, is a faculty member at the University of Wisconsin-Madison ("UW"). During 2015 the Company incurred approximately \$178,000 in expenses from UW for costs associated with clinical trial agreements. During 2014 the Company incurred approximately \$290,000 in expenses from UW which was also related to the costs associated with clinical trial agreements. The Company had accrued liabilities to UW of approximately \$40,000 and \$353,000 as of December 31, 2015 and 2014, respectively.

## 16. RESTRUCTURING COSTS AND OTHER CORPORATE CHANGES

On June 15, 2015, the Company appointed a new President and Chief Executive Officer, who was also named to the Company's Board as a Class II director. The former President, Chief Executive Officer and Class II director retired from each of those positions. In addition, during third quarter 2015 the Company eliminated certain personnel positions, which resulted in restructuring charges of approximately \$204,000 being recorded in the twelve months ended December 31, 2015.

Restructuring costs in 2014 related primarily to the restructuring of the Company's management and was composed of approximately \$208,000 for severance and stock-based compensation.

## 17. SUBSEQUENT EVENT

At a special meeting held on February 8, 2016, the Company's stockholders approved an amendment to the Company's certificate of incorporation to effect a reverse split of the Company's common stock at a ratio between 1:5 to 1:10 in order to ensure that adequate authorized but unissued shares would be available for anticipated future financings, and to satisfy requirements for the continued listing of the Company's common stock on the NASDAQ Capital Market. In addition, the proposal approved by the stockholders provided that if the reverse split was effected, the number of shares of common stock that the Company is authorized to issue would remain unchanged at 40,000,000. The Company's stockholders further authorized the board of directors to determine the ratio at which the reverse split would be effected by filing an appropriate amendment to the Company's certificate of incorporation. The board of directors authorized the ratio of the reverse split and corresponding reduction in authorized shares on February 24, 2016, and effective at the close of business on March 4, 2016, the Company's certificate of incorporation was amended to effect a 1-for-10 reverse split of the Company's common stock (the "2016 Reverse Split"). All share and per share numbers included in these consolidated financial statements give effect to the 2016 Reverse Split.

### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

### **Item 9A. Controls and Procedures.**

*Evaluation of disclosure controls and procedures.* Based on our management's evaluation (with the participation of our principal executive officer and principal financial officer), as of December 31, 2015, our management has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were not effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms due to the material weakness described below.

*Management's report on internal control over financial reporting.* Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the 1992 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's evaluation included such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on this evaluation and the identification of the material weakness in internal control over financial reporting below, our management concluded that our internal control over financial reporting was not effective as of December 31, 2015. This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting.

On March 24, 2015 our Annual Report on Form 10-K for the year ended December 31, 2014 was filed. At that time, our principal executive officer and principal financial officer had concluded that our internal control over financial reporting was effective as of December 31, 2014. Subsequent to performing that evaluation, our management, including our principal executive officer and principal financial officer, concluded that we did not maintain effective internal control over financial reporting as of December 31, 2014, due to a material weakness in our internal control over financial reporting, described below, related to our accounting for complex, non-recurring accounting issues. This material weakness has not been fully remediated as of December 31, 2015. Notwithstanding this material weakness, management has concluded that our audited consolidated financial statements included in this Annual Report on Form 10-K are fairly stated in all material respects in accordance with generally accepted accounting principles for each of the periods presented herein.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

The Company has experienced a decline in stock price and is actively seeking capital, which has added complexity to its financial reporting. The market pressures have added to the accounting complexity with issues such as goodwill, fixed asset impairment, and other related issues. As the complexity has increased, the accounting staff has not added resources in a sufficient manner to ensure thorough research of US GAAP; the accounting staff has multiple operational functions which limit their capacity to deal with these complexities in a timely manner.

Due to the added accounting complexities, limited resources, and the challenge of performing multiple functions for a development stage business with limited capital resources; Collectar management determined that the internal control over financial reporting for complex transactions may not always operate at the appropriate level of precision required to prevent or detect material misstatements of the Company's financial statements on a timely basis.. In response to this material weakness, the Company's management has expended, and will continue to expend, a substantial amount of effort and resources for the remediation and improvement of our internal control over financial reporting. While we have processes to properly identify and evaluate the appropriate accounting technical pronouncements and other literature for all significant or unusual transactions, we are improving these processes to ensure that the nuances of such transactions are effectively evaluated in the context of the increasingly complex accounting standards. Our plans at this time include acquiring enhanced access to accounting literature, research materials and documents and increased communication among our personnel and third party professionals with whom we consult regarding the application of complex accounting transactions. Our remediation plan can only be accomplished over time and will be continually reviewed to determine that it is achieving its objectives. We can offer no assurance that these initiatives will ultimately have the intended effects.

