

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, 2017

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:

<u>Title of Class</u>	<u>Name of each exchange on which registered</u>
Common stock, par value \$0.00001	NASDAQ Capital Market
Warrant to purchase common stock, expiring August 20, 2019	NASDAQ Capital Market
Warrant to purchase common stock, expiring April 20, 2021	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 (Do not check if a smaller reporting company) Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

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, 2017 was \$20,820,618.

As of March 15, 2018, there were 17,388,344 shares of the registrant's \$0.00001 par value common stock outstanding.

CELLECTAR BIOSCIENCES, INC.
FORM 10-K

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FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K of Collectar Biosciences, Inc. (the “Company”, “Collectar”, “we”, “us”, “our”) contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. Examples of our forward-looking statements include:

- our current views with respect to our business strategy, business plan and research and development activities;
- the progress of our product development programs, including clinical testing and the timing of commencement and results thereof;
- our projected operating results including research and development expenses;
- our ability to continue development plans for CLR 131, CLR 1700 series, CLR 1800 series, CLR 1900 series, CLR 2000 series, CLR 2100 series and CLR 2200 series;
- our ability to maintain orphan drug designation in the United States for CLR 131 as a therapeutic for the treatment of multiple myeloma and neuroblastoma, and the expected benefits of orphan drug status;
- our ability to pursue strategic alternatives;
- our ability to further our technologies into product candidates;
- our consumption of current resources and ability to obtain additional funding;
- our current view regarding general economic and market conditions including our competitive strengths; and
- assumptions underlying any of the foregoing; and any other statements that address events or developments that we intend or believe will or may occur in the future.

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

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

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 TM are trademarks of Collectar Biosciences, Inc. All other trademarks are the properties of their respective owners.

PART I

Item 1. Business.

Business Overview

We are a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer. Our core objective is to leverage our proprietary phospholipid drug conjugateTM (PDCsTM) delivery platform to develop PDCs that specifically target cancer cells to deliver improved efficacy and better safety as a result of fewer off-target effects. The PDCTM platform possesses the potential for the discovery and development of the next generation of cancer-targeting treatments and we plan to develop PDCs independently and through research and development collaborations.

Our lead PDC candidate, CLR 131, provides targeted delivery of the cytotoxic (cell-killing) radioisotope iodine 131. CLR 131 is in a Phase 1 clinical study for relapsed or refractory (R/R) multiple myeloma (MM) and a Phase 2 clinical study in R/R MM and a range of other B-cell malignancies. The company plans to initiate a Phase 1 study for pediatric solid tumors and lymphomas and a second Phase 1 study of CLR 131 in combination with external beam radiation for head and neck cancer. The company's pipeline also includes two pre-clinical PDC chemotherapeutic programs, CLR 1700 and 1900. CLR 1700 possess a Burton's tyrosine kinase inhibitor (BTK) payload and is targeted for development in hematologic cancers and CLR 1900 is being developed for solid tumors with a payload that inhibits mitosis (cell division) which is a validated pathway for cell apoptosis.

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

Our PDC platform provides selective delivery of a diverse range of oncologic payloads to cancerous cells, whether a hematologic cancer or solid tumor, the primary tumor, or a metastatic tumor and cancer stem cells. Our PDC platform takes advantage of a metabolic pathway utilized by all tumor cell types in all stages of the tumor "cycle." This allows the PDC molecules to gain access to the intracellular compartment of the tumor cells and for the PDCs to continue to accumulate over time, which enhances drug efficacy. The PDC platform's mechanism of entry does not rely upon specific cell surface epitopes or antigens as are required by other targeted delivery platforms. Specific cell surface epitopes are limited in number on the cell surface, undergo internalization and cycling upon binding and are not present on all tumor cells of a particular cancer type. This means a subpopulation of tumor cells will always remain. In addition to the benefits provided by the mechanism of entry, PDCs offer the potential advantage of having the ability to be conjugated to molecules in numerous ways, thereby increasing the types of molecules selectively delivered via the PDC.

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

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

A description of our PDC product candidates follows:

- CLR 131 is a small-molecule, cancer-targeting radiotherapeutic PDC designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. CLR 131 is our lead therapeutic PDC product candidate and is currently being evaluated in both Phase 2 and Phase 1 clinical studies. The 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 (MM) and the Phase 1 study was initiated in April 2015. This clinical study is a standard three-by-three dose escalation safety study in patients with relapse or refractory multiple myeloma (R/RMM). Multiple myeloma is an incurable cancer of the plasma cells and is the second most common form of hematologic cancers. This cancer type was selected for clinical, regulatory and commercial rationales, including multiple myeloma's highly radiosensitive nature, and continued unmet medical need in the relapse/refractory setting and has been determined to be a rare disease by the FDA based upon the current definition within the Orphan Drug Act. The primary goal of the Phase 1 study is to assess the compound's safety and tolerability in patients with relapsed or refractory multiple myeloma. Secondary objectives include the establishment of a recommended Phase 2 dose, both with and without dexamethasone, as well as an evaluation of therapeutic activity by assessing surrogate efficacy markers which include M protein, Free Light Chain (FLC), Progression Free Survival (PFS) and Overall Survival (OS). In March 2018, the FDA granted orphan drug designation for CLR 131 for the treatment of neuroblastoma. The FDA previously accepted our IND application for a Phase 1 open-label, dose-escalating study to evaluate the safety and tolerability of a single intravenous administration of CLR 131 in up to 30 children and adolescents with cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. We expect to initiate this study during the second quarter of 2018.

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

In July 2016, we were awarded a \$2,000,000 National Cancer Institute Fast-Track Small Business Innovation Research (SBIR) grant to further advance the clinical development of CLR 131. The funds are supporting the Phase 2 study initiated in March 2017 to define the clinical benefits of CLR 131 in R/RMM and other niche hematologic malignancies with high unmet clinical need. These niche hematologic malignancies include Chronic Lymphocytic Leukemia, Small Lymphocytic Lymphoma, Marginal Zone Lymphoma, Lymphoplasmacytic Lymphoma, and Diffuse Large B-Cell Lymphoma. The study will be conducted in approximately 10 top U.S. cancer centers in patients with orphan-designated relapse or refractory hematologic cancers. The study's primary endpoint is clinical benefit response (CBR), with additional endpoints of progression free survival PFS, median OS and other markers of efficacy following a single 25.0 mCi/m² dose of CLR 131, with the option for a second 25.0 mCi/m² dose approximately 75-180 days later.

Phase 1 Study in Patients with R/R Multiple Myeloma

In September 2017, Cohort 4 results were announced and these results showed that a single 30 minute infusion of 31.25mCi/m² of CLR 131 was safe and well tolerated by the three patients in the cohort. Additionally, all three patients experienced clinical benefit with one patient achieving a Partial Response (PR). We are monitoring response rates via surrogate markers of efficacy including M protein and free light chain FLC. The International Myeloma Working Group (IMWG) defines a partial response PR as a greater than or equal to 50 percent decrease in FLC levels (for patients in whom M protein is unmeasurable) or 50 percent decrease in M protein. The patient experiencing a partial response had an 82 percent reduction in FLC. This patient did not produce M protein, received seven prior lines of treatment including radiation, stem cell transplantation and multiple triple combination treatments including one with daratumumab that was not tolerated. One patient experiencing stable disease attained a 44 percent reduction in M protein.

The key clinical outcome for R/RMM patients is OS. Patients in the Phase 1 dose escalation study have attained the following Median OS as of November 3, 2017: Cohort 3 patients (single 25.0 mCi/m² dose) at 10 months, Cohort 2 patients (single 18.75mCi/m² dose) at 15.4 months and Cohort 1 (single 12.5mCi/m² dose) at 26.2 months. At the time of this document, Median OS data are still being collected and therefore should not be considered quality controlled final data.

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

On December 14, 2017, we filed an IND application with the Division of Oncology at the FDA for a proposed Phase 1 study of CLR 131 in children and adolescents with select rare and orphan designated cancers. The Phase 1 clinical trial of CLR 131 is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of a single intravenous administration of CLR 131 in up to 30 children and adolescents with cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. Secondary objectives of the study are to identify the recommended Phase 2 dose of CLR 131 and to determine preliminary antitumor activity (treatment response) of CLR 131 in children and adolescents. In March 2018, the FDA granted orphan drug designation for CLR 131 for the treatment of neuroblastoma, a rare pediatric cancer. We expect to initiate the Phase 1 study during the second quarter of 2018.

The study will be initiated with the pediatric oncologists and Nuclear Medicine/Radiology Group at the University of Wisconsin Carbone Cancer Center (UWCCC). Investigators at The University of Wisconsin have demonstrated uptake of CLR 131 and other fluorescently and isotopically tagged PDCs across a wide range of childhood solid cancer cell lines including, Ewing sarcoma, rhabdomyosarcoma, pediatric brain tumors such as high-grade gliomas, medulloblastoma and atypical teratoid rhabdoid tumor. In subsequent testing in mouse xenograft models of neuroblastoma, Ewing sarcoma, rhabdomyosarcoma and osteosarcoma, CLR 131 provided significant benefits on tumor growth rates and survival.

Phase 1 Study in R/R Head and Neck Cancer

In August 2016, the UWCCC was awarded a five year Specialized Programs of Research Excellence (SPORE) grant from the National Cancer Institute to improve treatments and outcomes for head and neck cancer (HNC) patients. HNC is the sixth most common cancer across the world with approximately 56,000 new patients diagnosed every year in the United States. As a key component of this grant, the UWCCC researchers will test CLR 131 in various animal HNC models as well as initiating the first human clinical trial combining CLR 131 and external beam radiation in patients with recurrent HNC. The UWCCC is currently anticipated to initiate this clinical trial in 2H 2018.

Pre-Clinical Pipeline

- CLR 1700 Series is an internally developed PDC program leveraging a payload which inhibits Burton's tyrosine kinase (BTK) and is designed to treat a broad range of hematologic cancers. The payload provides further specificity by targeting a pathway within hematologic cancers that is significantly upregulated in comparison to normal tissue. We believe that this additional level of targeting will allow us to provide a new drug candidate that has the ability to significantly improve patient outcomes. Leveraging our iterative discovery and screening process, we have been able to accelerate the development of this program.
- CLR 1800 Series is a collaborative PDC program with Pierre Fabre that we entered into in December 2015 and extended in October 2017. Pierre Fabre is the third largest French pharmaceutical company with an extensive oncology research and development infrastructure. The objective of the research collaboration is to co-design a library of PDCs employing Pierre Fabre's chemotherapeutics in combination with our proprietary cancer-targeting delivery vehicle. The newly developed PDCs may provide enhanced therapeutic indices to otherwise highly potent, non-targeted payloads through the targeted delivery to cancer cells provided by our cancer-targeting delivery vehicle. Significant progress has been achieved and the program continues to rapidly advance with a number of PDC molecules showing enhanced pharmacologic behavior over the parent compound alone.
- CLR 1900 Series is an internally developed proprietary PDC program leveraging a novel small molecule cytotoxic compound as the payload. The payload inhibits mitosis (cell division) and targets a key pathway required to inhibit rapidly dividing cells that results in apoptosis. We believe that this program could produce a product candidate targeted to select solid tumors. Currently, the program is in early preclinical development.

- CLR 2000 Series is a collaborative PDC program with Avicenna Oncology, or Avicenna, that we entered into in July 2017. Avicenna is a leading developer of antibody drug conjugates (ADCs). The objective of the research collaboration is to design and develop a series of PDCs utilizing Avicenna's proprietary cytotoxic payload. Although Avicenna is a leading developer of ADCs, this collaboration was sought as a means to overcome many of the challenges associated with ADCs, including those associated with the targeting of specific cell surface epitopes.
- CLR 2100 and 2200 Series are collaborative PDC programs with Onconova Therapeutics, Inc., or Onconova, that we entered into in September 2017. Onconova is a biotechnology company specializing in the discovery and development of novel small molecule cancer therapies. The collaboration is structured such that we will design and develop a series of PDCs utilizing different small molecules that Onconova was developing as payloads with the intent to show improved targeting and specificity to the tumor. At least one of the molecules was taken into Phase 1 clinical trials previously by Onconova. We would own all new intellectual property associated with the design of the new PDCs and both companies will have the option to advance compounds.

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 of a broad range of human cancers.

Technology Overview

Our product candidates are based on a cancer-targeting delivery platform of optimized Phospholipid Ether (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 product candidates 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 and non-radioactive molecules, including cytotoxic compounds can also be attached to the delivery vehicle.

We are focused on exploring the creation of additional PDCs ranging from newly discovered to well-characterized chemotherapeutic payloads under its CLR hemotherapeutic 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 PDC product candidates include our CLR 1700, 1800, 1900, 2000, 2100 and 2200 series of conjugated compounds currently being researched independently and through partnerships. All are small-molecule, 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.

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, positron emission tomography (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 and our multiple series of drug conjugates. The marked selectivity of our compounds for cancer cells versus non-cancer cells is due to the fact that cancer cells maintain an overabundance of lipid rafts and have stabilized these microdomains within the plasma membrane as compared to normal cells. For example, following cell entry via lipid rafts, CLR 131 is transported into the cytoplasm, where it traffics along the Golgi apparatus and is distributed to various peri-nuclear organelles (mitochondria, endoplasmic reticulum) 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.

Products in Development

CLR 131

CLR 131 is a small-molecule, 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) octadacyl 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, pediatric tumors and other cancer types including non-Hodgkin's lymphoma. 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 anti-cancer activity. Selective uptake and retention has been demonstrated in cancer stem cells compared with normal cells, offering the prospect of longer lasting anti-cancer activity.

Pre-clinical experiments in tumor models have demonstrated selective killing of cancer cells along with a safe and tolerable product 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). While single doses of CLR 131 have been effective and well tolerated in multiple preclinical animal models, CLR 131 has been shown to provide a statistically significant improvement in efficacy and survival when provided in a multi-dose format and remains well tolerated. In each study, the dose of CLR 131 was ~100 μCi , 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 repeat-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^2 CLR 131 in eight patients with relapsed or refractory advanced solid tumors. Single doses of CLR 131 were well tolerated and 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. Confirming 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^2 , 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. Dose escalation in four cohorts subsequently occurred with refractory cancer patients receiving single doses of 25 mCi/m², 31.25 mCi/m² or 37.5 mCi/m².

Tumor treatment with radioactive isotopes has been used as a fundamental cancer therapeutic for decades. The goals of targeted cancer therapy — selective delivery of effective doses of isotopes that destroy tumor tissue, sparing of surrounding normal tissue, and non-accumulation in vital organs such as the liver and kidneys — remain goals of new therapies as well. We believe our isotope delivery technology has the potential to achieve these goals. To date, CLR 131 has been shown in animal models 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. As a result, this may provide an accelerated regulatory pathway due to CLR 131's unique benefits such as a novel mechanism of action, ease of administration, and positive benefit/risk profile potential in various high unmet cancer populations. The IND application for multiple myeloma 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 have provided periodic clinical updates. CLR 131 is being evaluated as a monotherapy and will subsequently be explored as a combination therapy with chemotherapeutic agents, immunomodulatory agents and in combination with external beam radiotherapy. CLR 131 is being evaluated in a Phase 2 clinical study examining relapse refractory multiple myeloma patients as well as selected other B-cell hematological malignancies. Patients will receive a 25 mCi/m² dose infused over approximately 30 minutes with the option of a second 25 mCi/m² dose 75-180 days later based on physician assessment. This study is partially funded through a \$2,000,000 Fast Track NCI SBIR award which was granted in July 2016.

In September 2017, the CLR 131 Phase 1 Cohort 4 results were announced. These results showed that a single 30 minute infusion of 31.25mCi/m² of CLR 131 was safe and well-tolerated by the three patients in the cohort. We are also monitoring signals of efficacy, including surrogate markers M protein and FLC. IMWG defines a PR as a greater than or equal to 50 percent decrease in FLC levels (for patients in whom M protein is unmeasurable) or 50 percent decrease in M protein. Additionally, all three patients in the cohort experienced clinical benefit with one patient achieving a PR and two patients achieving stable disease. One patient experiencing stable disease attained a 44 percent reduction in M protein. The patient experiencing a partial response had an 82 percent reduction in FLC. This patient did not produce M protein, received seven prior lines of treatment including radiation, stem cell transplantation and multiple combination treatments including one with daratumumab that was not tolerated. Median OS for the study has not been reached at the time of this document and data is still being collected for the Phase 1 study and will not be considered final until the end of the study. As of November 3, 2017, patients in Cohort 1 who received a single 12.5mCi/m² dose experienced a median OS of 26.4 months with all patients remaining alive. Median OS for Cohorts 2 and 3 also continue to mature with patients experiencing OS of 15.6 months and 10 months, respectively as of November 3, 2017. The company has initiated a Phase 2 clinical study using Cohort 3's dose of 25.0 mCi/m² with the option of a second 25 mCi/m² dose 75-180 days later based on physician assessment. We may modify this dose based on safety and efficacy signals from the Phase 1 study's ongoing Cohort 5 multi dose regimen.

On December 14, 2017, we filed an IND application with the Division of Oncology at the FDA for a proposed Phase 1 study of CLR 131 in children and adolescents with select rare and orphan designated cancers. The Phase 1 clinical trial of CLR 131 is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of a single intravenous administration of CLR 131 in up to 30 children and adolescents with cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. Secondary objectives of the study are to identify the recommended Phase 2 dose of CLR 131 and to determine preliminary antitumor activity (treatment response) of CLR 131 in children and adolescents. The study will be initiated with the pediatric oncologists and Nuclear Medicine/Radiology Group at UWCCC. Investigators at The University of Wisconsin have demonstrated uptake of CLR 131 and other fluorescently and isotopically tagged PDCs across a wide range of childhood solid cancer cell lines including, Ewing sarcoma, rhabdomyosarcoma, pediatric brain tumors such as high-grade gliomas, medulloblastoma and atypical teratoid rhabdoid tumor. In subsequent testing in mouse xenograft models of neuroblastoma, Ewing sarcoma, rhabdomyosarcoma and osteosarcoma, CLR 131 provided significant benefits on tumor growth rates and survival. In March 2018, the FDA granted orphan drug designation for CLR 131 for the treatment of neuroblastoma, a rare pediatric cancer. We expect to initiate the Phase 1 study during the second quarter of 2018.