*Changes in internal control over financial reporting.* There have not been any significant changes in the Company's internal control of financial reporting other than as reported above.

The Chief Executive Officer and the Audit Committee perform significant roles in ensuring the accuracy and completeness of our financial reporting and the effectiveness of our disclosure controls and procedures. We have identified the changes described above as changes in the internal control over the financial reporting process that occurred during the Company's fiscal year of 2015 that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

*Important Considerations.* Any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. In addition, the design of any control system is based in part on certain assumptions about the likelihood of future events. The effectiveness of our disclosure controls and procedures is subject to various inherent limitations, including cost limitations, judgments used in decision making, assumptions about the likelihood of future events, the soundness of our systems, the possibility of human error, and the risk of fraud. Because of these and other inherent limitations of control systems, there can be no assurance that any system of disclosure controls and procedures will be successful in achieving its stated goals, including but not limited to preventing all errors or fraud or in making all material information known in a timely manner to the appropriate levels of management, under all potential future conditions, regardless of how remote.

**Item 9B. Other Information.**

None.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance.**

The information required by this item is incorporated herein by reference to our definitive proxy statement for our 2016 Annual Meeting of Stockholders under the captions "Proposal No. 1 — Election of Directors," "Executive Officers and Directors" and "Corporate Governance." The information required by this item with respect to compliance with Section 16(a) of the Exchange Act is incorporated herein by reference to our definitive proxy statement for our 2016 Annual Meeting of Stockholders under the caption "Section 16(a) Beneficial Ownership Reporting Compliance."

**Code of Ethics**

The board of directors has adopted a Code of Ethics applicable to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. A copy of the Code of Ethics is available at our website [www.collectar.com](http://www.collectar.com).

**Item 11. Executive Compensation.**

**Compensation of Directors and Executive Officers**

This section provides information, in tabular and narrative formats specified in applicable SEC rules, regarding the amounts of compensation paid to each of our named executive officers and related information. As a smaller reporting company, the Company has presented such information in accordance with the scaled disclosure requirements permitted under applicable SEC regulations.

The following table sets forth certain information concerning all cash and non-cash compensation awarded to, earned by or paid to our each of our named executive officers during the two year period ended December 31, 2015:

### Summary Compensation Table

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$) (1)	All Other Compensation (\$) (2)	Total (\$)
James Caruso <sup>(3)</sup> Chief Executive Officer	2015	\$ 204,545	\$ —	\$ 808,800	\$ 100,659	\$ 1,114,004
J. Patrick Genn Vice President of Business Development	2015	\$ 203,674	\$ —	\$ 22,045	\$ 1,101	\$ 226,820
	2014	\$ 203,674	\$ —	\$ —	\$ 1,101	\$ 204,775
Chad J. Kolean <sup>(4)</sup> Chief Financial Officer	2015	\$ 217,500	\$ —	\$ —	\$ 22,152	\$ 239,652
	2014	\$ 127,860	\$ —	\$ 122,480	\$ 657	\$ 250,997
Simon Pedder, Ph.D. <sup>(5)</sup> Former Chief Executive Officer	2015	\$ 160,416	\$ —	\$ —	\$ 564	\$ 160,980
	2014	\$ 262,500	\$ —	\$ —	\$ 90,847	\$ 353,347
Kathryn M. McNeil <sup>(6)</sup> Former Vice President of Investor Relations	2015	\$ 135,714	\$ —	\$ —	\$ 77,759	\$ 213,473
	2014	\$ 225,000	\$ —	\$ —	\$ 21,129	\$ 246,129

### All Other Compensation Detail<sup>(2)</sup>

Name and Principal Position	Year	Severance- Related Payments (\$)	Consulting Fees (\$)	Relocation (\$)	Life and Disability Premiums (\$)	Total All Other Compensation (\$)
James Caruso <sup>(3)</sup> Chief Executive Officer	2015	\$ —	\$ —	\$ 100,000	\$ 659	\$ 100,659
J. Patrick Genn Vice President of Business Development	2015	\$ —	\$ —	\$ —	\$ 1,101	\$ 1,101
	2014	\$ —	\$ —	\$ —	\$ 1,101	\$ 1,101
Chad J. Kolean <sup>(4)</sup> Chief Financial Officer	2015	\$ —	\$ —	\$ 21,027	\$ 1,125	\$ 22,152
	2014	\$ —	\$ —	\$ —	\$ 657	\$ 657
Simon Pedder, Ph.D. <sup>(5)</sup> Former Chief Executive Officer	2015	\$ —	\$ —	\$ —	\$ 564	\$ 564
	2014	\$ —	\$ 90,000	\$ —	\$ 847	\$ 90,847
Kathryn M. McNeil <sup>(6)</sup> Former Vice President of Investor Relations	2015	\$ 76,630	\$ —	\$ —	\$ 1,129	\$ 77,759
	2014	\$ —	\$ —	\$ 20,000	\$ 1,129	\$ 21,129

(1) The reported amounts represent the aggregate grant date fair value computed in accordance with ASC 718. All assumptions made regarding the valuation of equity awards can be referenced in Note 9 to the financial statements included in our Annual Report on Form 10-K/A filed with the SEC on May 20, 2015.

(2) Other compensation includes our group term life and disability insurance programs, relocation assistance, severance paid upon termination and pre-employment consulting fees. Consulting fees reflect amounts paid to Dr. Pedder for the fiscal year ended December 31, 2014 for consulting services prior to his appointment as President and Chief Executive Officer effective April 1, 2014.

(3) Mr. Caruso was appointed as President and Chief Executive Officer effective June 15, 2015.

(4) Mr. Kolean was appointed as Vice President, Chief Financial Officer and Treasurer effective May 28, 2014.

(5) Dr. Pedder retired effective June 15, 2015.

(6) Ms. McNeil resigned effective July 28, 2015.

## Employment Agreement

*James Caruso.* We have entered into an employment agreement (the “Employment Agreement”) with Mr. Caruso, effective as of June 15, 2015, pursuant to which Mr. Caruso serves as President and Chief Executive Officer of the Company. Under the Employment Agreement, the Company is paying Mr. Caruso a base salary at the rate of \$375,000 per year beginning on June 15, 2015. The Employment Agreement also provided for reimbursement of certain expenses in connection with Mr. Caruso’s temporary accommodation in and relocation to the Madison, Wisconsin area. Mr. Caruso is eligible for an annual bonus, based on performance, of up to 50% of his base salary at the discretion of the Compensation Committee of the Board of Directors. The agreement also provides for a continuation of Mr. Caruso’s salary and benefits for six months following a termination without cause, or a constructive dismissal following a change in control. In the event of a termination without cause, contingent upon the execution of a release agreement in favor of the Company, the Company will also provide for a one-year acceleration of unvested options, and such vested options will remain exercisable for a period of one year following the termination date. In the event of a change in control event, as defined, all unvested options will become exercisable for a period of one year following the change in control event.

## Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information with respect to outstanding equity awards at December 31, 2015 with respect to the named executive officers.

Name	Year of Grant	Individual Grants		Exercise or base price (\$/share)	Expiration date
		Number of securities underlying unexercised options (# exercisable)	Number of securities underlying unexercised options (# unexercisable)		
James Caruso	6/15/2015 <sup>(1)</sup>	—	37,500	\$ 26.40	6/15/2025
Chad J. Kolean	5/28/2014 <sup>(2)</sup>	1,000	1,000	\$ 74.00	5/28/2024
J. Patrick Genn	2/26/2015 <sup>(2)</sup>	250	750	\$ 26.90	2/26/2025
	12/13/2013 <sup>(2)</sup>	417	108	74.00	12/13/2023
	12/14/2012	750	—	150.00	12/14/2022
	12/16/2011	375	—	90.00	12/16/2021
	5/18/2011	750	—	280.00	5/18/2021

- (1) These shares vest annually in increments of one-fourth over four years from the date of grant. The exercise price equals the closing price on the date of grant.
- (2) These shares vest quarterly in increments of one-twelfth over three years from the date of grant. The exercise price equals the closing price on the date of grant.

Options granted pursuant to the 2015 and 2006 Stock Incentive Plans will become fully vested upon a termination event within one year following a change in control, as defined. A termination event is defined as either termination of employment other than for cause or constructive termination resulting from a significant reduction in either the nature or scope of duties and responsibilities, a reduction in compensation or a required relocation.