CLR 1700 Series

CLR 1700 Series is an internally developed PDC program leveraging a payload which inhibits BTK and is designed to treat a broad range of hematologic cancers. The payload provides further specificity by targeting a pathway within hematologic cancers that is significantly upregulated in comparison to normal tissue. We believe that this additional level of targeting will allow us to provide a new drug candidate that has the ability to significantly improve patient outcomes. Leveraging our iterative discovery and screening process, we have been able to accelerate the development of this program.

CLR 1800 Series

CLR 1800 Series is a collaborative PDC program with Pierre Fabre that we entered into in December 2015. Pierre Fabre is the third largest French pharmaceutical company with an extensive oncology research and development infrastructure. The objective of the research collaboration is to co-design a library of PDCs employing Pierre Fabre's chemotherapeutics in combination with our proprietary cancer-targeting delivery vehicle. The newly developed PDCs may provide enhanced therapeutic indices to otherwise highly potent, non-targeted payloads through the targeted delivery to cancer cells provided by our cancer-targeting delivery vehicle. Significant progress has been achieved and the program continues to rapidly advance with a number of PDC molecules showing enhanced pharmacologic behavior over the parent compound alone.

CLR 1900 Series

CLR 1900 Series is an internally developed proprietary PDC program leveraging a novel small molecule cytotoxic compound as the payload. The payload inhibits mitosis (cell division) and targets a key pathway required to inhibit rapidly dividing cells that results in apoptosis. We believe that this program could produce a product candidate targeted to select solid tumors. Currently, the program is in early preclinical development.

CLR 2000 Series

CLR 2000 Series is a collaborative PDC program with Avicenna Oncology, or Avicenna, that we entered into in July 2017. Avicenna is a leading developer of antibody ADCs. The objective of the research collaboration is to design and develop a series of PDCs utilizing Avicenna's proprietary cytotoxic payload. Although Avicenna is a leading developer of ADCs, this collaboration was sought as a means to overcome many of the challenges associated with ADCs, including those associated with the targeting of specific cell surface epitopes.

CLR 2100 and 2200 Series

CLR 2100 and 2200 Series are collaborative PDC programs with Onconova Therapeutics, Inc., or Onconova, that we entered into in September 2017. Onconova is a biotechnology company specializing in the discovery and development of novel small molecule cancer therapies. The collaboration is structured such that we will design and develop a series of PDCs utilizing different small molecules that Onconova was developing as payloads with the intent to show improved targeting and specificity to the tumor. At least one of the molecules was taken into Phase 1 clinical trials previously by Onconova. We would own all new intellectual property associated with the design of the new PDCs and both companies will have the option to advance compounds.

Market Overview

Our target market is broad and represents the market for the treatment of cancer. The American Cancer Society estimated that approximately 1.69 million new cancer cases were expected to be diagnosed in the U.S. in 2016 and approximately 596,000 people were expected to die of cancer, which is the equivalent of about 1,630 per day. The global market for cancer drugs reached \$107 billion in annual sales (June 2015), and could reach \$150 billion by 2020, according to a report dated June 2016 by the IMS Institute for Healthcare Informatics, a unit of drug data provider IQVIA. This growth will be driven by emerging targeted therapies, which are expected to change the cancer treatment landscape (Cowen Report), and an increased use of cancer drug combination regimens.

Multiple Myeloma

According to the National Cancer Institute SEER database, multiple myeloma is the second most common hematologic cancer with a U.S. incidence rate and a relapse or refractory patient population of 10,000 to 15,000. The Global Data Report for 2015 estimated the Multiple Myeloma dollar market size to be \$8.9B in 2014 and is forecasted to increase to \$22.4B in 2023. The increase in drug sales over this period will be mainly driven by the increasing incidence of MM in each of the seven key markets with the U.S. market remaining the largest potential market.

Chronic Lymphocytic Lymphoma and Small Lymphocytic Lymphoma/Lymphoplasmacytic Lymphoma/Mantle Cell Lymphoma/Marginal Zone Lymphoma

According to the National Cancer Institute SEER data base, chronic lymphocytic lymphoma and small lymphocytic lymphoma represents about 47,000 cases per year in the US. Lymphoplasmacytic lymphoma is one of the rarer forms of lymphoma with approximately 5,000 new cases per year in the U.S. Meanwhile, mantle cell and marginal zone lymphomas combined represent approximately 22,000 patients per year. The incidence rate in these diseases significantly increases with an aging population (majority of patients over the age of 60). According to a Datamonitor report from 2016, the markets for these conditions are expected to grow at a compound annual growth rate of nearly 5.5% in the U.S. and 7.6% in Europe until 2024 with combined sales of approximately \$2B.

Diffuse Large B-Cell Lymphoma

Diffuse large B-cell lymphoma (DLBCL) is an *aggressive* (fast-growing) lymphoma that can arise in lymph nodes or outside of the lymphatic system, in the gastrointestinal tract, testes, thyroid, skin, breast, bone, or brain. DLBCL is one of the most common forms of lymphoma with an incidence of approximately 57,000 patients per year (National Cancer Institute SEER data base). Datamonitor reports that the DLBCL market will expand at a compound annual growth rate of approximately 2.9%.

Neuroblastoma

Neuroblastoma, a neoplasm of the sympathetic nervous system, is the most common extracranial solid tumor of childhood, accounting for approximately 7.8% of childhood cancers in the U.S. The National Cancer Institute states the incidence is about 10.54 cases per 1 million per year in children younger than 15 years and 90% are younger than 5 years at diagnosis. Over 650 new cases are diagnosed each year in North America. Approximately 50% of patients present with metastatic disease requiring systemic treatment. Clinical consequences include abdominal distension, proptosis, bone pain, pancytopenia, fever and paralysis. Although the prognosis is favorable in children under one year of age with an 86 to 95% 5-year survival, in children aged one to 14 years the 5-year survival ranges from 34 to 68%.

Pediatric High Grade Glioma

Pediatric high grade glioma (HGG) represent a rare and orphan pediatric tumor that has limited treatment options. HGGs are usually defined as tumors of glial origin with the most common pediatric HGGs being anaplastic astrocytoma and glioblastoma multiform. The Central for Brain Tumor Registry of the United States estimate the incidence at approximately 3,600 pediatric patients per year.

Manufacturing

In January 2018, we initiated the planned shutdown of our radiopharmaceutical manufacturing facility in Madison, Wisconsin. This facility was designed to provide pilot and small scale production of our lead clinical program CLR 131. In December 2017, we successfully transferred the manufacturing of CLR 131 to Centre for Probe Development and Commercialization (CPDC), a validated cGMP manufacturing organization specializing in radiopharmaceuticals, as our exclusive source to supply drug product for our ongoing research and clinical trials, including our Phase 1 and Phase 2 studies of CLR 131. We believe that CPDC and our other third party manufacturers have the ability to supply large scale clinical and commercial scale material. Our third party manufacturing partners have been inspected and approved to supply clinical and commercial radiopharmaceutical material by the FDA and the European Medicines Agency.

CLR 131 drug product is made via a five-step synthetic scheme. The release specifications for the drug product have been established and validated. Through process improvements, we have been able to achieve a longer expiry dating for the compound extending finished product shelf-life to further facilitate ex-U.S. distribution from North America.

The drug substance base molecule is a dry powder produced via a six-step synthetic scheme. The release specifications for the drug substance have been established and validated. We have successfully executed large scale production of the drug substance via a contract manufacturing organization that has been inspected and approved by the FDA and the European Medicines Agency. We have also demonstrated 60-month stability for the drug substance in desiccated and refrigerated forms at small scale and are replicating this at large scale.

Sales and Marketing

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 an agreement for a contract sales organization (CSO) or partnering arrangement with one or more biotechnology or pharmaceutical company with strong product development and commercialization expertise and distribution infrastructure in the U.S., Europe and/or Japan. While we currently do not plan to build our own commercial organization for the launch and commercialization of our compounds, we may reconsider that in the future.

Competition for Our Clinical-Stage Compounds

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 for the treatment of liquid and solid tumors. While a number of indications were evaluated as the initial target treatment for CLR 131, multiple myeloma and hematologic cancers were selected for initial clinical development principally because of its highly radio-sensitive nature, single or multi-dose treatment, and novel mechanism of action relative to all existing classes of approved drugs. As a result, we believe CLR 131 is a therapeutic option in the relapse or refractory setting either as a monotherapy or in combination with currently approved agents, some of which are radio-sensitizing and maintain a differential adverse event profile from that of CLR 131.

Intellectual Property

Our core technology platform is based on research conducted at the University of Michigan in 1994, where phospholipid ether analogs were initially designed, synthesized, radiolabeled, and evaluated. This research was transferred to the University of Wisconsin - Madison between 1998 and the subsequent founding of Cellerar in 2002 to further develop and commercialize the technology. We obtained exclusive rights to the related technology patents owned by University of Michigan in 2003 and continued development of the PDC platform while obtaining ownership of numerous additional patents and patent applications (with various expiry until 2034 without extensions). We have established a broad U.S. and international intellectual property rights portfolio around our proprietary cancer-targeting PLE technology platform including CLR 131 and our PDC Programs.

PDC chemotherapeutic Programs

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 and were published by the U.S. Patent & Trade Office (USPTO) in May of 2016. These patent applications further protect composition of matter and method of use for PDCs developed with our proprietary phospholipid-ether delivery vehicle conjugated with any existing or future cytotoxic agents, including chemotherapeutics for targeted delivery to cancer cells and cancer stem cells. Additional cytotoxic PDC compounds are covered by pending patent applications directed to the composition of matter and method of use for cancer therapy provide intellectual property protection in the United States and up to 148 additional countries. These applications, if granted, offer protection extending through at least 2035 in the U.S. and key international markets.

CLR 131

We have taken a broad approach to creating market exclusivity for CLR 131 both within the U.S. and globally, including all major markets. This approach includes numerous patents, patent applications and regulatory filings to provide maximum market exclusivity. Our patent portfolio for CLR 131 includes all of the typical filings as well as unique methods of use, methods of manufacturing, use in combinations, use to treat cancer stem cells, novel formulations, etc. In addition, to our patents, we were granted orphan designation for CLR 131 for the treatment of multiple myeloma by the U.S. FDA in December 2014 and expect to file additional orphan designations for other rare diseases. We continue to evaluate CLR 131 in additional hematologic and solid tumor orphan designated indications. Our patents have a variety expected expiry with some potentially being extended on a country-by-country basis. In March 2018, the FDA granted orphan drug designation for CLR 131 for the treatment of neuroblastoma, a rare pediatric cancer. We expect to initiate a Phase 1 study during the second quarter of 2018.

We expect to continue to file patent applications and acquire licenses to other patents covering methods of use, composition of matter, formulation, method of manufacture and other patentable claims related to CLR 131 and new PDCs. These patent applications will be filed in key commercial markets worldwide. The issued patents will generally expire between 2025 and 2035, unless extended, most likely under clinical development extensions.

In addition to the above noted patents /applications directed to CLR 131 and our PDC pipeline portfolio, we own other patents/applications directed to different forms of phospholipid ethers, methods of use and methods of manufacturing of phospholipid ethers.

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 five years in the U.S. and up to ten years in Europe).

Licenses / Collaborations

On September 18, 2017, we entered into an arrangement with Onconova Therapeutics, Inc. (Onconova). Under this arrangement, Onconova will provide us a selection of its proprietary compounds. We will use our proprietary technology to perform research studies on such compounds with the goal of developing new conjugates. We agree to perform the studies within 24 months. We granted Onconova an exclusive option to acquire a royalty-bearing license with respect to each conjugate developed. In the event an executed license agreement for a particular conjugate is not obtained, then Onconova's exclusive option shall terminate with respect to such conjugate.

On July 9, 2017, we entered into an arrangement with Avicenna Oncology GMBH (Avicenna). Under this arrangement, Avicenna will provide us a selection of its proprietary toxins. We will use our proprietary conjugation capabilities to proceed with the conjugation in order to obtain PDCs. We will process various *in vitro* and *in cellulo* screening against such PDCs to develop new conjugates. We granted Avicenna an exclusive option to acquire an exclusive license to our intellectual property with respect to each conjugate developed. In the event the parties cannot reach agreement on the terms of a definitive agreement despite good faith negotiations, Avicenna's exclusive option terminates as to such conjugate. Avicenna also granted to us an exclusive option to acquire an exclusive license to its intellectual property with respect to the material provided. In the event the parties do not reach agreement on the terms of a definitive agreement, our exclusive option terminates as to the material of Avicenna.

On December 14, 2015, we entered into an arrangement with Institut de Recherche Pierre Fabre (IRPF). Under this arrangement, IRPF will provide us a selection of its proprietary cytotoxics for use in an *in vivo* proof-of-concept study to evaluate the potential to create new drug conjugates (NDCs) in combination with our proprietary PDC platform technology. We are entitled to all intellectual property associated with the NDCs developed as part of the research collaboration. If we decide to further develop any of the NDCs for pre-clinical studies, we will enter into discussions with IRPF to acquire an option to in-license the IRPF materials. In the event that we propose to enter into a business relationship with a third party for advancement of the NDCs, we 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 we do 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 parties will enter into business discussions relating to IRPF's use of the results of the study and certain of our proprietary technologies relating to the IRPF materials. We agreed to perform the study by June 15, 2018 and our obligation to grant a right of first refusal will continue for four years following the date on which we provide the results of the study to IRPF.

Research and Development

Our primary activity to date has been research and development. The research has historically been conducted at our facility in Madison, Wisconsin and through third party laboratories and academic universities. The clinical development has been completed primarily through contract research organizations at hospitals and academic centers. We have established a collaboration outsourcing model to leverage third party expertise, accelerate project timelines, improve productivity and limit spend and fixed costs. Our research and development expenses were approximately \$9,466,000 and \$4,750,000 for 2017 and 2016, 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 delay in approving or refusal to approve a product by the FDA or other health authorities. Violations of regulatory requirements also may result in enforcement actions, which include civil money penalties, injunctions, seizure of regulated product, and civil and criminal charges. 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 is carried out, the sponsor is still responsible for obtaining all the data usually obtained in both Phase 1 and Phase 2 studies.

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, an 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 2018, the NDA review fee alone is \$2,421,495, 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 ten 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 cGMP requirements, 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, 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 payors 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. Payors 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 payors 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, 2017, we had 15 full-time employees.

Legal Proceedings

We are a party to proceedings in the ordinary course of business, however we do not anticipate that the outcome of such matters and disputes will materially affect the Company's financial statements.

Corporate Information

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

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.collectar.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 operating losses for the foreseeable future. At December 31, 2017, our consolidated cash balance was approximately \$10 million. We believe our cash balance at December 31, 2017 is adequate to fund operations into early first quarter 2019. We will require additional funds to conduct research and development, establish and conduct clinical and preclinical trials, establish commercial-scale manufacturing arrangements and provide for the marketing and distribution of our products. Our ability to execute our operating plan depends on our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. We plan to actively pursue financing alternatives. However, there can be no assurance that we will obtain the necessary funding in the amounts we seek or that it will be available on a timely basis or upon terms acceptable to us. If we obtain capital by issuing debt or preferred stock, the holders of such securities could obtain rights that are superior to those of holders of our common stock.

Our capital requirements and our ability to meet them depend on many factors, including:

- the number of potential products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with preclinical studies and clinical trials;
- the time and costs involved in obtaining regulatory clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and our ability to sell our drugs;
- costs involved in establishing manufacturing capabilities for clinical trial and commercial quantities of our drugs;
- competing technological and market developments;
- claims or enforcement actions with respect to our products or operations,
- market acceptance of our products;
- costs for recruiting and retaining management, employees and consultants;

- our ability to manage computer system failures or security breaches;
- costs for educating physicians regarding the application and use of our products;
- whether we are able to maintain our listing on a national exchange;
- uncertainty and economic instability resulting from 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 additional funds through the issuance of any combination of common stock, preferred stock, warrants, through debt financings or by executing collaborative arrangements with corporate partners or other sources, any of which may be dilutive to existing stockholders or have a material effect on our current or future business prospects. 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 and commercialize ourselves. 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. In such an event, our business, prospects, financial condition, and results of operations may be adversely affected.

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 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. Whether we achieve profitability or not will depend on our success in developing, manufacturing, and marketing our product candidates. Our primary activity to date has been research and development and conducting clinical trials. Development of our product candidates requires a process of preclinical and clinical testing during which our product candidates could fail. We do not expect to have any products on the market for several years. We currently have no product revenues, and may not succeed in developing or commercializing any products that will generate product or licensing revenues. We may not be able to enter into agreements with 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 any product candidates.

As of December 31, 2017, we had working capital of approximately \$8.8 million and stockholders' equity of approximately \$10.8 million. 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, 2017, the Company incurred aggregated net losses of approximately \$84.3 million. The net loss for the twelve months ended December 31, 2017 was approximately \$13.6 million. We may never achieve profitability.

Our financial statements as of December 31, 2017 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2017 financial statements, in their report, included an explanatory paragraph referring to our recurring losses since inception and expressed 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 rely on a collaborative outsourced business model and disruptions with these third-party collaborators may impede our ability to gain FDA approval and commercialization of any products could be delayed or impaired.

We are in the pre-clinical and clinical trial phases of product development and commercialization. In connection with our announcement that we have ceased manufacturing and are in process of closing manufacturing operations located at our corporate headquarters in 2018, we have implemented a collaboration outsourcing model to more efficiently manage spend and fixed costs. We rely, and will increasingly rely, on contracts with third parties to use their facilities to conduct our research, development and manufacturing.

We have engaged CPDC, a validated cGMP manufacturing organization specializing in radiopharmaceuticals, as our exclusive source to supply drug product for our ongoing research and clinical trials, including our Phase 1 and Phase 2 studies of CLR 131. In addition, we are in the process of expanding capacity for a Phase 3 study through our relationship with CPDC. In addition, we rely exclusively on contract research organizations (CROs) to conduct research and development. Any inability of CPDC or other collaborators to fulfill the requirements of their agreements with us may delay or impair our ability to gain FDA approval and commercialization of our drug delivery technology and products.

Our reliance on third-party collaborators may expose us to the risk of not being able to directly oversee the activities of these parties. Furthermore, these collaborators, whether foreign or domestic, may experience regulatory compliance difficulties, mechanical shutdowns, employee strikes, or other unforeseeable acts that may delay fulfillment of their agreements with us. Failure of any of these collaborators 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 third-party collaborators. 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.

In addition, if our products are approved for commercial sale, we will need to work with our existing third-party collaborators to ensure sufficient capacity, or engage additional parties with the capacity, 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 capacity, or identify suitable manufacturing partners on acceptable terms.

Controls we or our third-party collaborators have in place to ensure compliance with laws may not be effective to ensure compliance with all applicable laws and regulations.