## Director Compensation

The following table sets forth certain information about the compensation of our non-executive directors who served during the year ended December 31, 2015.



<b>Name and Principal Position</b>	<b>Year</b>	<b>Director Fees (\$)<sup>(2)</sup></b>	<b>Option Awards (\$)</b>	<b>All other compensation (\$)</b>	<b>Total (\$)</b>
Paul L. Berns, Chairman of the Board <sup>(1)</sup>	2015	\$ 47,250	\$ 21,807	\$ —	\$ 69,057
Stephen A. Hill, Director <sup>(1)</sup>	2015	51,250	22,909	—	74,159
Stefan Loren, Director <sup>(1)</sup>	2015	20,000	21,568	—	41,568
John Neis, Director <sup>(1)</sup>	2015	48,750	21,807	—	70,557
Jamey Weichert, Director <sup>(3)</sup>	2015	—	—	—	—

(1) As of December 31, 2015, outstanding options to purchase common stock held by directors were as follows: Mr. Berns 1,500, Dr. Hill 2,936; Mr. Loren 1,000, and Mr. Neis 2,250.

(2) Director fees include all fees earned for director services including quarterly fees, meeting fees and committee chairman fees.

(3) Dr. Weichert is our founder and Chief Scientific Officer. He was compensated in 2015 as an employee, but he did not receive any compensation as a director.

During 2015, we paid our non-employee directors a cash fee of \$5,000 per quarter. The non-employee directors also received a fee of \$1,500 for any board or committee meeting attended and \$750 for each telephonic board or committee meeting in which the director participated. We also paid our chairman an additional annual fee in the amount of \$15,000, our non-employee director who serves as the chair of the Audit Committee an additional annual fee of \$10,000 and our non-employee directors who served as the chairman of the Compensation Committee and the Nominating and Corporate Governance Committee an additional annual fee of \$5,000. We reimbursed directors for reasonable out-of-pocket expenses incurred in attending board and committee meetings and undertaking certain matters on our behalf. Directors who are our employees do not receive separate fees for their services as directors.

For 2016, we will pay our non-employee directors an annual cash fee of \$35,000. We will also pay our chairman an additional annual fee of \$20,000, our non-employee director who serves as the chair of the Audit Committee an additional annual fee of \$15,000, our non-employee directors who serve on the Audit Committee an additional annual fee of \$5,000, and our non-employee director who serves as the chairman of the Compensation Committee and the Nominating and Corporate Governance Committee an additional annual fee of \$7,500.

#### **Certain Relationships and Related-Person Transactions**

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

One of our directors, John Neis, is a managing director of Venture Investors LLC, which beneficially owns approximately 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 (“UW”). During 2015 the Company incurred approximately \$178,000 in expenses from UW for costs associated with clinical trial agreements. During 2014 the Company incurred approximately \$290,000 in expenses from UW which was also related to the costs associated with clinical trial agreements. The Company had accrued liabilities to UW of approximately \$40,000 and \$353,000 as of December 31, 2015 and 2014, respectively.

#### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this item with respect to the security ownership of certain beneficial owners and the security ownership of management is incorporated herein by reference to our definitive proxy statement for our 2016 Annual Meeting of Stockholders under the caption “Security Ownership of Certain Beneficial Owners and Management.”

#### **Equity compensation plans**

The information required by this item with respect to the equity compensation plans is incorporated herein by reference to this Form 10-K, Item 5, under the caption “Equity compensation plans.”

**Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this item with respect to certain relationships and related transactions is incorporated herein by reference to our definitive proxy statement for our 2016 Annual Meeting of Stockholders under the caption “Certain Relationships and Related-Person Transactions.” The information required by this item with respect to director independence is incorporated herein by reference to our definitive proxy statement for our 2016 Annual Meeting of Stockholders under the caption “Corporate Governance — Director Independence.”

**Item 14. Principal Accounting Fees and Services.**

The information required by this item is incorporated herein by reference to our definitive proxy statement for our 2015 Annual Meeting of Stockholders under the captions “Proposal No. 6 — Ratification of Appointment of our Independent Registered Public Accounting Firm” and “Other Matters — Audit and Other Fees.”