We and our third party collaborators are subject to federal, state and local laws and regulations governing the storage, use, and disposal of these materials and some waste products. Current or future regulations may impair our research, development, manufacturing, and commercialization efforts. At our facility in Madison, Wisconsin, research and development, manufacturing, and administration of our drugs involved the controlled use of hazardous materials, including chemicals and radioactive materials, such as radioactive isotopes. We believe that our safety procedures for the storage, use, and disposal of these materials has been in compliance 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. In connection with the shutdown of our manufacturing, research and development activities in Madison, Wisconsin, we are currently working with the State of Wisconsin agencies on transitioning our manufacturer's license and the radioactive materials license to a distribution license only.

If our third party collaborators are unable to maintain the required licenses and permits for any reason, it will negatively impact our manufacturing, research and development activities. In addition, we may be required to indemnify third party collaborators against certain liabilities arising out of any failure by them to comply with such regulations and/or laws. If we or our third party collaborators fail to comply with any of these regulations and/or laws a range of consequences could result, including, but not limited to, the suspension or termination of clinical trials, failure to obtain approval of a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation.

We may incur unanticipated costs in connection with our shutdown of our manufacturing operations in Madison, Wisconsin.

In January 2018, we began implementing shutdown of our manufacturing operations at our corporate headquarters in Madison, Wisconsin and announced a plan to terminate our manufacturing staff in 2018. In connection with the shutdown of our manufacturing operations, we are responsible for decommissioning activities. Should the actual costs to fulfill these obligations exceed these estimated costs financial condition, our financial condition, and results of operations may be adversely affected.

We rely on a small number of 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 depends to a significant degree on the continued services of our executive officers, including our Chief Executive Officer, James V. Caruso. Our management and other employees may voluntarily terminate their employment with us at any time and there can be no assurance that these individuals will continue to provide services to us. In addition, our success will 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. 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.

At present, our success depends solely on the successful development and commercialization of our compounds in development, which cannot be assured.

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 a hematologic or solid tumor cancer including multiple myeloma and B-Cell lymphomas or solid tumor cancer types; the development of new PDCs, specifically new products developed from our CLR CTX Chemotherapeutic PDC program and the advancement of our PDC agents through research and development; and/or commercialization partnerships.

We are a biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer. We leverage our PDC platform to specifically target treatments to cancer cells. The PDC platform possesses the potential for the discovery and development of the next generation of cancer-targeting agents. The PDC platform features include the capacity to link with almost any molecule, provide a significant increase in targeted oncologic payload delivery and the ability to target all tumor cells. As a result, we believe that we can generate PDCs to treat a broad range of cancers with the potential to improve the therapeutic index of oncologic drug payloads, enhance or maintain efficacy while reducing adverse events by minimizing drug delivery to healthy cells, and increasing delivery to cancerous cells and cancer stem cells.

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 including the following:

- future clinical trial results may show that our cancer-targeting and delivery technologies are not well tolerated by patients at their effective doses or are not efficacious;
- future clinical trial results may be inconsistent with testing results obtained to-date;
- even if our cancer-targeting and delivery 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 and delivery 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 and delivery 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 and delivery technologies for some other reason, our business, prospects, financial condition, and results of operations may be adversely affected.

Failure to complete the development of our technologies, 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 approval 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 or other drugs undergoing development in clinical trials. 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 will 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 expect to rely on our patents as well as specialized regulatory designations such as orphan drug classification for our product candidates, but regulatory drug designations may not confer marketing exclusivity or other expected commercial benefits.

We expect to file for orphan drug designation or other regulatory designations (fast track, break-through, priority review, etc.) as appropriate for our product candidates. Orphan drug status confers seven years of marketing exclusivity under the Federal Food, Drug, and Cosmetic Act in the United States, 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 131 as a therapeutic for the treatment of multiple myeloma and neuroblastoma. While we have been granted this orphan designation, 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 without our patent portfolio. 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 if not for our patent portfolio. Furthermore, although the orphan drug designation and exclusivity are in effect right now, the FDA has the authority to modify this assessment at any time.

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 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 payors 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, payors, 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.

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 develop our business or become competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our technologies and proposed products non-competitive 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 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.

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 valid or not, could result in substantial costs, could place a significant strain on our financial and managerial resources, and could harm our reputation. 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, 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. Also, we typically obtain agreements from these parties, which provide 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.

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

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. 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 cost-effective or 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 educate physicians in a timely manner 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.

If users of our products are unable to obtain adequate reimbursement from third-party payors, 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 payors 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 are 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 payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations, and other payors 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, may also 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 payors 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 payors and providers are instituting, and the effect of any healthcare reform, could materially harm our ability to operate profitably.

Our business and operations may be materially adversely affected in the event of computer system failures or security breaches.

Despite the implementation of security measures, our internal computer systems, and those of our third-party manufacturers, CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, fire, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption in our business. For example, the loss of clinical trial data from ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, loss of trade secrets or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, access to our clinical data, or disruption of the manufacturing process, we could incur liability and the further development of our drug candidates could be delayed. We may also be vulnerable to cyber-attacks by hackers or other malfeasance. This type of breach of our cybersecurity may compromise our confidential information and/or our financial information and adversely affect our business or result in legal proceedings. Further, these cybersecurity breaches may inflict reputational harm upon us that may result in decreased market value and erode public trust.

Failure to maintain effective internal controls could adversely affect our ability to meet our reporting requirements.

We are required to establish and maintain appropriate internal controls over financial reporting. 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.

Effective internal controls are necessary for us to provide reasonable assurance with respect to our financial reports and to effectively prevent fraud. Failure to maintain effective internal controls 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 our business and results of operations could be harmed, we could fail to meet our reporting obligations, and there could be a material adverse effect on our common stock price.

Risks Related to Our Equity Securities

We have in the past received notices from Nasdaq of non-compliance with its listing rules and delisting with Nasdaq could impact the price of our common stock and our ability to raise funds.

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, we no longer met this requirement. However, the rules also provide us a period of 180 calendar days in which to regain compliance. On March 4, 2016, we effected a reverse stock split at a ratio of 1-for-10, which, among other things, resulted in an increase in the bid price adequate to allow us to regain compliance with the minimum bid price requirement. On March 21, 2016, Nasdaq notified us that we had regained compliance with the minimum bid price requirement.

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 submitted a plan to Nasdaq to regain compliance, which was approved by Nasdaq, that required a number of actions to be completed by February 10, 2016, including the filing of a registration statement with the SEC for an underwritten public offering of equity and the closing of that offering. The registration statement was timely filed, however we did not complete the offering by that date. Nasdaq issued a second notice of non-compliance on February 11, 2016, which the Company appealed. At a hearing on March 31, 2016, we requested, and Nasdaq subsequently granted, an extension of time to effect transactions to allow us to regain compliance and to report the same. On April 20, 2016, we closed an underwritten offering, and on May 16, 2016, Nasdaq issued a determination that we had evidenced compliance with all requirements for continued listing on The Nasdaq Capital Market and, accordingly, the listing qualifications matter had been closed.

We have not received any other notices of non-compliance with Nasdaq listing rules. However, any future failure to comply with Nasdaq's listing rules and any resulting delisting from the Nasdaq would reduce the visibility, liquidity and price of our common stock and could limit our ability to raise funds in the future.

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 listing on the Nasdaq exchange.

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 equity 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 dilute our common stock, affect the rights of our stockholders, reduce the market price of our common stock, 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 obligate us to issue additional shares of common stock to certain of our stockholders.

Provisions of our certificate of incorporation, 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 of directors (the 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 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;
- 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 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 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 \$15,000 per month under an agreement that expires on September 14, 2018, subject to two-year extensions. On January 3, 2018, we informed the landlord that we are not extending the lease but instead intend to de-commission and vacate the premises on or before September 14, 2018. We plan to enter into new leases for administrative staff in Wisconsin and New Jersey.

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.

Fiscal Year 2017	High	Low
First Quarter	\$ 3.07	\$ 1.21
Second Quarter	2.34	1.50
Third Quarter	2.06	1.40
Fourth Quarter	2.04	1.08

Fiscal Year 2016	High	Low
First Quarter	\$ 12.30	\$ 3.25
Second Quarter	5.05	1.00
Third Quarter	3.57	2.06
Fourth Quarter	2.91	1.12

On March 15, 2018 there were 325 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 15th 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. During 2016, we issued 75,000 options to our Senior Vice President that were not issued pursuant to our 2015 Stock Incentive Plan. These options vest annually over three 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, 2017 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	799,229	\$ 3.84	869,766
Equity compensation plans not approved by stockholders	112,500	\$ 10.75	—
Total	911,729	\$ 4.69	869,766

Item 6. Selected Financial Data.

Not applicable.

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

Overview

We are a clinical stage biopharmaceutical company focused on the development of targeted treatments for cancer. Our core objective is to leverage our proprietary PDC delivery platform to develop therapeutic PDCs that specifically target cancer cells to deliver improved efficacy and better safety as a result of fewer off-target effects. The PDC platform possesses the potential for the discovery and development of the next generation of cancer-targeting treatments and we plan to develop PDCs independently and through research and development collaborations.

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, 2017 and 2016

Research and Development. Research and development expense for the year ended December 31, 2017 was approximately \$9,466,000 (composed of approximately \$1,769,000 in clinical project costs, \$1,702,000 of manufacturing and related costs, approximately \$1,107,000 in pre-clinical projects, \$1,546,000 in depreciation expense, inclusive of approximately \$1,200,000 of one-time de-commissioning expense, and \$3,342,000 in general unallocated research and development costs) compared to approximately \$4,750,000 (composed of approximately \$1,047,000 in clinical project costs, \$370,000 of manufacturing and related costs, \$100,000 in pre-clinical projects and \$3,233,000 in general unallocated research and development costs) for 2016. The overall increase in research and development of approximately \$4,716,000, or 99% was due primarily to the initiation of the Phase 2 clinical study of CLR 131 in hematologic malignancies and the establishment of secondary manufacturing and supplier capabilities, the combination of which represented approximately \$2,215,000. Additionally, increases of approximately \$1,200,000 of accelerated depreciation expense related to the reassessed estimated useful life of the leasehold improvements and laboratory equipment beginning on December 1, 2017 through December 31, 2017 (one month remaining life), personnel and related travel of approximately \$530,000 and purchased services primarily related to pre-clinical studies of \$1,100,000 represented the remainder of the increase, which was slightly offset by reduced costs related to the SBIR funding of approximately \$514,000. We expect 2018 research and development expense to be comparable to 2017 expenses, excluding the accelerated depreciation expense in 2017 related to the reassessed estimated useful life of the leasehold improvements and laboratory equipment.

General and Administrative. General and administrative expense for the year ended December 31, 2017 was approximately \$4,135,000 compared to approximately \$4,699,000 in 2016. The decrease of \$564,000, or 12%, in general and administrative costs was primarily related to a decrease in accounting and legal fees of approximately \$289,000, a decrease in personnel related costs of approximately \$94,000, and a decrease in purchased services related to consulting, investor relations and public company compliance related costs including printing of approximately \$183,000.

Gain on Revaluation of Derivative Warrants. We recorded a gain on the revaluation of derivative warrants of approximately \$22,000 in 2017 and \$3,262,000 in 2016. These amounts, which are non-cash in nature, represent the change in fair value (resulting primarily from renegotiating the terms of the warrants which resulted in their no longer being classified as derivatives, changes in the Company's stock price, and reduced remaining time over which the warrants will remain outstanding), 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.

Interest income (expense), net. Interest income, net, for the year ended December 31, 2017 was approximately \$17,000, as compared to approximately \$8,000 for the year ended December 31, 2016. The increase is due to the interest earned on the Company's cash equivalents. In 2017 the Company had approximately \$1,000 of interest expense related to the Company's outstanding debt owed to the Wisconsin Department of Commerce, as compared to \$1,500 in 2016.

Deemed Dividend on Preferred Stock. During the years ended December 31, 2017, and 2016, the Company closed on equity offerings that included the issuance of Preferred Stock that included a beneficial conversion feature ("BCF") which is also reflected as a deemed dividend. The deemed dividends of approximately \$1,449,000 or \$0.10 per share, and approximately \$3,180,000 or \$0.70 per share, for the years ended December 31, 2017 and 2016, respectively have been included in the calculation of net loss attributable to common stockholders of approximately \$15,011,000 and \$9,360,000 for the years ended December 31, 2017 and 2016 respectively.

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, 2017, we had approximately \$10 million in cash and cash equivalents. To date we have raised capital aggregating approximately \$175 million.

On October 12, 2017 the Company closed on a registered direct offering of 1.95 million shares of its common stock and 41,041,294 shares of its preferred stock convertible into 2.2 million shares of common stock and a concurrent private placement of warrants to purchase 3.1 million shares of common stock. The gross proceeds were approximately \$7.8 million with net proceeds to the Company of approximately \$7.1 million. The Company allocated the proceeds to the common stock, the Series B Preferred Stock and the Series D warrants on a relative fair value basis. Using the effective conversion price of the Series B Preferred Stock, the Company determined that there was a beneficial conversion feature (BCF) of \$1,448,945. The BCF did not impact total Stockholders' Equity but is reflected as a deemed dividend in arriving at net loss attributable to common stockholders.

On November 29, 2016 the Company closed on an underwritten public offering (the "November 2016 Underwritten Offering") of 1.6 million shares of common stock, 68 shares of Series A preferred stock convertible into 4,533,336 share of common stock, and Series C warrants to purchase approximately 6.1 million shares of common stock, reflecting the exercise in full of the Underwriter's over-allotment option. The gross proceeds of the offering amounted to \$9.2 million with net proceeds to the Company of approximately \$8.3 million. The Company allocated the proceeds to the common stock, the Series A Preferred Stock and the Series C warrants on a relative fair value basis. Using the effective conversion price of the Series A Preferred Stock, the Company determined that there was a beneficial conversion feature of \$3,179,981. The BCF did not impact total Stockholders' Equity but is reflected as a deemed dividend in arriving at net loss attributable to common stockholders.

On April 20, 2016 the Company closed an underwritten public offering (the "April 2016 Underwritten Offering") of 1,871,321 shares of its common stock and Series B pre-funded warrants to purchase 1,908,021 shares of common stock, plus the issuance of Series A warrants to purchase 3,779,342 shares of common stock, reflecting the exercise in full of the Underwriter's over-allotment option. The gross proceeds of the offering amounted to approximately \$8.0 million with net proceeds to the Company of approximately \$7.2 million.

On April 13, 2016, the Company entered into an exchange and amendment agreement (the “Warrant Restructuring Agreement”) pursuant to which the Company agreed with the holders of 2015 Series A Warrants that upon the consummation of the April 2016 Underwritten Offering, the exercise price of the 2015 Series A Warrants would be reduced to the public offering price per share of the shares of common stock sold in this offering and that the warrants would be amended such that the exercise price would no longer be subject to adjustment in connection with future equity offerings we may undertake. In consideration of this amendment, the Company agreed to issue to each of those holders a new warrant to purchase an additional number of shares of common stock equal to twice the number of shares of common stock underlying the 2015 Series A Warrants held by them (the “Incremental Series A Warrants”). These warrants have an exercise price equal to \$2.13 (the public offering price of the shares of common stock sold in the April 2016 Underwritten Offering), became exercisable on October 20, 2016, and expire on the fifth anniversary of that date.

During the year ended December 31, 2017, approximately \$11,020,000 of cash was used in operations. During this period we reported a net loss of approximately \$13,562,000. This loss included the following non-cash items: approximately \$759,000 in stock-based compensation, and approximately \$1,546,000 in depreciation and amortization expense, offset by a gain of approximately \$22,000 related to warrants that are classified as derivative instruments. After adjustment for these non-cash items, changes in working capital provided cash of \$259,000, which was the result of \$451,000 from the timing of payments of accounts payable and accrued expenses and an increase in prepaid and other assets of approximately \$192,000.

During the year ended December 31, 2017, we purchased approximately \$347,000 in fixed assets, primarily in support of the CLR 131 manufacturing capabilities located at our third party supplier.

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 \$84.3 million at December 31, 2017. During the year ended December 31, 2017, we generated a net loss of approximately \$13.6 million and we expect that we will continue to generate operating losses for the foreseeable future. At December 31, 2017, our consolidated cash balance was approximately \$10 million. We believe this cash balance is adequate to fund budgeted operations into early first quarter 2019. 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, there can be no assurance that we will obtain the necessary funding. Other than the uncertainties regarding our ability to obtain additional funding, there are currently no known trends, demands, commitments, events or uncertainties that are likely to materially affect our liquidity.

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, 2017 and 2016 there was approximately \$1.7 million 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 paid 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. In conjunction with the preferred stock financings in 2017 and 2016, we were required to separately estimate the fair value of each of the common stock, preferred stock and warrants issued in such financings. 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

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors
Cellecstar Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cellecstar Biosciences, Inc. and Subsidiary (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

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 consolidated financial statements, the entity has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about its 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.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Baker Tilly Virchow Krause, LLP

We have served as the Company's auditor since 2016.

Madison, Wisconsin
March 21, 2018

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

	<u>December 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 10,006,421	\$ 11,444,619
Restricted cash	55,000	55,000
Prepaid expenses and other current assets	877,996	693,569
Total current assets	<u>10,939,417</u>	<u>12,193,188</u>
FIXED ASSETS, NET	244,713	1,444,058
GOODWILL	1,675,462	1,675,462
OTHER ASSETS	11,872	11,872
TOTAL ASSETS	<u><u>\$ 12,871,464</u></u>	<u><u>\$ 15,324,580</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of notes payable	\$ —	\$ 86,591
Accounts payable and accrued liabilities	1,867,758	1,416,433
Derivative liability	105,050	127,125
Capital lease obligations, current portion	3,036	2,727
Deferred rent	138,944	—
Total current liabilities	<u>2,114,788</u>	<u>1,632,876</u>
LONG-TERM LIABILITIES:		
Deferred rent	—	146,583
Capital lease obligations, less current portion	2,213	5,249
Total long-term liabilities	<u>2,213</u>	<u>151,832</u>
Total liabilities	<u>2,117,001</u>	<u>1,784,708</u>
COMMITMENTS AND CONTINGENCIES (Notes 12 and 13)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized;		
Series A preferred stock; 0 and 17 issued and outstanding as of December 31, 2017 and 2016, respectively	—	865,136
Series B preferred stock; 18 and 0 issued and outstanding as of December 31, 2017 and 2016, respectively	995,782	—
Common stock, \$0.00001 par value; 80,000,000 and 40,000,000 shares authorized at December 31, 2017 and 2016, respectively; 16,661,446 and 10,368,325 shares issued and outstanding at December 31, 2017 and 2016, respectively	167	104
Additional paid-in capital	94,107,830	83,461,658
Accumulated deficit	<u>(84,349,316)</u>	<u>(70,787,026)</u>
Total stockholders' equity	<u>10,754,463</u>	<u>13,539,872</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u><u>\$ 12,871,464</u></u>	<u><u>\$ 15,324,580</u></u>

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

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2017	2016
COSTS AND EXPENSES:		
Research and development	\$ 9,465,666	\$ 4,750,414
General and administrative	4,135,304	4,699,338
Total costs and expenses	13,600,970	9,449,752
LOSS FROM OPERATIONS	(13,600,970)	(9,449,752)
OTHER INCOME (EXPENSE):		
Gain on revaluation of derivative warrants	22,075	3,261,529
Interest income (expense), net	16,605	7,897
Total other income, net	38,680	3,269,426
NET LOSS	(13,562,290)	(6,180,326)
DEEMED DIVIDEND ON PREFERRED STOCK	(1,448,945)	(3,179,981)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	(15,011,235)	(9,360,307)
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	\$ (1.07)	\$ (2.14)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	14,031,329	4,366,617

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

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Par Amount			
BALANCE AT DECEMBER 31, 2015	—	—	858,140	9	66,256,494	(64,606,700)	1,649,803
Reverse stock split fractional shares	—	—	(127)	—	(594)	—	(594)
Issuance of common stock, warrants and preferred stock, net of issuance costs	68	3,460,543	3,471,321	35	12,036,286	—	15,496,864
Warrant exercises	—	—	2,638,901	26	652,511	—	652,537
Stock-based compensation	—	—	—	—	529,159	—	529,159
Cashless option exercise	—	—	73	—	—	—	—
Conversion of preferred shares into common shares	(51)	(2,595,407)	3,400,017	34	2,595,373	—	—
Reclassification to equity for warrants that are no longer derivative instruments	—	—	—	—	1,392,429	—	1,392,429
Net loss	—	—	—	—	—	(6,180,326)	(6,180,326)
BALANCE AT DECEMBER 31, 2016	17	\$ 865,136	10,368,325	\$ 104	\$ 83,461,658	\$ (70,787,026)	\$ 13,539,872
Issuance of common stock, warrants and preferred stock, net of issuance costs	41	2,265,257	1,954,388	20	4,789,588	—	7,054,865
Warrant exercises	—	—	1,975,506	20	2,963,239	—	2,963,259
Stock-based compensation	—	—	—	—	758,757	—	758,757
Cashless option exercise	—	—	2,403	—	—	—	—
Conversion of preferred shares into common shares	(40)	(2,134,611)	2,360,824	23	2,134,588	—	—
Net loss	—	—	—	—	—	(13,562,290)	(13,562,290)
BALANCE AT DECEMBER 31, 2017	18	\$ 995,782	16,661,446	\$ 167	\$ 94,107,830	\$ (84,349,316)	\$ 10,754,463

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

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended	
	December 31,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (13,562,290)	\$ (6,180,326)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,546,048	356,665
Stock-based compensation	758,757	529,159
Gain on revaluation of derivative warrants	(22,075)	(3,261,529)
Changes in:		
Prepaid expenses and other current assets	(184,427)	(464,355)
Accounts payable and accrued liabilities	451,325	740,509
Deferred rent	(7,639)	(2,341)
Cash used in operating activities	<u>(11,020,301)</u>	<u>(8,282,218)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(346,703)	(72,251)
Cash used in investing activities	<u>(346,703)</u>	<u>(72,251)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on capital lease obligations	(2,727)	(2,448)
Reverse stock split fractional shares	—	(594)
Proceeds from issuance of common stock, net of underwriting issuance costs	4,905,945	12,363,057
Proceeds from issuance of preferred stock	2,265,257	3,460,543
Cash paid for issuance costs	(116,337)	(326,736)
Proceeds from conversion of warrants	2,963,259	652,537
Payments on long-term obligations	(86,591)	(243,631)
Deferred financing costs	—	38,569
Cash provided by financing activities	<u>9,928,806</u>	<u>15,941,297</u>
INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(1,438,198)	7,586,828
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF PERIOD	11,499,619	3,912,791
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF PERIOD	<u>\$ 10,061,421</u>	<u>\$ 11,499,619</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest expense	\$ 364	\$ 4,349
Reclassification to equity for warrants that are no longer derivative instruments	\$ —	\$ 1,392,429
Beneficial conversion feature and related deemed dividend on preferred stock	\$ 1,448,945	\$ 3,179,981

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

Collectar Biosciences, Inc. (the Company) is a clinical stage biopharmaceutical company focused on the development of targeted treatments for cancer and leveraging its proprietary phospholipid drug conjugate (PDC™) platform to develop the next generation of tumor targeting treatments. Its 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 \$84,349,000 at December 31, 2017. During the year ended December 31, 2017, the Company generated a net loss of approximately \$13,562,000 and the Company expects that it will continue to generate operating losses for the foreseeable future. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company believes that its cash balance at December 31, 2017 is adequate to fund operations at budgeted levels into early first quarter 2019. The Company's ability to execute its operating plan beyond first quarter 2019 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, raising substantial doubt about the Company's ability to continue as a going concern within one year of the date these financial statements are issued. 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, 2017 are presented on a consolidated basis.

Prior Period Presentation — The Company allocated the proceeds of the November 2016 Underwritten Offering between the Series A Preferred Stock and the Series C Warrants based on fair value and correctly recorded the Series A Preferred Stock as equity, however the embedded beneficial conversion feature (BCF) associated with the Series A Preferred Stock was not properly considered. ASC 470-20 required the Company to reflect in its presentation of net loss attributable to common stockholders a BCF of approximately \$3.2 million. Additionally, shares used in computing basic and diluted net loss per common share were overstated by approximately 0.2 million shares. The net effect was to increase net loss attributable to common shareholders per share by (\$0.78). These had no effect on cash, cash flows or total shareholders' equity during 2016 and had no effect on cash, cash flows, net income or total stockholders' equity for any subsequent periods. After considering the quantitative and qualitative effects to the 2016 annual financial statements, as well as the quarterly period financial statements within 2016, in the opinion of management, it is not material to assessing the financial condition or operations of the Company.

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and the accounts of its wholly-owned subsidiary. All inter-company 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, 2017 and 2016 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 (3 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).

In December 2017, the Company concluded that the manufacturing processes would be transferred to a third party. As part of the transfer, the Company also began the process of de-commissioning the manufacturing facility. In connection with the de-commissioning, the Company determined that certain research and development assets will no longer be used by the Company and had materially ceased being used by December 31, 2017. As a result, the Company reassessed the estimated useful life of the research and development assets and concluded they should be accelerated beginning on December 1, 2017 through December 31, 2017 (one month remaining life). The Company also reassessed the estimated useful life of the leasehold improvements and concluded that they should be accelerated beginning on December 1, 2017 through December 31, 2017 (one month remaining life). These reassessments of the estimated useful lives have been accounted for as changes in an estimate. The effect of these changes in estimates was to increase 2017 depreciation expense by approximately \$1,176,000, increase 2017 net loss by approximately \$1,176,000, and increase 2017 basic and diluted net loss attributable to common stockholders per share by \$0.08.

Goodwill — Intangible assets at December 31, 2017 and 2016 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 significant 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).

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2017-04, Simplifying the Test for Goodwill. The standard streamlines the methodology for calculating whether goodwill is impaired based upon whether the carrying amount of goodwill exceeds the reporting unit's fair value. ASU 2017-04 applies to public business entities and those other entities that have goodwill reported in their financial statements and have not elected the private company alternative for the subsequent measurement of goodwill and is effective for annual and interim reporting periods beginning after December 15, 2019, with early adoption permitted. The Company does not expect that the adoption of this standard will have a material effect on its financial statements.

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 FASB Accounting Standards Codification (“ASC”) Topic 505, *Equity*. As such, the Company recognizes expense based on the estimated fair value of options granted to non-employees over their vesting period, which is generally the period during which services are rendered and deemed completed by such non-employees.

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

Income Taxes — Income taxes are accounted for using the liability method of accounting. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement basis and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some portion of the deferred tax assets will not be realized. Management has provided a full valuation allowance against the Company’s gross deferred tax asset. Tax positions taken or expected to be taken in the course of preparing tax returns are required to be evaluated to determine whether the tax positions are “more likely than not” to be sustained by the applicable tax authority. Tax positions deemed not to meet a more-likely-than-not threshold would be recorded as tax expense in the current year. There were no uncertain tax positions that require accrual to or disclosure in the financial statements as of December 31, 2017 and 2016.

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 533,065 at December 31, 2017 and 2016, 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, 2017 and 2016, 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, 2017 and 2016 is on deposit in interest-bearing transaction accounts with well-established financial institutions. At times, such amounts may exceed the FDIC insurance limits. As of December 31, 2017, uninsured cash balances totaled approximately \$9,600,000.

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.

Recent Accounting Pronouncements - In July 2017, the FASB issued Accounting Standards Update (“ASU”) No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815)*. The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity’s own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company is currently evaluating the method of adoption and the impact of adopting ASU 2017-11 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 shares of common stock in a February 2013 public offering (the “February 2013 Public Offering Warrants”). On February 20, 2014, warrants to purchase 27,500 of common stock expired. On May 20, 2016, warrants to purchase 16,250 shares of common stock were exercised. The remaining warrants to purchase 38,750 shares of common stock are classified within the Level 3 hierarchy.

In August 2014, as part of an underwritten public offering, the Company issued warrants to purchase 494,315 shares of common stock (the “August 2014 Warrants”). The 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 as Level 2 within the hierarchy.

During 2016, the fair value of certain warrants was reclassified to equity when they were no longer required to be accounted for as derivative instruments.

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, 2017 and 2016:

	December 31, 2017			Fair Value
	Level 1	Level 2	Level 3	
Liabilities:				
February 2013 Public Offering Warrants	\$ —	\$ —	\$ 5,050	\$ 5,050
August 2014 Warrants	—	100,000	—	100,000
Total	<u>\$ —</u>	<u>\$ 100,000</u>	<u>\$ 5,050</u>	<u>\$ 105,050</u>

	December 31, 2016			Fair Value
	Level 1	Level 2	Level 3	
Liabilities:				
February 2013 Public Offering Warrants	\$ —	\$ —	\$ 27,125	\$ 27,125
August 2014 Warrants	—	100,000	—	100,000
Total	<u>\$ —</u>	<u>\$ 100,000</u>	<u>\$ 27,125</u>	<u>\$ 127,125</u>

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:

	Year Ended December 31,	
	2017	2016
Volatility	76-118%	92.72-134%
Risk-free interest rate	1.03-1.39%	0.53-1.15%
Expected life (years)	0.14-0.89	1.14-1.89
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.

	Year Ended December 31,	
	2017	2016
Beginning fair value of warrants	\$ 27,125	\$ 2,067,000
Reclassification to equity for warrants that are no longer derivative liabilities	—	(1,392,429)
Gain on derivatives resulting from change in fair value or extinguishment	(22,075)	(647,446)
Ending fair value of warrants	<u>\$ 5,050</u>	<u>\$ 27,125</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, 2017 or 2016.

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. Our analysis concluded that as of December 31, 2017, goodwill was not impaired.

5. FIXED ASSETS

Fixed assets consisted of the following at December 31:

	<u>2017</u>	<u>2016</u>
Office and laboratory equipment	\$ 3,751,059	\$ 3,351,065
Computer software	4,000	4,000
Leasehold improvements	2,333,443	2,333,443
Construction in process	—	56,640
Total fixed assets	<u>6,088,502</u>	<u>5,745,148</u>
Less— accumulated depreciation and amortization	<u>(5,843,789)</u>	<u>(4,301,090)</u>
Fixed assets, net	<u>\$ 244,713</u>	<u>\$ 1,444,058</u>

For the years ended December 31, 2017 and 2016, the Company incurred approximately \$1,546,000 and \$357,000 of depreciation and amortization expense, respectively.

6. AGREEMENTS

2017 Material Transfer Agreement with Onconova

On September 18, 2017, the Company entered into an arrangement (the “Onconova MTA”) with Onconova Therapeutics, Inc. (“Onconova”). Under this arrangement, Onconova will provide a selection of its proprietary compounds to the Company. The Company will use its proprietary technology to perform research studies on such compounds with the goal of developing new conjugates. The Company agrees to perform the studies within 24 months. The Company granted to Onconova an exclusive option to acquire from the Company a royalty-bearing license with respect to each conjugate developed. In the event an executed license agreement for a particular conjugate is not obtained, then Onconova’s exclusive option shall terminate with respect to such conjugate.

2017 Material Transfer Agreement with Avicenna

On July 9, 2017, the Company entered into an arrangement (the “Avicenna MTA”) with Avicenna Oncology GMBH (“Avicenna”). Under this arrangement, Avicenna will provide a selection of its proprietary toxins to the Company. The Company will use its proprietary conjugation capabilities to proceed with the conjugation in order to obtain PDCs. The Company will process various *in vitro* and *in cellulo* screening against such PDCs to develop new conjugates. The Company granted to Avicenna an exclusive option to acquire an exclusive license to the Company’s intellectual property with respect to each conjugate developed. In the event the parties cannot reach agreement on the terms of a definitive agreement despite good faith negotiations, Avicenna’s exclusive option shall terminate as to such conjugate. Avicenna also granted to the Company an exclusive option to acquire an exclusive license to Avicenna’s intellectual property with respect to Avicenna’s material. In the event the parties cannot reach agreement on the terms of a definitive agreement despite good faith negotiations, the Company’s exclusive option shall terminate as to such material of Avicenna.

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 pre-clinical 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 June 15, 2018 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.

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 expired in December 2016, at which point the U. Mich. License expired. The Company was responsible for an annual license fee of \$10,000 and was required to pay costs associated with the maintenance of the patents covered by the U. Mich. License. The Company made all payments as they became due, there were no defaults under the U. Mich. License, nor was the Company notified of a default by U. Mich.

The Company did not incur any expenses for the reimbursement of patent maintenance fees to U. Mich. during the years ended December 31, 2017 and 2016.

7. NOTES PAYABLE

During the year ended December 31, 2017, the two loans with initial principal amounts totaling \$450,000 from the Wisconsin Economic Development Corporation, dated September 15, 2010, were paid in full.

8. STOCKHOLDERS’ EQUITY

Authorized Share Increase

At a special meeting held on September 12, 2017, the Company’s stockholders approved the ratification of the approval of the Certificate of Amendment to our Certificate of Incorporation to increase the number of authorized shares by 40,000,000 to 80,000,000 which was previously approved by the Company’s stockholders at our annual meeting of stockholders held on May 31, 2017.

October 2017 Registered Direct Offering

On October 12, 2017, the Company closed on a registered direct offering (the “October 2017 Registered Direct Offering”), priced at-the-market, of 1,954,388 shares of its common stock and 41.0412949 shares of its Series B Preferred Stock. The Series B Preferred Stock was offered at \$100,000 per share and is immediately convertible into approximately 53,369 shares of common stock for a total of 2,190,330 shares upon conversion at a price of \$1.87375 per share. The common stock was offered at \$1.87375 per share. Gross offering proceeds to the Company were \$7.76 million. In a concurrent private placement, the Company offered purchasers in the registered direct offering Series D warrants to purchase an aggregate of 3,108,538 shares of common stock, or 0.75 shares of common stock for each share of common stock purchased directly or issuable upon conversion of shares of preferred stock. The Series B Preferred Stock is non-voting, has no dividend rights (except to the extent dividends are also paid on common stock), liquidation preference, or other preferences over common stock. The Series D warrants are immediately exercisable at an exercise price of \$1.78 per share and expire seven years from the closing. The Series D warrants, which are callable by the Company under certain circumstances, will not trade. Gross proceeds were approximately \$7.8 million with net proceeds to the Company of approximately \$7.1 million.

In order to account for the October 2017 Registered Direct Offering, the Company allocated the proceeds to the common stock, the Series B Preferred Stock and the Series D warrants on a relative fair value basis. Then using the effective conversion price of the Series B Preferred Stock, the Company determined that there was a beneficial conversion feature of \$1,448,945. The BCF did not impact total Stockholders’ Equity but is reflected as a deemed dividend in arriving at net loss attributable to common stockholders.

On or prior to December 31, 2017, 23 shares of Series B Preferred Stock issued in the October 2017 Registered Direct Offering were converted into 1,227,485 shares of common stock. As of December 31, 2017, 18.0412949 shares of Series B Preferred Stock remained outstanding.

November 2016 Underwritten Offering

On November 23, 2016, the Company entered into an Underwriting Agreement with Ladenburg Thalmann & Co. Inc., as representative of the several underwriters named therein, in connection with the Company’s Registration Statement on Form S-1. Pursuant to the Underwriting Agreement, the Company agreed to sell to the Underwriter 800,000 shares of common stock, 68 shares of Series A preferred stock convertible into 4,533,356 shares of common stock (the “Series A Preferred Stock”) and Series C warrants to purchase 5,333,356 shares of common stock (the “Series C Warrants”), plus up to an additional 800,000 shares of common stock and Series C Warrants to purchase up to an additional 800,000 shares of common stock in the event of the exercise by the Underwriter of its over-allotment option. The public offering price of a share of common stock together with a Series C Warrant to purchase one share of common stock was \$1.50. The public offering price to purchase one share of Series A Preferred Stock, each of which is convertible into 66,667 shares of common stock, together with a Series C Warrant to purchase 66,667 shares of common stock was \$100,000. The Series A Preferred Stock is non-voting, has no dividend rights (except to the extent dividends are also paid on common stock), liquidation preference, or other preferences over common stock. The Series C Warrants have an exercise price of \$1.50 per share, and are exercisable for five years from the date of issuance.

The sale of securities pursuant to the Underwriting Agreement, including the entire over-allotment option, closed on November 29, 2016 (the “November 2016 Underwritten Offering”). Gross proceeds were \$9.2 million with net proceeds to the Company of approximately \$8.3 million.

In order to account for the November 2016 Underwritten Offering, the Company allocated the proceeds to the common stock, the Series A Preferred Stock and the Series C warrants on a relative fair value basis. Then using the effective conversion price of the Series A Preferred Stock, the Company determined that there was a beneficial conversion feature of \$3,179,981. The BCF did not impact total Stockholders’ Equity but is reflected as a deemed dividend in arriving at net loss attributable to common stockholders.