**PART IV**

**Item 15. Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>	<b>Filed with this Form 10-K</b>	<b>Incorporated by Reference</b>		
			<b>Form</b>	<b>Filing Date</b>	
2.1	Agreement and Plan of Merger by and among Novelos Therapeutics, Inc., Cell Acquisition Corp. and Collectar, Inc. dated April 8, 2011		8-K	April 11, 2011	2.1
3.1	Second Amended and Restated Certificate of Incorporation		8-K	April 11, 2011	3.1
3.2	Certificate of Ownership and Merger of Collectar Biosciences, Inc. with and into Novelos Therapeutics, Inc.		8-K	February 11, 2014	3.1
3.3	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation		8-K	June 13, 2014	3.1
3.4	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation		8-K	June 19, 2015	3.2
3.5	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation		8-K	March 4, 2015	3.1
3.6	Amended and Restated By-laws		8-K	June 1, 2011	3.1
4.1	Form of common stock certificate		S-1/A	November 9, 2011	4.1
10.1	Form of non-plan non-qualified stock option used from February to May 2005*		SB-2	November 16, 2005	10.4
10.2	Form of non-plan non-qualified stock option used after May 2005*		SB-2	November 16, 2005	10.5
10.3	2006 Stock Incentive Plan, as amended*		8-K	December 18, 2013	10.1
10.4	Form of Incentive Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan*		8-K	December 15, 2006	10.1
10.5	Form of Non-Statutory Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan*		8-K	December 15, 2006	10.2
10.6	Common Stock Purchase Warrant dated February 11, 2009		8-K	February 18, 2009	4.2
10.7	Form of Common Stock Purchase Warrant issued pursuant to the Consent and Waiver of Holders of Series C Convertible Preferred Stock and Series E Convertible Preferred Stock dated July 6, 2010		S-1A	July 7, 2010	10.53

10.8	Form of Common Stock Purchase Warrant dated April 8, 2011	8-K	April 11, 2011	4.3
10.9	Securities Purchase Agreement dated April 8, 2011	8-K	April 11, 2011	10.1
10.10	License Agreement between Collectar, LLC and the Regents of the University of Michigan dated September 14, 2003, as amended through June 2010	S-1	July 1, 2011	10.31
10.11	Lease Agreement between Collectar, LLC and McAllen Properties LLC, as amended and extended	S-1	July 1, 2011	10.32
10.12	Loan Agreement between the Wisconsin Department of Commerce and Collectar, Inc. dated September 15, 2010	S-1	July 1, 2011	10.33
10.13	General Business Security Agreement dated September 15, 2010	S-1	July 1, 2011	10.34
10.14	Form of Warrant dated December 6, 2011	S-1/A	November 9, 2011	4.2
10.15	Placement Agent Agreement dated April 9, 2012 between the Company and Rodman and Renshaw, LLC	S-1	April 9, 2012	10.31
10.16	Securities Purchase Agreement dated June 7, 2012	8-K	June 11, 2012	10.1
10.17	Amendment Agreement dated May 11, 2012 between the Company and Rodman and Renshaw, LLC	S-1/A	May 14, 2012	10.33
10.18	Form of Common Stock Purchase Warrant dated June 13, 2012	8-K	June 11, 2012	4.1
10.19	Securities Purchase Agreement between the Company and Renova Industries Ltd.	10-Q	November 6, 2012	10.2
10.20	Form of Securities Purchase Agreement	8-K	February 14, 2013	10.1
10.21	Form of Common Stock Purchase Warrant	8-K	February 14, 2013	4.1
10.22	Amendment and restated Placement Agent Agreement dated January 8, 2013 between the Company and Burrill LLC	S-1/A	January 31, 2013	10.37
10.23	Retention Agreement between the Company and Christopher Pazoles dated July 26, 2013*	10-Q	November 13, 2013	10.2
10.24	Retention Agreement between the Company and Joanne M. Protano dated July 26, 2013*	10-Q	November 13, 2013	10.3