As of December 31, 2017, all 68 shares of Series A Preferred Stock issued in the November 2016 Underwritten Offering were converted into 4,533,356 shares of common stock.

April 2016 Underwritten Offering

On April 15, 2016, the Company entered into an Underwriting Agreement with Ladenburg Thalmann & Co., Inc. in connection with the Company's Registration Statement on Form S-1. Pursuant to the Underwriting Agreement, the Company agreed to sell to the Underwriter 1,378,364 shares of common stock, Series B prefunded warrants to purchase 1,908,021 shares of common stock and Series A warrants to purchase 3,286,385 shares of common stock, plus up to an additional 492,957 shares of common stock and Series A warrants to purchase up to an additional 492,957 shares of common stock in the event of the exercise by the Underwriter of its over-allotment option. The public offering price of a share of common stock together with a Series A warrant to purchase one share of common stock was \$2.13. The public offering price of a Series B pre-funded warrant to purchase one share of common stock together with a Series A warrant to purchase one share of common stock was \$2.12. The Series B pre-funded warrants had an exercise price of \$0.01 per share, were immediately exercisable and do not expire. The Series A warrants have an exercise price of \$3.04 per share, are exercisable for five years from the date of issuance, and are callable by the Company under certain circumstances.

On April 20, 2016, the Company closed an underwritten public offering (the "April 2016 Underwritten Offering") of 1,871,321 shares of its common stock and Series B pre-funded warrants to purchase 1,908,021 shares of common stock, plus the issuance of Series A warrants to purchase 3,779,342 shares of common stock, reflecting the exercise in full of the Underwriter's over-allotment option. The gross proceeds of the offering amounted to approximately \$8.0 million with net proceeds to the Company of approximately \$7.2 million. All of the Series B pre-funded warrants issued in the April 2016 Underwritten Offering were exercised on or prior to June 30, 2016.

Warrant Restructuring

On April 13, 2016, the Company entered into an exchange and amendment agreement (the "Warrant Restructuring Agreement") pursuant to which the Company agreed to exchange the 2015 Pre-Funded Warrants relating to 48,273 shares of the Company's common stock for shares of a newly designated Series Z Convertible Preferred Stock (the "Series Z Preferred Stock") having an aggregate stated value equal to approximately \$1,062,000, which was the aggregate purchase price of the 2015 Pre-Funded Warrants. The exchange of the 2015 Pre-Funded Warrants for shares of Series Z Preferred Stock was conditioned upon the Company obtaining the approval of its stockholders as required by the applicable rules and regulations of the Nasdaq Stock Market. The Company agreed to hold a meeting of stockholders to obtain their approval of the issuance of the Series Z Preferred Stock and the shares of common stock issued upon conversion on June 29, 2016; however, prior to that date, the holders of all the 2015 Pre-Funded Warrants chose to exercise them, eliminating the need for the exchange.

Pursuant to the Warrant Restructuring Agreement, the Company also agreed with the holders of 2015 Series A Warrants that upon the consummation of the 2016 Underwritten Offering, the exercise price of the 2015 Series A Warrants would be reduced to the public offering price per share of the shares of common stock sold in this offering and that the warrants would be amended such that the exercise price would no longer be subject to adjustment in connection with future equity offerings we may undertake. In consideration of this amendment, the Company agreed to issue to each of those holders a new warrant to purchase an additional number of shares of common stock equal to twice the number of shares of common stock underlying the 2015 Series A Warrants held by them (the "Incremental Series A Warrants"). These warrants have an exercise price equal to \$2.13 (the public offering price of the shares of common stock sold in the 2016 Underwritten Offering), become exercisable on October 20, 2016, and expire on the fifth anniversary of that date.

2016 Reverse Stock Split and Recapitalization

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 remained 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 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.

Common Stock Warrants

The following table summarizes information with regard to outstanding warrants to purchase common stock as of December 31, 2017.

<u>Offering</u>	<u>Number of Shares Issuable Upon Exercise of Outstanding Warrants</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
October 2017 Series D Warrants	3,108,538	\$ 1.78	October 14, 2024
November 2016 Public Offering Series C	4,157,850	\$ 1.50	November 29, 2021
April 2016 Underwritten Registered Series A	3,626,942	\$ 3.04	April 20, 2021
October 2015 Incremental Series A	300,006	\$ 2.13	October 20, 2021
October 2015 Private Placement Series A	86,365	\$ 2.13	April 1, 2021
October 2015 Offering – Placement Agent	3,750	\$ 28.30	October 1, 2020
August 2014 Public Offering ⁽¹⁾	504,019	\$ 46.80	August 20, 2019
February 2013 Public Offering ⁽¹⁾	38,750	\$ 1.50 ⁽²⁾	February 20, 2018
February 2013 Public Offering – Placement Agents	3,854	\$ 125.00	February 4, 2018
Total	<u>11,830,074</u>		

- (1) These warrants have a certain type of cash settlement feature or their exercise price 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 9,704 warrants issued in August 2014.
- (2) Due to the issuance of common stock at \$1.50 per share as part of the November 2016 Underwritten Offering, the remaining outstanding warrants issued as part of the February 2013 Public Offering were adjusted to reflect the revised exercise price of \$1.50 each.

Reserved Shares

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

	<u>December 31,</u>	
	<u>2017</u>	<u>2016</u>
Warrants	11,830,074	10,716,952
Preferred stock	962,845	1,133,339
Stock options and grants	911,729	471,433
Total number of shares reserved for future issuance	<u>13,704,648</u>	<u>12,321,724</u>

9. STOCK-BASED COMPENSATION

Increase in 2015 Stock Incentive Plan. At the 2017 annual meeting of stockholders held on May 31, 2017, the Company’s stockholders approved an increase in the number of shares of common stock available for issuance under our 2015 Stock Incentive Plan by 1,200,000 shares.

2015 Stock Incentive Plan. The 2015 Stock Incentive Plan was adopted on June 9, 2015 authorizing an aggregate of 420,000 shares for issuance (after taking into account the 2016 10:1 reverse stock split). On May 31, 2017, our stockholders approved the Amended and Restated 2015 Stock Incentive Plan (the “2015 Plan”) to increase the authorized shares by 1,200,000 shares. A total of 1,620,000 shares of common stock are authorized for issuance under the 2015 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. Upon adoption of the 2015 Plan, shares were no longer available for grant under our 2006 Stock Incentive Plan (the “2006 Plan”). All outstanding awards under the 2006 Plan remained 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 be added to the number of shares available for grant under the 2015 Plan. As of December 31, 2017, there are an aggregate of 869,766 shares available for future grants under the 2015 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 2006 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 2006 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.

Restricted Stock Grants. During 2017, the Company issued 460,000 shares under the 2015 Plan of restricted common stock with a weighted average grant date fair value of \$2.10. The shares vest annually over a three year period. The following table summarizes the restricted stock grants:

Outstanding at December 31, 2016	—
Granted	460,000
Vested	—
Forfeited	(80,000)
Outstanding at December 31, 2017	<u>380,000</u>

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:

	Year Ended December 31,	
	2017	2016
Employee and director stock options and stock grants:		
Research and development	\$ 147,821	\$ 58,044
General and administrative	610,936	471,453
	<u>758,757</u>	<u>529,497</u>
Non-employee consultant stock option grants:		
Research and development	—	(338)
General and administrative	—	—
	<u>—</u>	<u>(338)</u>
Total stock-based compensation	<u>\$ 758,757</u>	<u>\$ 529,159</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% was applied to all unvested options for employees and directors, respectively, during the periods ended December 31, 2017 and 2016. 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:

	Year Ended December 31,	
	2017	2016
Volatility	107-110%	104-105%
Risk-free interest rate	1.89-2.18%	1.29-1.39%
Expected life (years)	6	6
Dividend	0%	0%
Weighted-average exercise price	\$ 1.91	\$ 1.97
Weighted-average grant-date fair value	\$ 1.58	\$ 1.59

Stock Option Activity

A summary of stock option activity is as follows:

	Number of Shares Issuable Upon Exercise of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2015	70,933	\$ 78.63		
Granted	475,300	\$ 1.97		
Exercised	(166)	\$ 1.48		
Expired	(16,153)	\$ 156.53		
Forfeited	(58,481)	\$ 7.00		
Outstanding at December 31, 2016	471,433	\$ 7.59		
Granted	112,300	\$ 1.91		
Exercised	(20,833)	\$ 1.48		
Expired	(2,004)	\$ 116.61		
Forfeited	(29,167)	\$ 1.48		
Outstanding at December 31, 2017	531,729	\$ 6.55		
Vested, December 31, 2017	254,777	\$ 9.79	8.27	\$ —
Unvested, December 31, 2017	276,952	\$ 3.57	8.72	\$ —
Exercisable at December 31, 2017	254,777	\$ 9.79	8.27	\$ —

Exercise prices for all grants made during the twelve months ended December 31, 2017 and 2016 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. 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, 2017 and 2016 was \$1.58 and \$1.59, respectively. The total fair value of shares vested during the years ended December 31, 2017 and 2016 was \$636,071 and \$440,443, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2017 was \$7.74 and \$2.91, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2016 was \$20.03 and \$3.27, respectively.

The weighted average grant date fair value of options expired during the years ended December 31, 2017 and December 31, 2016 was \$61.12 and \$116.32, respectively. The weighted average grant date fair value of options forfeited during the years ended December 31, 2017 and December 31, 2016 was \$1.19 and \$2.54, respectively. The number of options vested during the years ended December 31, 2017 and December 31, 2016 was 203,608 and 68,180, respectively. The number of options unvested at January 1, 2017 and January 1, 2016 was 397,427 and 47,253, respectively. The weighted average grant date fair value of options unvested at January 1, 2017 and January 1, 2016 was \$3.27 and \$23.93, respectively.

As of December 31, 2017, there was \$1,218,812 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, the Company expects to recognize \$672,865, \$474,340, and \$71,607 during 2018, 2019, and 2020 respectively. The Company expects options to purchase 643,813 shares to vest in the future.

10. INCOME TAXES

	2017	2016
Tax provision (benefit)		
Current		
Federal	\$ —	\$ —
State	—	—
Total current	—	—
Deferred		
Federal	13,626,404	(4,053,114)
State	1,969,262	99,883
Total deferred	15,595,666	(3,953,231)
Change in valuation allowance	(15,595,666)	3,953,231
Total	\$ —	\$ —

Deferred tax assets consisted of the following at December 31:

	<u>2017</u>	<u>2016</u>
Deferred tax assets		
Federal net operating loss	\$ 24,353,504	\$ 36,472,996
Federal research and development tax credit carryforwards	4,947,879	3,808,862
State net operating losses and tax credit carryforwards	1,589,927	2,628,006
Capitalized research and development expenses	5,772,165	8,834,640
Stock-based compensation expense	1,445,078	2,162,703
Depreciable assets	166,793	—
Other	121,680	235,681
Total deferred tax assets	<u>38,397,026</u>	<u>54,142,888</u>
Deferred tax liabilities		
Depreciable assets	—	(150,196)
Total deferred tax liabilities	<u>—</u>	<u>(150,196)</u>
Net deferred tax assets	38,397,026	53,992,692
Less— valuation allowance	(38,397,026)	(53,992,692)
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:

	<u>Year ended December 31,</u>	
	<u>2017</u>	<u>2016</u>
Income tax benefit using U.S. federal statutory rate	34.00%	34.00%
State income taxes	(9.58)%	(1.07)%
Permanent items	(2.55)%	17.88%
Federal tax credits	8.43%	9.55%
Change in valuation allowance	115%	(63.97)%
Federal rate change	(143.50)%	—
Other	(1.80)%	3.61%
Total	<u>0.00%</u>	<u>0.00%</u>

As of December 31, 2017, the Company had federal and state net operating loss carryforwards (“NOLs”) of approximately \$115,969,000 and \$15,862,000 respectively, which expire in 2018 through 2037 and in 2028 through 2031, respectively. In addition, the Company has federal and state research and development and orphan drug credits of approximately \$4,948,000 and \$759,000, respectively, which expire in 2018 through 2037 and in 2024 through 2032, 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 continuing losses and uncertainty associated with the utilization of the deferred tax assets in the future, management has provided a full allowance against the net 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, 2017 or 2016, 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, 2014. Additionally, the Company may be subject to examination by the IRS for years beginning prior to January 1, 2014 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.

On December 22, 2017 The Tax Cuts and Jobs Act (the “Act”) was enacted. The Act significantly revised the U.S. corporate income tax law by lowering the corporate Federal income tax rate from 35% to 21%. As of December 31, 2017, the Company has assessed the effects of the corporate rate reduction on its existing deferred tax balances which resulted in the valuation allowance equal to the effect of the rate reduction on the ending deferred tax asset was also reflected. In addition to the rate reduction, the Act also requires companies with foreign subsidiaries to pay a one-time transition tax on earnings that were previously tax deferred. As of December 31, 2017, the Company does not maintain any foreign subsidiaries and does not have previously deferred foreign earnings subject to the transition tax.

11. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss attributable to common stockholders per share is computed by dividing net loss attributable to common stockholders, 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, 2017 and 2016, 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:

	Year Ended December 31,	
	2017	2016
Warrants	11,830,074	10,716,952
Stock options and grants	911,729	471,433
Preferred shares as converted into common stock	960,642	1,133,339

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 provided for the option to extend the lease under its original terms for seven additional two-year terms. Rent was \$8,050 per month for the first year and then escalated thereafter by 3% per year for the duration of the term including any lease extension terms. The lease also required the payment of monthly rent of \$1,140 for approximately 3,400 square feet of expansion space. The monthly rent for the expansion space was 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 March 2016, the Company exercised its option to extend the lease for an additional two-year term that commenced on September 15, 2016 and continues through September 14, 2018.

As of December 31, 2017, future minimum lease payments under this non-cancelable lease are approximately as follows:

Years ending December 31, 2018	\$ 104,936
	<u>\$ 104,936</u>

Rent expense was approximately \$130,000 and \$131,000 for the years ended December 31, 2017 and 2016, respectively.

On January 3, 2018, the Company informed the landlord that it was not extending the lease for an additional two-year term but instead intends to de-commission and vacate the premises on or before September 14, 2018.

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.

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. SUBSEQUENT EVENTS

In January 2018, the Company began implementing the shutdown of its manufacturing operations at the headquarters in Madison, Wisconsin as part of its plan to transfer finished product manufacturing to a third party manufacturer with the capacity to provide FDA approved commercial grade and pivotal trial finished product. The company also anticipates a reduction in its fixed costs and overall expenditures. It is anticipated that the shutdown will be completed in the first half of 2018.

On January 3, 2018, the Company notified affected employees of its plan to reduce its workforce by six positions. The workforce reduction will primarily occur in the quarter ending March 31, 2018.

On January 3, 2018, the Company informed the landlord that it was not extending the lease for an additional two-year term but instead intends to de-commission and vacate the premises on or before September 14, 2018.

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, 2017, our management has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

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 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 2013 *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, our management concluded that our internal control over financial reporting was effective as of December 31, 2017. This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm, as allowed by the SEC.

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

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 2018 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 2018 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.cellestar.com.

Item 11. Executive Compensation.

Compensation of Directors and Executive Officers

The information required by this item is incorporated herein by reference to our definitive proxy statement for our 2018 Annual Meeting of Stockholders under the caption “Executive Compensation.”

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 2018 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 2018 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 2018 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 2018 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.

Exhibit No.	Description	Incorporated by Reference		Exhibit No.
		Form	Filing Date	
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 13, 2014	3.1
3.3	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	June 13, 2014	3.1
3.4	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	June 19, 2015	3.2
3.5	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	March 4, 2016	3.1
3.6	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	June 1, 2017	3.2
3.7	Amended and Restated By-laws	8-K	June 1, 2011	3.1
3.8	Form of Certificate of Designation of Series A Preferred Stock	S-1/A	November 18, 2016	3.7
3.9	Form of Certificate of Designation of Series B Preferred Stock	8-K	October 11, 2017	3.1
4.1	Form of common stock certificate	S-1/A	November 9, 2011	4.1
4.2	Form of Series A Preferred Stock certificate	S-1/A	November 18, 2016	4.2
4.3	Form of Series D Common Stock Purchase Warrant	8-K	October 11, 2017	4.1
4.4	Form of Series B Preferred Stock certificate	8-K	October 11, 2017	4.2
10.1	2006 Stock Incentive Plan, as amended **	8-K	December 18, 2013	10.1
10.2	Form of Non-Statutory Stock Option under Novelos Therapeutics, Inc.'s 2006 Stock Incentive Plan**	8-K	December 15, 2006	10.2
10.3	Common Stock Purchase Warrant dated February 11, 2009**	8-K	February 18, 2009	4.2
10.4	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-1/A	July 7, 2010	10.53
10.5	Form of Common Stock Purchase Warrant dated April 8, 2011	8-K	April 11, 2011	4.3
10.6	Securities Purchase Agreement dated April 8, 2011	8-K	April 11, 2011	10.1
10.7	Lease Agreement between Collectar, LLC and McAllen Properties LLC, as amended and extended	S-1	July 1, 2011	10.32
10.8	Form of Warrant dated December 6, 2011	S-1/A	November 9, 2011	4.2
10.9	Form of Common Stock Purchase Warrant dated June 13, 2012	8-K	June 11, 2012	4.1
10.10	Form of Common Stock Purchase Warrant	8-K	February 14, 2013	4.1
10.11	Form of Convertible Debenture	8-K	February 10, 2014	4.1
10.12	Form of Common Stock Purchase Warrant	8-K	February 10, 2014	4.2
10.13	Form of Warrant Agreement between Collectar Biosciences, Inc. and American Stock Transfer and Trust Company	S-1/A	July 7, 2014	10.31
10.14	2015 Stock Incentive Plan	10-Q	August 12, 2015	10.1
10.15	Employment Agreement between the Company and James Caruso, dated June 15, 2015**	10-Q	August 12, 2015	10.2
10.16	Form of Series B Pre-Funded Warrant	8-K	September 30, 2015	4.1
10.17	Registration Rights Agreement dated September 28, 2015	8-K	September 30, 2015	10.2
10.18	Amendment and Exchange Agreement dated April 13, 2016	S-1/A	April 14, 2016	10.43
10.19	Form of Series A Warrant	S-1/A	April 14, 2016	4.2
10.20	Form of Series B Pre-Funded Warrant	S-1/A	April 14, 2016	4.3
10.21	Form of Warrant Agency Agreement	S-1/A	April 14, 2016	4.4
10.22	Form of Series C Warrant	S-1/A	November 18, 2016	4.3
10.23	Form of Warrant Agency Agreement	S-1/A	November 18, 2016	4.4
10.24	Collectar Biosciences, Inc. Amended and Restated 2015 Stock Incentive Plan**	8-K	June 1, 2017	10.1
10.25	Form of Restricted Common Stock Agreement**	10-Q	August 14, 2017	10.1
10.26	Securities Purchase Agreement, dated as of October 10, 2017, by and among Collectar Biosciences, Inc. Inc. and the Purchasers	8-K	October 11, 2017	10.1
10.27	Registration Rights Agreement, dated as of October 10, 2017, by and among Collectar Biosciences, Inc. Inc. and the Purchasers	8-K	October 11, 2017	10.2
10.28	Employment Agreement between the Company and John E. Friend dated March 27, 2017**	10-Q	November 9, 2017	10.4
10.29	Employment Agreement between the Company and Jarrod Longcor dated July 14, 2016**	10-Q	November 9, 2017	10.3
10.30	Form of Non-Statutory Stock Option**	S-8	November 9, 2017	10.2
10.31	Stock Option Agreement with James V. Caruso**	S-8	November 9, 2017	10.4
10.32	Stock Option Agreement with Jarrod Longcor**	S-8	November 9, 2017	10.5
10.33*	Master Services Agreement for Clinical Research and Related Services between the Company and INC Research, LLC dated October 6, 2016*			
21.1*	List of Subsidiaries			

- [23.1*](#) [Consent of Independent Registered Public Accounting Firm](#)
- [31.1*](#) [Certification of chief executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](#)
- [31.2*](#) [Certification of chief financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](#)
- [32.1*](#) [Certification of chief executive officer and chief financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002](#)
- 101* [Interactive Data Files](#)

* Filed herewith.

** 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 21, 2018

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 and
Director (Principal Executive Officer)
March 21, 2018

By: /s/ John P. Hamill
John P. Hamill
Title: Interim Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)
March 21, 2018

By: /s/ Frederick W. Driscoll
Frederick W. Driscoll
Title: Director
March 21, 2018

By: /s/ Stephen A. Hill
Stephen A. Hill
Title: Director
March 21, 2018

By: /s/ Stefan D. Loren
Stefan D. Loren
Title: Director
March 21, 2018

By: /s/ John L. Neis
John L. Neis
Title: Director
March 21, 2018

By: /s/ Douglas J. Swirsky
Douglas J. Swirsky
Title: Director
March 21, 2018

**MASTER SERVICES AGREEMENT FOR
CLINICAL RESEARCH AND RELATED SERVICES**

INC RESEARCH, LLC
CELLECTAR BIOSCIENCES, INC.

MSA

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This MASTER SERVICES AGREEMENT (“Agreement”), effectively dated as of the last date of authorized signature herein (“Effective Date”), is made by and between **Cellectar Biosciences, Inc.** (“Sponsor”), with principal offices located at 3301 Agriculture Drive, Madison, Wisconsin 53716 and **INC Research, LLC**, together with its Affiliates (“INC Research”), a Delaware limited liability company, with principal offices located in the United States at 3201 Beechleaf Court, Suite 600, Raleigh, North Carolina 27604-1547.

WITNESSETH:

WHEREAS, Sponsor is engaged in the business of developing, manufacturing, distributing, and/or selling pharmaceutical products, biotechnological products, and/or medical devices;

WHEREAS, INC Research is engaged in the business of providing clinical research services, data management, and related services in the pharmaceutical, biotechnology, and medical device industries;

WHEREAS, Sponsor and INC Research desire to agree on terms which will be applied to govern INC Research’s provision of services for Sponsor (excluding INC Research Phase I Services as defined in Section 1) in connection with support of clinical investigation, management and/or research of a particular Study or Studies; and

WHEREAS, both Parties desire to comply with the terms and conditions hereinafter provided in connection with Study research.

NOW, THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and adequacy of which hereby are mutually acknowledged, the Parties intending to be legally bound do hereby agree as follows:

1. DEFINITIONS.

Terms contained in this Agreement shall have the meanings set forth in this section and as they may be defined throughout this Agreement.

- 1.1 “Affiliates” shall mean any corporation or organization that directly or indirectly controls, is controlled by or is under common control with such Party. “Control”, “controls”, or “controlled” shall mean the possession, direct or indirect, of the power to direct, or the power to cause the direction of the management and policies of an entity, whether through ownership of fifty percent (50%) of voting securities, by contract or otherwise. Any reference to “INC Research” in this Agreement shall be deemed to include its Affiliates unless otherwise so stated as being applicable to INC Research, LLC, or an individual Affiliate exclusively.
- 1.2 “Applicable Laws and Regulations” shall mean any and all international, national, federal, state, and local laws and regulations, including, without limitation, the regulations and guidelines of the FDA, the Food, Drug, and Cosmetic Act and, as applicable, accepted standards of Good Clinical Practice (“GCP”) and International Conference on Harmonization (“ICH”) guidelines that may be applicable to a Study or the Services.

- 1.3 “Change Order” shall mean an amendment to a Work Order that captures a change in the scope of Services or other Study specific parameters, which may include an increase or decrease in the Direct Costs and expenses and/or any timeline adjustments required due to the change in assumptions. Each Change Order shall be agreed in writing between the Parties and expressly approved by an authorized individual on behalf of each Party.
- 1.4 “Clinical Trial Agreement” shall mean the signed contractual agreement between Sponsor (or INC Research) and the Investigator and/or Site that manages the relationship, financial support and/or proprietary information during the performance of the Study by such Investigator and/or Site.
- 1.5 “Commercially Reasonable Efforts” shall mean the efforts and resources which would be used (including without limitation the promptness in which such efforts and resources would be applied) by a Party, consistent with generally accepted industry standards, with regard to the activity to be undertaken by such Party.
- 1.6 “Confidential Information” shall mean all non-public, protected and/or proprietary information in the broadest sense communicated, observed, or heard, by either Sponsor or INC Research, including either Party's employees, consultants, agents, Affiliates, and/or the Study-related Investigators and/or Sites, and Third Party Vendors that relates to past, present or future research, development, processes, protocol(s), financial statements, personnel information, pricing and/or business activities of the Party disclosing the Confidential Information (hereinafter “the Disclosing Party”) and its respective systems, procedures, algorithms, and data of which the Party receiving the Confidential Information (the “Receiving Party”) may construct, acquire, access, or possess by reason of this Agreement. Confidential Information will include any “Confidential Information” disclosed previously by a Disclosing Party to a Receiving Party in connection with the discussions among the Parties with respect to the subject matter of this Agreement. The Parties further agree that Confidential Information shall include that information discovered during an audit of either Party’s or its respective Affiliates’ facilities.
- 1.7 “Direct Costs” shall mean the applicable price charged for labor in the performance of Services to be performed under this Agreement, as set forth in the applicable Work Order.
- 1.8 “FDA” shall mean the United States Food and Drug Administration.

- 1.9 “Force Majeure” shall mean an event or occurrence beyond a Party’s control such as, but not limited to, the following: acts of God, war, threat of war, government retaliation against foreign enemies, government regulation or advisory, disasters, floods, fire, earthquakes, pandemics, accidents or other casualty, strikes or threats of strikes (exception: neither Party may terminate or suspend this Agreement for strikes, labor disputes, or work stoppages involving its respective employees or agents), civil disorder, terrorist acts and/or threats of terrorism, acts of foreign enemies, or curtailment of transportation services making it illegal, impossible, or commercially impracticable to perform its obligations under this Agreement.
- 1.10 “Licensed Software” shall mean software created by INC Research on SAS® platform and which is configured to process, analyze, summarize, and report clinical trial data.
- 1.11 “INC Research Phase I Services” shall mean Phase I services performed at an INC Research facility, where INC Research would serve as a Study Investigator/Site.
- 1.12 “INC Research Property” means work product templates, inventions, processes, know-how, improvements, trade-secrets, other intellectual property and assets, including, but not limited to INC Research Licensed Software, methods, procedures and techniques, manuals, personnel information, internal audit training and policies, financial data, technical expertise and software, which have been or may be independently developed by INC Research and relate to INC Research’s business or operations.
- 1.13 “Indemnity Claim” means any matter upon which an indemnified party intends to base a claim for indemnification.
- 1.14 “Investigator” means a qualified clinical investigator as defined in ICH E6 4.1.1 engaged to conduct a clinical investigation of a particular Study and/or Study Product.
- 1.15 “Party” means either INC Research or Sponsor; and both collectively as “Parties”.
- 1.16 “Pass Through Costs” shall mean any costs that are not Direct Costs incurred by INC Research in the performance of Services, including without limitation, such costs as Service-related travel and Third Party Vendor fees for items such as printing, laboratory fees, shipping and facsimile costs, language translation, telephone charges, advertising, investigator meeting expenses, and/or other expenses associated with the conduct of the Study. Travel costs include, but are not limited to, those associated with reasonable transportation, lodging, internet connection, and meals.
- 1.17 “Protocol” means the particular written protocol including the clinical testing procedures, conditions, and instructions for conducting a particular Study.
- 1.18 “Regulatory Authority” shall mean the FDA or any other state or governing national or multinational regulatory authority or government agency that is equivalent to or has any similar regulatory functions and responsibilities as the FDA.

- 1.19 “Services” shall mean the particular clinical research services and other tasks to be performed by INC Research for a given Study pursuant to this Agreement, as more fully set forth in the Work Order applicable to such Study.
- 1.20 “Site” shall mean a hospital, clinic, institution, academic institution, or office of a practicing physician participating in the conduct of the Study.
- 1.21 “Sponsor Losses” shall mean third party claims, actions, damages, liabilities, costs and expenses (including reasonable legal counsel fees and expenses) incurred by Sponsor.
- 1.22 “Study” or “Studies” shall mean the clinical investigation, management and/or research activities related to a particular human clinical trial, or similar Sponsor project conducted pursuant to the applicable Protocol or Sponsor instructions, including any management and oversight thereof.
- 1.23 “Study Product” means, for a given Study, the therapeutic compound of Sponsor that is the subject of such Study, as well as any applicable placebo, potential product, or device administered as a result of the Protocol.
- 1.24 “Study Records” refers to all information regardless of purpose, format, location, system or origination that is a result of the conduct of a Study and/or performance of Services by INC Research and/or any INC Research sub-contracted service providers.
- 1.25 “Third Party Vendor” shall mean any person or party other than INC Research or Sponsor involved with the provision of services or goods under a Work Order (including but not limited to hospitals, IRBs, laboratories, pharmacists, Investigators, and/or Sites).
- 1.26 “Work Order” means an individual project agreement executed between Sponsor and INC Research for a given Study that: (a) expressly references this Agreement; (b) is made with respect to such specific Study; (c) is signed by both Parties; and (d) specifies the parameters of and sets forth the details of the clinical research services to be performed by INC Research in conducting the Study.

2. SERVICES.

- 2.1 Work Order. Each Work Order will specify the basic parameters of a Study, including, without limitation, the scope of work, Study-specific assumptions, estimated time period for completing Services, estimated budget, payment and currency schedules, resource allocation and/or, as applicable, other specific Services to be performed by INC Research. Each Work Order is hereby incorporated herein by reference, subject to mutually agreeable Change Orders.

An Affiliate of a Party can enter into, or perform Services in association with, Work Orders under this Agreement with the other Party or an Affiliate of the other Party, with such Affiliates being bound by the terms and conditions contained herein, and provided that each of INC Research, LLC or Collectar Biosciences, Inc., as applicable, shall remain responsible for the actions and omissions of its Affiliates.

Each Work Order shall constitute a unique agreement and shall stand alone with respect to any other Work Order entered under this Agreement. The performance of obligations under any one Work Order shall not affect, and shall at all times be unrelated to, the performance of any other Work Order entered into under this Agreement. To the extent that terms and/or provisions of a Work Order conflict with the terms and/or provisions of this Agreement, the terms and/or provisions of this Agreement shall control unless the Work Order expressly and specifically states otherwise.

- 2.2 Change Orders. In the event Sponsor requests a change in the scope of Services as originally defined in the Work Order or if there are changes to the assumptions upon which the Work Order is based (including, but not limited to, changes in an agreed upon starting date for a Study or suspension of the Study by Sponsor), the Parties will agree to such change in writing prior to engaging in out of scope activities (“Contract Modification”).

Once the need for a potential Contract Modification is identified, INC Research may provide written description of the Contract Modification, including any resulting impact to the Study budget, through use of a Change Notification Form (CNF). The CNF will be submitted to Sponsor for verification of the modifications to the scope of Services, and any resulting Study budget implications. Sponsor’s execution of the CNF shall serve as Sponsor approval and instruction for INC Research to proceed with the modification of Services (and resulting budget revisions) as set forth in the CNF. The Parties acknowledge that upon signature of the CNF by Sponsor, the services set forth in the CNF shall be considered Services to be performed by INC Research under the Work Order, and shall therefore be governed by and subject to the terms and conditions of this Agreement and corresponding Work Order.

A Change Order shall be completed upon the cumulative CNF(s) Direct Cost and Pass Through Costs equaling to or exceeding the threshold amount as set forth in the requisite Work Order.

Notwithstanding the above, an exception will apply if a modification reasonably involves the safety of a human subject or the integrity of the Study data, in which case INC Research shall quickly act on the requested change, and when practicable, give notice promptly to Sponsor by telephone or electronic communication that such scope change occurred and a Contract Modification may be required.

CNFs and Change Orders may be approved and forwarded via hand-delivery, facsimile, electronic mail, portable document format (PDF), or overnight courier. Absent compelling reasons, Change Order requests will be considered and a response will be affirmatively given to INC Research within fifteen (15) calendar days of Sponsor's receipt of same. The Parties agree to work together in good faith and use Commercially Reasonable Efforts to ensure that the Study timelines are not adversely affected, it being understood, however, that INC Research is under no obligation to perform any out of scope work until a CNF and/or Change Order is agreed to by both Parties.

- 2.3 Professional Standards. Each Party shall use Commercially Reasonable Efforts to progress the Study in a timely manner applying professional standards consistent with GCP and in adherence to Applicable Laws and Regulations.

The major Study milestones and target dates will be described in the applicable Work Order. Subject to mutually agreed Change Order(s), both Parties agree that the Work Order shall set forth a reasonable schedule for the Services to be performed, and each Party will use Commercially Reasonable Efforts to comply with the timelines stated therein.

- 2.4 Interruption or Delay. In the event that any Study is placed on hold for a period of thirty (30) days or more, Sponsor will compensate INC Research for Study obligations incurred per the Work Order and the Parties will negotiate a commercially reasonable fee to compensate INC Research for retention and training of INC Research-assigned resources for the Study. Such compensation shall be set forth in a Change Order as described in Section 2.2 herein.

In the event that a milestone-based Study is interrupted or delayed for any other reasons beyond INC Research's reasonable control, to the extent that such milestone(s) are affected, INC Research shall be entitled to receive payment for Services properly performed under the applicable Work Order.

Sponsor acknowledges and agrees that INC Research will require documents, data records, and cooperative efforts by Sponsor and/or other designees in order to properly perform the Services outlined in each Work Order, and that INC Research is not responsible for errors, delays, or other consequences arising from the failure of Sponsor or such designees to provide such data, records, or cooperative efforts. In the event of a delay caused by actions neither directed by nor attributable to INC Research, which affect INC Research's ability to meet any timelines, the Parties shall re-negotiate in good faith to amend the targeted dates accordingly.

For the sake of clarity, INC Research shall not be responsible for errors, omissions and/or delays during the conduct of any Study, to the extent such delays are caused by or result from (i) Sponsor's actions or omissions, (ii) any Third Party Vendor's actions or omissions, (iii) a Force Majeure event or (iv) any other causes outside the direct control of INC Research. The financial burden of any additional costs associated with such delays is the responsibility of Sponsor.

3. TRANSFER OF SPONSOR OBLIGATIONS/RESPONSIBILITIES.

The transfer of obligations and/or responsibilities from Sponsor to INC Research pursuant to Applicable Laws and Regulations will be mutually agreed and set forth in each individual Work Order. Any such regulatory responsibilities not specifically transferred to INC Research shall remain the regulatory responsibility of Sponsor. Under no circumstance shall INC Research be required to accept responsibilities and conduct itself contrary to Applicable Laws and Regulations.

4. INVOICING, COMPENSATION AND PAYMENT.

4.1 Direct Cost Compensation. In exchange for valuable consideration with regard to INC Research's performance of the Services hereunder, Sponsor shall pay INC Research for Direct Costs in accordance with a detailed budget as described in each applicable Work Order. Unless otherwise agreed to in the requisite Work Order, INC Research may submit, at its discretion, at a minimum, monthly invoices or other substantiating internal documentation to Sponsor for timely payment in accordance with this Section 4.

4.2 Pass Through Cost Compensation. Sponsor shall advance INC Research for Pass Through Costs incurred by INC Research from Sponsor-approved Third Party Vendors in connection with INC Research's performance of Services. Unless otherwise agreed to in the Work Order, INC Research shall submit at least monthly invoices or other substantiating internal documentation to Sponsor for payment in accordance with this Section 4.

As set forth in a Work Order, INC Research may negotiate the Investigator grants, and/or Site Clinical Trial Agreement terms and/or other Study-related agreements on behalf of Sponsor and at Sponsor's direction. Sponsor shall be obligated to provide timely feedback in connection with any such negotiations, and INC Research shall not be responsible for any undue delays attributable to Sponsor's failure to provide approvals and timely responses. Investigator grant fees and other approved Site fees, including payments for screening failures and non-complete subjects, will be billed to Sponsor at mutually agreed upon amounts for the applicable Study. Said fees shall be paid in advance of INC Research's expectation to pay the Investigator and/or Site, and Sponsor shall be responsible for any adverse action taken by an Investigator or Site as a result of failure to pay grant amounts and other costs due and payable in a timely manner. INC Research shall have no liability for any failure to make payments if required funding is not provided to INC Research in advance by Sponsor. Each Clinical Trial Agreement with Investigators shall contain a statement to that effect. INC Research shall have no duty to pursue collection of allegedly unearned fees paid to Investigators and/or Sites.