10.25	Consulting Agreement between the Company and Simon Pedder dated October 4, 2013*	10-Q	November 13, 2013	10.4
10.26	Employment Agreement between the Company and Simon Pedder dated October 4, 2013*	10-Q	November 13, 2013	10.5
10.27	Waiver Agreement between the Company and Renova Assets Ltd. dated October 9, 2013	8-K	October 10, 2013	10.1
10.28	Securities Purchase Agreement dated February 5, 2014	8-K	February 10, 2014	10.1
10.29	Form of Convertible Debenture	8-K	February 10, 2014	4.1
10.30	Form of Common Stock Purchase Warrant	8-K	February 10, 2014	4.2
10.31	Form of Warrant Agreement between Collectar Biosciences, Inc. and American Stock Transfer and Trust Company	S-1/A	July 7, 2014	10.31
10.32	Form of Underwriting Agreement	S-1/A	July 7, 2014	1.1
10.33	Form of Note Purchase and Security Agreement	10-Q	August 4, 2014	10.1
10.34	Form of 8% Secured Promissory Note	10-Q	August 4, 2014	10.2
10.35	Form of Consent Agreement with Debenture Holders	10-Q	August 4, 2014	10.3
10.36	2015 Stock Incentive Plan	10-Q	August 12, 2015	10.1
10.37	Employment Agreement between the Company and James Caruso, dated June 15, 2015*	10-Q	August 12, 2015	10.2
10.38	Placement Agency Agreement dated September 28, 2015 between the Company and Ladenburg Thalmann & Co. Inc.	8-K	September 30, 2015	1.1
10.39	Form of Series B Pre-Funded Warrant	8-K	September 30, 2015	4.1
10.40	Form of Series A Warrant	8-K	September 30, 2015	4.2
10.41	Securities Purchase Agreement dated September 28, 2015	8-K	September 30, 2015	10.1

10.42	Registration Rights Agreement dated September 28, 2015		8-K	September 30, 2015	10.2
21.1	List of Subsidiaries	X			
23.1	Consent of Independent Registered Public Accounting Firm	X			
31.1	Certification of chief executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of chief financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1	Certification of chief executive officer and chief financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
101	Interactive Data Files	X			

\* Management contract or compensatory plan or arrangement.

## SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### CELLECTAR BIOSCIENCES, INC.

By: /s/ James V. Caruso  
James V. Caruso  
Title: Chief Executive Officer  
March 10, 2016

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By: /s/ James V. Caruso  
James V. Caruso  
Title: Chief Executive Officer (Principal Executive Officer)  
March 10, 2016

By: /s/ Chad J. Kolean  
Chad J. Kolean  
Title: Chief Financial Officer (Principal Financial Officer and  
Principal Accounting Officer)  
March 10, 2016

By: /s/ Paul L. Berns  
Paul L. Berns  
Title: Chairman of the Board of Directors  
March 10, 2016

By: /s/ Stephen A. Hill  
Stephen A. Hill  
Title: Director  
March 10, 2016

By: /s/ John Neis  
John Neis  
Title: Director  
March 10, 2016

By: /s/ Stefan Loren  
Stefan Loren  
Title: Director  
March 10, 2016

By: /s/ Jamey P. Weichert  
Jamey P. Weichert  
Title: Chief Scientific Officer and Director  
March 10, 2016

**CELLECTAR BIOSCIENCES, INC.  
LIST OF SUBSIDIARIES**

Set forth below is a list of the subsidiaries of Collectar Biosciences, Inc. as of December 31, 2015:

<u>Subsidiary Name</u>	<u>Jurisdiction of Organization</u>
Collectar, Inc.	Wisconsin

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We have issued our report dated March 11, 2016, with respect to the consolidated financial statements included in the Annual Report of Collectar Biosciences, Inc. on Form 10-K for the year ended December 31, 2015. We consent to the incorporation by reference of said report in the Registration Statements of Collectar Biosciences, Inc. on Forms S-3 (File No. 333-208189 and File No. 333-201429) and on Forms S-8 (File No. 333-195255 and File No. 333-164398).

/s/ GRANT THORNTON LLP

Appleton, Wisconsin  
March 11, 2016

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**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, James V. Caruso, Chief Executive Officer, Collectar Biosciences, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Collectar Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed, under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2016

/s/ James V. Caruso  
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James V. Caruso  
Principal Executive Officer

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**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Chad J. Kolean, Chief Financial Officer, Collectar Biosciences, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Collectar Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed, under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2016

/s/ Chad J. Kolean  
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Chad J. Kolean  
Principal Financial Officer

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**CERTIFICATION PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Collectar Biosciences, Inc. (the "Company") for the year ended December 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James V. Caruso, Chief Executive Officer of the Company, and I, Chad J. Kolean, Chief Financial Officer of the Company, certify, to the best of our knowledge and belief, pursuant to 18 U.S.C. § 1350, adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ James V. Caruso  
James V. Caruso  
Principal Executive Officer

/s/ Chad J. Kolean  
Chad J. Kolean  
Principal Financial Officer

Dated: March 10, 2016

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Collectar Biosciences, Inc. and will be retained by Collectar Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

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