In addition, Sponsor shall reimburse INC Research for all costs and expenses incurred by INC Research or others engaged by INC Research on behalf of Sponsor to ensure patient safety, continuity of treatment and compliance with Applicable Laws and Regulations, to the extent that such costs are actual, reasonable and verifiable. Such costs may include, but are not limited to, reasonable and customary costs incurred associated with the diagnosis of an adverse reaction, adverse event or personal injury involving the Study Product or associated with the applicable Protocol. In the event that an Investigator reasonably assesses that a diagnostic procedure(s) is/are medically necessary and connected to the Study, yet the suspected adverse event is later deemed not to be Study-related, then Sponsor shall be required to pay for reasonable costs of said diagnostic procedure(s).

- 4.3 **Invoicing.** Sponsor shall render all payments due and payable to INC Research within forty-five (45) days of the receipt of an invoice. Sponsor further agrees to reasonably consider payments schedules within each Work Order to allow INC Research to maintain cash neutrality by invoicing in advance as stipulated in the Work Order. Sponsor shall pay INC Research interest in an amount equal to one and one-half percent (1 ½%) (or such maximum lesser amount allowed by Applicable Laws and Regulations) per month with regard to all undisputed amounts past due and payable. Sponsor shall also reimburse INC Research for all costs incurred in collecting any late payments, including, without limitation, attorneys' fees.

All invoices shall be deemed received: (i) five (5) business days after the date postmarked if sent by mail; (ii) on the date of delivery and/or read receipt if they are sent electronically; or (iii) upon signature if delivered by overnight delivery service. In the event that any non-disputed amounts remain unpaid for ten (10) days after the invoice due date, INC Research may stop work on the Services until it receives such past due payment. However, prior to any such work stoppage, INC Research shall give five (5) business days' notice of its intent to cease Services to allow escalation of the issue within Sponsor's organization and the Parties shall discuss resolution of the nonpayment of non-disputed amounts in good faith. Other than as may be required under Applicable Laws and Regulations, INC Research shall have no liability to Sponsor for any costs or damages as a result of such suspension caused by Sponsor's failure to pay non-disputed amounts in accordance with the payment terms contained herein.

If any portion of an invoice is disputed, then Sponsor shall pay the undisputed amounts according to the payment terms herein. If Sponsor, in good faith identifies items in an invoice which are disputed, Sponsor will notify INC Research in writing, noting its objection to the disputed item(s) with specificity, within twenty (20) business days of receipt of the invoice. Invoices for which no written objection is received by INC Research by Sponsor within such twenty (20) business day period shall be deemed accepted by Sponsor as true and correct. INC Research will respond to such written notification within ten (10) business days of receipt of the disputed notification. This communication exchange will continue until documentation justifying the charge has been provided to Sponsor or until INC Research reduces or deletes the disputed amount to Sponsor's reasonable satisfaction. Any dispute over invoiced amounts due that cannot be resolved by direct good faith negotiation between the parties shall be resolved in accordance with Section 13.9 (Dispute Resolution) of this Agreement. Should INC Research be required to utilize a third party invoicing service/system as mandated by Sponsor, any costs associated with such utilization shall be invoiced to Sponsor as incurred, without mark-up.

Sponsor shall not withhold payment of any amounts due and payable under this Agreement by reason of any setoff any claim or dispute with INC Research, whether relating to INC Research's breach, bankruptcy or otherwise.

- 4.4 Study Close and Financial Records. Within the latter of (i) ninety (90) days after the conclusion of the Services; or (ii) sixty (60) days after the receipt of a final invoice from a Third Party Vendor for each Work Order, INC Research will submit to Sponsor a final invoice with an accounting of all amounts invoiced by INC Research, and all payments made by Sponsor. Any overpayment by Sponsor shall be credited or refunded to Sponsor by INC Research within thirty (30) days of the final invoice. Any underpayment by Sponsor shall be paid to INC Research within thirty (30) days after receipt by Sponsor of such final invoice.

INC Research shall keep and maintain complete and accurate books and records in sufficient detail to determine amounts owed to INC Research hereunder. Such books and records shall be maintained for at least one (1) year following completion or termination of a Work Order and shall be made available for inspection, copying and audit by Sponsor in accordance with Section 9 and for the purpose of determining the accuracy of amounts invoiced.

- 4.5 Taxes. INC Research shall invoice Sponsor, and Sponsor shall promptly pay or reimburse INC Research for taxes or duties actually incurred by INC Research which are imposed upon INC Research by any governmental agency, including, but not limited to Value Added Tax, Stamp Tax and/or General Sales Tax, as a result of this Agreement with the exception of taxes based on INC Research's income. If requested by INC Research, Sponsor shall deliver to INC Research official documentation for such taxes paid.

If any payments made by the Parties under this Agreement become subject to withholding taxes under Applicable Laws and Regulations, each Party shall be authorized to withhold such taxes as are required under Applicable Laws and Regulations, pay such taxes to the appropriate government authority, and remit the balance due to the other Party net of such taxes. The Parties agree to cooperate in good faith to qualify the transactions for any exemptions or reductions in the amount of otherwise applicable withholding tax provided under Applicable Laws and Regulations (including the provisions of any relevant income tax treaty) and to complete such forms as necessary for such purpose.

4.6 **Currency.** Unless otherwise agreed in the applicable Work Order, Sponsor shall make all payments to INC Research in United States dollars (“US Currency”), and accordingly INC Research shall invoice Sponsor for all Direct Costs and Pass Through Costs in US Currency. If Direct Costs are incurred in a currency other than US Currency, then INC Research and Sponsor will define the mechanism for currency exchange adjustment in the Work Order. If Pass Through Costs are incurred in a currency differing from US Currency, then INC Research shall invoice Sponsor using the exchange rate published in oanda.com at the average bid rate on the day the expense invoice is generated by INC Research.

5. TERM AND TERMINATION.

5.1 **General Term.** This Agreement shall commence as of the Effective Date and shall continue for a period of five (5) years, or until earlier terminated as provided below. Any Work Orders in existence as of the date of expiration or termination of this Agreement shall continue to be governed by the terms and conditions of this Agreement unless such Work Order is specifically terminated in accordance with the terms herein, or as otherwise mutually agreed in writing by the Parties.

5.2 **Termination.** Either Party may terminate this Agreement or any and all associated Work Order(s) upon sixty (60) days written notice to the other Party. Upon receipt of notice of termination, INC Research shall use reasonable efforts to avoid incurring additional costs and expenses on the project during the closeout or winding down period.

Either Party may terminate this Agreement or any individual Work Order as follows:

- a) On written notice effective immediately if the other Party commits a material breach of this Agreement or a Work Order which cannot be cured, or for a material breach of this Agreement or a Work Order which is capable of cure but is not cured within thirty (30) days of receipt of written notice from the other Party (“material breach” being defined herein as failure to substantially comply with any material provision of this Agreement or any Work Order, including without limitation failure by Sponsor to pay any undisputed portion of an invoice within thirty (30) days of receipt of notice of an overdue invoice);
- b) On written notice effective immediately if the other Party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, files or has filed against it, a petition in bankruptcy, or has a receiver appointed for a substantial part of its assets;
- c) On written notice effective immediately if the other Party ceases, or threatens to cease, to carry on business or maintain itself as a going concern; or
- d) On written notice effective immediately as a result of reasonably compelling scientific evidence that patient safety is at risk should the Study continue, Study data integrity compromise, and/or reasonable belief that Applicable Laws and Regulations will be materially violated should this Agreement continue in effect.

5.3 Termination Obligations. Upon receipt of a termination notice, the Parties will promptly meet and agree upon any winding down activities and associated costs for any Study prior to the performance of any additional tasks not otherwise addressed in a Work Order. Costs associated with any winding down period will be invoiced to Sponsor on fee for service basis using the rates in effect as of the termination date unless otherwise agreed upon by the Parties.

5.4 Payment Obligations Upon Termination. In the event of termination of any Work Order, Sponsor will pay to INC Research any Direct Costs and Pass Through Costs incurred and/or actual costs resulting from commitments (including the fulfillment of any regulatory requirements), which cannot reasonably be cancelled and which were entered into by INC Research with respect to the Services at the time of notice of termination and five percent (5%) of the remainder of the Direct Costs set forth in the Work Order; provided that INC Research has used Commercially Reasonable Efforts to minimize such costs.

In the event of excess payment to INC Research by Sponsor, INC Research shall either apply such excess payment as a credit against other amounts due and payable or promptly refund such excess if there are no outstanding payments owed INC Research. Sponsor shall pay INC Research any additional amounts owed, but not yet paid, for Services performed or expenses incurred up to the effective date of termination.

Any payment(s) due and payable under this Section 5.4 shall be made in accordance with Section 4.3 of this Agreement.

5.5 Study Records Retention. At Sponsor's request and expense, and following satisfaction of Sponsor's obligations, if the provision of INC Research's Services, and/or Services provided by any INC Research sub-contracted service providers, under this Agreement are terminated by either Party for any reason, INC Research shall transfer all regulatory responsibility for the Study Records to Sponsor and provide Sponsor with all applicable Study Records. The transfer of Study Records will occur within ninety (90) days following the effective date of termination unless otherwise mutually agreed upon in writing by the Parties. INC Research may elect to retain copies of some or all such Study Records according to INC Research's standard practices for preserving its business records and in accordance with Applicable Laws and Regulations. INC Research shall maintain any such copies of Study Records as Confidential Information of Sponsor.

INC Research will not retain any regulatory responsibility for the Study Records and will not store Sponsor's Study Records on its premises on Sponsor's behalf after the termination or expiration of the Work Order. The Parties may mutually agree to extend Services related to the Study Records in a Change Order, or in a separate agreement, that details the terms for the extended retention period and compensation for such retention. In the event that Sponsor is unable or refuses to accept the return of the Study Records for any reason, INC Research may elect to dispose of any Study Records according to its policies and in a confidential manner unless otherwise prohibited by Applicable Laws and Regulations. INC Research will demonstrate due diligence in contacting Sponsor to provide notification of the intention to dispose of Study Records at least ninety (90) days prior to disposition

6. INDEMNIFICATION, LIABILITY AND INSURANCE.

- 6.1 Indemnification by Sponsor. Sponsor shall defend, indemnify, and hold harmless INC Research, its Affiliates and its and their respective directors, officers, employees, agents and Third Party Vendors from and against any and all third party losses, claims, actions, damages, liabilities, awards, costs and expenses (including reasonable legal counsel fees and expenses), whether joint or several, relating to or arising from or in connection with this Agreement or the Services contemplated herein, including without limitation, any Study, Protocol, specifications, or Study Product, performed or administered as a result of this Agreement and or its associated Work Order(s), or any litigation, investigation or other proceeding relating to any of the foregoing except to the extent that such third party claims arise from (i) the negligence or reckless or willful act or omission of INC Research, its Affiliates or its and their respective directors, officers, employees, or agents; or (ii) any breach of this Agreement by INC Research, its Affiliates, or its and their respective directors, officers, employees, or agents.
- 6.2 Indemnification by INC Research. INC Research shall defend, indemnify, and hold harmless Sponsor, its Affiliates and its and their respective directors, officers, employees, and agents from and against any and all Sponsor Losses, but only to the extent such Sponsor Losses are related to or arise from or in connection with INC Research's negligence or intentional misconduct, except to the extent that such Sponsor Losses arise from (i) the negligence or reckless or willful act or omission of Sponsor, its Affiliates or its and their respective directors, officers, employees, or agents; or (ii) any breach of this Agreement by Sponsor, its Affiliates, or its and their respective directors, officers, employees, or agents.
- 6.3 Indemnification Procedures. The Party seeking indemnity will give the indemnifying Party prompt written notice of an Indemnity Claim under this Section 6. The indemnified Party shall have the right to participate jointly with the indemnifying Party, at its own expense, in the defense, settlement or other disposition of any Indemnity Claim. With respect to any Indemnity Claim relating solely to the payment of money damages and which could not result in the indemnified Party becoming subject to injunctive or other equitable relief or otherwise adversely affect the business of the indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the indemnified Party hereunder, the indemnifying Party shall have the sole right to defend, settle or otherwise dispose of such Indemnity Claim, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate, provided that the indemnifying Party shall offer evidence of its ability to pay any damages claimed and with respect to any such settlement shall have obtained the written release of the indemnified Party from the Indemnity Claim. The indemnifying Party shall obtain the written consent of the indemnified Party, which shall not be unduly withheld, conditioned or delayed, prior to ceasing to defend, settle or otherwise dispose of any Indemnity Claim if, as a result thereof, the indemnified Party would become subject to injunctive or other equitable relief or the business of the indemnified Party would be adversely affected in any manner.

- 6.4 Third Party Vendor Indemnification. Upon reasonable request by Sponsor-approved Third Party Vendors utilized in connection with this Agreement, Sponsor shall execute and provide a separate letter of indemnification with such Third Party Vendors, in a form mutually acceptable to the parties. If requested by Sponsor, and at Sponsor's expense, INC Research will assist administratively with the tasks related to this Section 6.4. Notwithstanding the above, INC Research shall not be required to indemnify any Third Party Vendors required by Sponsor or mutually selected between the Parties to be obtained in accordance with a Study, and INC Research shall not be responsible for any delays resulting from negotiations involving Sponsor and Third Party Vendors which are related to the indemnification rights of any such Third Party Vendor.
- 6.5 Limitation of Liability. In no event will either Party be liable for any indirect, special, incidental or consequential damages in connection with or related to this Agreement (including loss of profits, use, data, or other economic advantage), howsoever arising, either out of breach of this Agreement, including breach of warranty, or in tort, even if the other Party has been previously advised of the possibility of such damage. INC Research's total liability for damages shall be limited to the value of the Services completed under the applicable Work Order (excluding Pass Through Costs).
- 6.6 Insurance. Upon written request, each Party shall provide the other with a copy of its effective Certificate of Insurance or such other documented evidence offering that it has adequate coverage consistent with human clinical trial industry standards. Sponsor shall maintain coverage at such amounts that are the greater of a) the levels detailed in the requisite Work Order or b) compulsory amounts indicated by local statutory requirements in the country in which the Services are being performed. Each such INC Research and Sponsor policy shall be in effect during the term of the applicable Work Order and for at least three (3) years after the termination or expiration of such Work Order, in either a primary policy or an extended reporting period endorsement. Sponsor's liability shall not be limited to that which is recoverable by insurance.

If requested by Sponsor to contract with any Third Party Vendors, Sponsor hereby authorizes INC Research to provide such Third Party Vendors with a copy of Sponsor's Certificate of Insurance. Sponsor represents and warrants that its insurance (i) does not have an exclusion for the Study Product, (ii) covers the Study which is the subject of this Agreement or any Work Order and (iii) has no exclusions that would impede a patient from making a claim against the policy and will provide a Certificate of Insurance showing evidence of such declaration.

7. CONFIDENTIALITY.

7.1 Obligations. Either Sponsor or INC Research may become the recipient of Confidential Information of the other during the term of this Agreement. The Receiving Party shall treat the Disclosing Party's Confidential Information as confidential and proprietary and shall protect it with the same level of prudence and care as it would protect its own proprietary or confidential information, but in no event less than reasonable care. The Receiving Party shall not disclose the Confidential Information to any third party except to the extent that they reasonably need to know the disclosed information to carry out the purposes of this Agreement. Additionally, INC Research is authorized to disseminate limited, blinded, and automatized Protocol or Study information necessary to perform core business functions as well as for the purpose of soliciting and evaluating Third Party Vendor bids and project costing.

7.2 Exceptions. Confidential Information shall not include, and these confidentiality obligations shall not operate as a restriction on each Party's right to use, disclose, or otherwise deal with information which:

- a) was in the Receiving Party's possession prior to the time it was acquired from the Disclosing Party and which was not directly or indirectly acquired from the Disclosing Party;
- b) is or lawfully becomes generally available to the public through no fault of Receiving Party;
- c) is lawfully and independently made available to the Receiving Party by a third party;
- d) is released from its confidential status by the Disclosing Party; or
- e) is independently developed by or for the Receiving Party without the use of the Disclosing Party's Confidential Information as evidenced by the Receiving Party's written records.

Nothing in this Agreement shall be construed to restrict the Parties from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case the Party requested to make such disclosure shall, to the extent permitted by law, timely inform the other Party and use all Commercially Reasonable Efforts to limit the disclosure and maintain the confidentiality of such Confidential Information to the extent possible. In addition, the Party required to make such disclosure shall permit the other Party to attempt to limit such disclosure by appropriate legal means.

7.3 Term of Confidentiality. These obligations of confidentiality shall remain in effect for a period of seven (7) years after the expiration or termination of this Agreement.

8. PROPRIETARY RIGHTS/LICENSURE.

8.1 Ownership. All materials, documents, information, programs and suggestions initially provided to INC Research by Sponsor or on behalf of Sponsor in connection with any Study shall be the exclusive property of Sponsor. Any copyrightable work created by INC Research in direct connection with the performance of INC Research's Services as outlined in this Agreement and contained in the Study data shall be considered work made for hire, whether published or unpublished, and all rights therein shall be the property of Sponsor as author and owner of copyright in such particular work. Notwithstanding the above, Sponsor acknowledges that any INC Research Property that is improved, modified or developed by INC Research under or during the term of this Agreement shall be the sole and exclusive property of INC Research.

8.2 Publication. Sponsor shall be free to publish or utilize Study data for promotion or other purposes. At Sponsor's own expense, Sponsor may request collaboration from INC Research or its Study-related Third Party Vendors to assist with preparation of the manuscript. If INC Research is required to negotiate and/or execute Clinical Trial Agreements, Sponsor will consider publication requests initiated by such Study-related Institution(s) and/or Site(s). INC Research shall have no liability whatsoever for any delay resulting from such Sponsor consideration and response.

8.3 Licensure. Sponsor certifies that all relevant required licenses, including but not limited to those connected with drug dictionaries, and in particular the Uppsala Monitoring Centre and the Medical Dictionary for Regulatory Activities (MedDRA), shall at all times during the course of this Agreement be in full force and effect. In accordance with the requisite licensing agreement and validation requirements, Sponsor agrees to provide evidence of such licensure to INC Research and/or permits INC Research to seek validation from the licensor.

8.4 Software Rights. INC Research may facilitate the distribution of software and associated software documentation in accordance with this Agreement. INC Research may accordingly grant Sponsor a non-exclusive right to use, store, disseminate such software and associated program documentation for the sole purpose of conducting a clinical trial for which INC Research is providing relevant Services. Notwithstanding the above, the distribution of INC Research Licensed Software shall be governed solely by the terms of Appendix A of this Agreement.

9. RIGHT TO AUDIT.

- 9.1 INC Research will permit Sponsor-designated representatives (unless such representatives are competitors of INC Research) to examine, at a reasonable time and during normal business hours, raw Study data, financials and other relevant information, which Sponsor may reasonably require in order to confirm that the Study is being conducted in conformance with the Protocol and in compliance with Applicable Laws and Regulations. Such audits shall be limited to one audit per twelve-month period at no-cost to Sponsor. Additional audits shall be at Sponsor's expense. Sponsor will provide INC Research with a minimum of thirty (30) days advance notice of its intention to conduct such audit in order for INC Research to facilitate the availability of appropriate staff. INC Research will notify Sponsor as soon as practical if any Regulatory Authority requests an inspection or commences an unscheduled inspection that includes any aspect of Sponsor's project(s) in the inspection scope.
- 9.2 Both Parties shall promptly notify the other Party of any Regulatory Authority inspections, investigation or inquiry concerning any Study or project of Sponsor for which INC Research is performing Services ("Inspection"). Where appropriate and permitted by the Regulatory Authority, Sponsor will have the right to be present at any such Inspections if they occur on INC Research premises. INC Research will have primary responsibility for preparing any responses for Inspections occurring on INC Research premises and Sponsor shall be responsible for providing information to INC Research required for providing adequate responses to Inspection findings as required. Sponsor, its agents and consultants shall strictly observe all obligations of confidentiality concerning any documents, information, data or materials in accordance with Section 7.1 herein. Commercially reasonable costs associated with hosting and responding to any Inspection (including any preparation, participation, follow-up and resolution of findings), shall be reimbursed by Sponsor on a time and materials basis.
- 9.3 If, during the course of conducting the Services, INC Research becomes aware of information which indicates possible fraud/misconduct by an Investigator and/or at a Site, and after a reasonable investigation determines that the possibility of fraud/misconduct is substantiated, INC Research will promptly inform Sponsor of its findings and present an action plan for Sponsor's approval. It will be Sponsor's responsibility to conduct a full investigation outside of the action plan unless delegated to INC Research by Sponsor, in which case Sponsor shall pay for all reasonable costs incurred by INC Research to perform such investigation. If fraud or misconduct (hereafter together referred to as "fraud" for purposes of this section 9.3) is confirmed, then it will be the responsibility of Sponsor to notify the FDA or any other appropriate Regulatory Authority. After completion of its investigation, Sponsor will provide evidence satisfactory to INC Research either (i) that fraud was not committed or, (ii) if fraud was committed, that confirms the proper reporting of the fraud to the appropriate Regulatory Authority. If Sponsor does not investigate the possible fraud within a reasonable time, or if fraud is confirmed by investigation and Sponsor does not fulfill its obligations to report the fraud within a reasonable time, then INC Research may report its suspicions of possible fraud to the appropriate Regulatory Authority and notify Sponsor of this action in writing.

10. DISCLAIMER

- 10.1 Sponsor acknowledges that the results of the Services to be provided as outlined herein are inherently uncertain and that, accordingly, there can be no assurance, representation or warranty by INC Research that the Study Product will be successfully marketed by Sponsor.
- 10.2 Sponsor acknowledges that INC Research shall not be responsible for the authenticity of the Study Product.
- 10.3 Sponsor acknowledges that the terms of this Agreement exclude all implied warranties including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.
- 10.4 Sponsor acknowledges that the Services to be provided by INC Research as outlined herein are based upon information supplied by INC Research and Sponsor, as well as others, and that INC Research does not guarantee or warrant the results of such Services to any functions or other standards. In connection with deliverables associated with this Agreement and/or its associated Work Order(s), the sole remedy of Sponsor for any breach or default of INC Research which is not cured by INC Research within a reasonable cure period shall be termination of this Agreement and/or its associated Work Order.
- 10.5 Independent Contractor. INC Research is performing the Services as an independent contractor and not as an employee, agent, franchise, partner of, or joint venturer with Sponsor. Any Third Party Vendors are understood to be exercising independent judgment, and shall not be deemed to be employees, subcontractors, and/or agents of INC Research; and under no circumstance shall INC Research be responsible for the conduct of, or the independent or medical judgment, of any such third party.

11. NOTICES

This Agreement, including any exhibits, may be amended or modified only by an instrument of equal formality signed by duly authorized representatives of the respective Parties. All formal or legal notices, requests, demands or other communications hereunder, other than communications reasonably deemed to be day-to-day within the duties of project management shall be in writing and shall be deemed given if personally delivered or disseminated by nationally recognized courier or certified mail with return receipt within five (5) days after prior mailing to the address set forth below:

If to: Collectar Biosciences, Inc.
3301 Agriculture Drive
Madison, WI 53716
Phone: 608-441-8120
Facsimile: 608-441-8121

If to: INC RESEARCH, LLC
Attention: Global Sponsor Solutions
INC Research, LLC
3201 Beechleaf Court
Suite 600
Raleigh, NC 27604-1547
Phone: 919-876-9300
Facsimile: 919-882-0425

12. FORCE MAJEURE

The performance of this Agreement by either Party, in part or in full, may be impacted by a Force Majeure event. In such a case, either Party may terminate, suspend, or partially perform its obligations under this Agreement, without liability or further obligation, by written notice to the other Party if such obligations are delayed, prevented, or frustrated by any of the above events, or similar events or occurrences, to the extent such events or occurrences are beyond the reasonable control of the Party whose reasonable performance is prevented, made impracticable, or partially curtailed; provided, however, that Sponsor must perform its obligations to pay for all INC Research non-cancellable expenses incurred as a result of the above events or similar intervening causes. Sponsor also agrees to pay all reasonable expenses incurred in connection with Sponsor-directed meetings whereby any of the above actions or threats of actions prevent the attendees from attending or delay the departure of attendees from a designated meeting facility. Unless otherwise agreed by the Parties in writing, any deadline or time for performance which falls due during or subsequent to such Force Majeure event shall be automatically extended for a minimum period of time equal to the period of disability.

13. GENERAL PROVISIONS

- 13.1 Compliance with Government Regulations. To the extent applicable, both Sponsor and INC Research shall comply with any applicable validated methodology, generally accepted professional standards of care, and all Applicable Laws and Regulations of each country where the Services will be conducted, including without limitation ICH Guidelines for GCP. The Parties will also comply to the extent applicable with the United States Federal anti-kickback statute (42 U.S.C. 1320a-7b), and the related safe harbor regulations. Should any such government regulatory requirements be changed, each Party will use Commercially Reasonable Efforts to satisfy the new requirements. In the event that compliance with such new regulatory requirements necessitates a change in the Services, the Parties will evaluate a Contract Modification to be mutually agreed for the changes in the Services.

Both Sponsor and INC Research warrant that they are, and will remain, in compliance with the Foreign Corrupt Practices Act ("FCPA") and/or all other, applicable anti-bribery laws or regulations. A breach of this warranty, will allow the non-breaching Party to immediately terminate this Agreement and/or any associated Work Order.

Nothing contained in this Agreement shall be construed in any manner as an obligation or inducement for either Party to recommend that any person or entity purchase the other Party's products or services, or those of any organization affiliated with the other Party.

- 13.2 **Qualifications.** Each Party hereby represents that it has not been debarred and has not been convicted of a crime which could lead to debarment under the Generic Drug Enforcement Act of 1992. Each Party hereby represents that to the best of its knowledge it has not utilized, and will use its reasonable efforts not to utilize, the services of any individual or legal entity in the performance of Services or obligations under this Agreement that has been convicted of a crime which could lead to debarment. In the event that INC Research becomes aware that any of its officers, directors or employees has become debarred, then INC Research shall notify Sponsor promptly.
- 13.3 **Survival of Terms.** The rights, duties and obligations under Sections 4, 6, 7, 8, 9, 10, 13 and Appendix A shall survive the termination or expiration of this Agreement.
- 13.4 **Binding Agreement.** This Agreement shall be binding upon the Parties hereto and shall inure to the benefits of the Parties hereto. No modification of this Agreement shall be deemed effective unless engaged in writing and executed as described herein, and any waiver granted shall not be deemed effective unless in writing, executed by the Party against whom enforcement of the waiver is sought.
- 13.5 **Data Protection.** If any of the Services under this Agreement will involve the collection or processing of personal data (as defined by applicable data protection legislation) within the European Economic Area ("EEA"), then Sponsor shall serve as the Data Controller of such Personal Data, as defined by the European Union Data Protection Directive 95/46/EC, (the "Directive"), and INC Research shall act only as the Data Processor under the written instructions of Sponsor regarding the handling of personal data in connection with this Agreement. Where INC Research's processing of such personal data takes place in countries that have not received an "adequacy" finding pursuant to Articles 25 and 26 of the Directive, INC Research shall make transfers of such personal data to INC Research Affiliates and contractors in such countries in compliance with the applicable requirements of Articles 25 and 26 of the Directive concerning international and onward data transfers. In addition to its adherence to the Directive, INC Research, LLC subscribes to the "Safe Harbor Principles" issued by the U.S. Commerce Department on July 21, 2000 and as a result, currently appears on the Department's Safe Harbor list (available at <http://www.export.gov/safeharbor>) as a member of both the European Union – United States and Switzerland – United States Safe Harbor Programs. In the event of a lapse of INC Research, LLC's Safe Harbor status, INC Research will promptly remedy such a lapse or work with Sponsor to find an alternative means of meeting the adequacy requirements of the Directive. If the Safe Harbor framework is amended, INC Research, LLC shall update its processes and certifications as needed to continue compliance with the Safe Harbor Programs. If requested by INC Research, in order to enable INC Research to comply with the Directive, Sponsor will execute any documents necessary for such compliance which may include the INC Research standard Data Processing Agreement and/or an EU model clause contract deemed by the European Commission to offer sufficient data protection safeguards in relation to any transfer of personal data out of the EEA, unless the parties deem that there is another exemption that it believes satisfies the Directive's requirements and that adherence encompasses the personal data that is the subject of the transfer. Each Party represents that procedures compatible with the relevant directives, data protection laws and regulations will be employed so that processing and transfer of relative personal data and identifiers, relating to all data subjects or protected information will not be impeded.

- 13.6 Entire Agreement. The making, execution, and delivery of this Agreement by INC Research and Sponsor have been induced by no representations, statements, warranties, or agreements other than those herein expressed. This Agreement, in conjunction with its attachments, embodies the entire and integrated understanding between the Parties hereto and supersedes all prior agreements or understandings, negotiations, or representations either written or oral, regarding its subject matter.
- 13.7 No Effect to Printed Standard Terms. Regardless of anything to contrary, no printed standard terms appearing on any proposal, purchase order, invoice, quotation, or other documentation relating to the Services will be effective in adding to or changing the terms of this Agreement or any Work Order.
- 13.8 Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Delaware, excluding that body of law known as choice of law, and shall be binding upon the Parties hereto in the United States and worldwide.
- 13.9 Dispute Resolution. In the event a dispute arises between the Parties over the interpretation and application of this Agreement, the Parties shall attempt to settle such a dispute first by good faith negotiation and consultation between themselves with senior representatives with authority to resolve the dispute.

If such efforts do not result in a resolution, and at least thirty (30) days have elapsed since notification of the dispute, then the Parties may next seek to mediate their dispute using a professional mediator from the American Arbitration Association (AAA). The Parties agree to convene with the mediator, with senior representatives of the Parties present (having authority to resolve the dispute), for at least one session.

If mediation does not result in the resolution of a dispute or sixty (60) days have elapsed since the notification of the dispute, the Parties agree to resolve the dispute through arbitration before a single arbitrator in accordance with the Commercial Arbitration Rules of the AAA, then pertaining (available at www.adr.org), except where those rules conflict with this provision, in which case this provision controls. Any court with jurisdiction shall enforce this clause and enter judgment on any award. The arbitrator shall be selected within ten (10) business days of commencement of the arbitration from the AAA's National Roster of Arbitrators pursuant to agreement or through selection procedures administered by the AAA. Within forty-five (45) days of initiation of arbitration, the Parties shall reach agreement upon and thereafter follow procedures assuring that the arbitration will be concluded and the award rendered within no more than eight (8) months from selection of the arbitrator or, failing agreement, procedures meeting such time limits designated by the AAA. The arbitration shall be held in a mutually agreed neutral setting and shall apply the substantive law of Delaware, except that the interpretation and enforcement of this arbitration provision shall be governed by the Federal Arbitration Act. The arbitrator shall be bound by the expressed terms of this Agreement. Each Party shall bear their own costs in connection with any of the remedial actions set forth above.

By agreeing to arbitration, the Parties do not intend to deprive any competent court of such court's jurisdiction to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of the arbitration proceedings and the enforcement of any award or judgment. Without prejudice to such provisional remedies in aid of arbitration as may be available under the jurisdiction of a national court, the court of arbitration shall have full authority to grant provisional remedies and to award damages for failure of any party to respect the court of arbitration's order to that effect.

- 13.10 Waiver. Waiver or forbearance by either Party or the failure by either Party to claim a breach of any provision of this Agreement or to exercise any right or remedy provided by hereunder, or under Applicable Laws and Regulations, shall not constitute a waiver with respect to any subsequent breach of this Agreement.
- 13.11 Severability. If any part, term, provision or provisions of this Agreement shall be held to be invalid, illegal, unenforceable or in conflict with the law of jurisdiction, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 13.12 Headings Not Controlling. Headings used in this Agreement are for reference purposes only and shall not be used to modify the meaning of the terms and conditions of this Agreement.

13.13 Counterparts. This Agreement along with any requisite Work Order may be executed in several counterparts by duly authorized individuals on behalf the Parties, each document of which shall be deemed an original but all of which shall constitute one and the same instrument.

IN WITNESS WHEREOF, the undersigned have caused this Agreement to be executed by a duly authorized individual on behalf of each requisite Party effective as of the Effective Date. In the event that the Parties execute this Agreement by exchange of portable document format, other electronically signed copies or facsimile signed copies, the Parties agree that, upon being signed by both Parties, this Agreement shall become effective and binding and that such copies will constitute evidence of the existence of this Agreement. Thereafter, the Parties agree that in connection with request for information that either Party may need from the other related to the Services provided hereunder, both Parties expressly permit communication via facsimile or electronic means to the extent allowed by Applicable Laws and Regulations to be disseminated in that manner.

INC RESEARCH, LLC

By: /s/ Andrew I. Shaw
Name: Andrew I. Shaw
Title: Assistant General Counsel
Date: Sep 27, 2016

CELLECTAR BIOSCIENCES, INC.

By: /s/ Jarrod Longcor
Name: Jarrod Longcor
Title: SVP Corp. Dev & Operations
Date: Oct. 6, 2016

INC RESEARCH, LLC

By: /s/ Jason Meggs
Name: Jason Meggs
Title: SVP Global Business Finance
Date: Sep 27, 2016

INC RESEARCH, LLC

CELLECTAR BIOSCIENCES, INC.

MSA

APPENDIX A
Software License Terms

Sponsor acknowledges that INC Research is the sole owner of Licensed Software and that should Sponsor desire a non-exclusive license to utilize the Licensed Software, Sponsor shall be subject to the terms as delineated in this Appendix A (“Appendix”). Accordingly, INC Research is willing to grant Sponsor such a non-exclusive license, subject to the terms and conditions set forth in the Agreement, and more specifically in this Appendix. Should any of the terms of the Agreement conflict, in any way, with the terms of this Appendix, the terms of this Appendix shall govern, solely over matters as they relate to the Software License Terms.

1. LICENSE.

1.1. License Grant.

1.1.1. Subject to the terms and conditions set forth in this Appendix A, INC Research hereby grants to Sponsor and Sponsor accepts from INC Research, a non-exclusive right and license (the “License”) to utilize, reproduce, and distribute the Licensed Software only for: (i) internal, non-commercial purposes in connection with the clinical trial data with which the Licensed Software was provided by INC Research (the “Data Set”); and (ii) submission to government agencies in connection with Sponsor’s applications for approval of the Data Set from such government agencies.

1.1.2. This License is not a sale of the original or any copy of the Licensed Software.

1.2. Updates and Support. Unless otherwise agreed in writing between the parties pursuant to a separate agreement, Sponsor will not be entitled to receive any enhancements, updates or new versions of the Licensed Software, and INC Research shall not be obligated to maintain or support the Licensed Software in any way.

1.3. Ownership. Sponsor acknowledges that the Licensed Software is the valuable, confidential, and proprietary property of INC Research as described in the Agreement, the development of which required the investment of substantial time, effort and financial resources by INC Research, and further acknowledges that INC Research shall retain exclusive title to this property both during the term and after the termination of the Agreement. Sponsor agrees that, both during the term of the Agreement and after its termination, it will not contest, directly or indirectly, INC Research’s ownership, title, right or interest in the Licensed Software. Without limitation, Sponsor acknowledges the validity of any copyrights, patents, or trade secrets (collectively “Intellectual Property”) that may arise out of the Licensed Software, agrees that any rights in and to the Intellectual Property in the Licensed Software shall remain the exclusive property of INC Research at all times (INC Research Property), and agrees that it will take no action inconsistent with such rights. EXCEPT AS OTHERWISE PROVIDED IN THE AGREEMENT, SPONSOR SHALL NOT, IN WHOLE OR IN PART, AT ANY TIME DURING THE TERM OF OR AFTER THE TERMINATION OF THE AGREEMENT: (i) SELL, TRANSFER, ASSIGN, LEASE, RENT, OR SUBLICENSE THE LICENSED SOFTWARE TO ANY THIRD PARTY; (ii) DISCLOSE, COPY OR REPRODUCE IN ANY MANNER, DISPLAY, OR DISTRIBUTE THE LICENSED SOFTWARE TO ANY THIRD PARTY; (iii) MODIFY, DISASSEMBLE, DECOMPILE, REVERSE ENGINEER OR TRANSLATE THE LICENSED SOFTWARE; OR (iv) ALLOW ANY PERSON OR ENTITY TO COMMIT ANY OF THE ACTIONS DESCRIBED IN (i) THROUGH (iii) ABOVE. Sponsor shall take appropriate action, by instruction, agreement, or otherwise, with respect to its employees and contractors permitted under the Agreement to have access to the Licensed Software, to ensure that all of Sponsor's obligations under this Section shall be satisfied.

2. REPRESENTATIONS.

2.1. Mutual Representations. Each of the parties hereto represents and warrants to the other that:

2.1.1. Each is a legal entity duly organized and validly existing under the laws of the state of its formation and has full power and authority to execute, deliver and perform the terms of this Appendix.

2.1.2. This Appendix is not in conflict with any other agreements to which it is a party.

2.1.3. The execution, delivery and performance by such party of this Appendix have been duly authorized by all necessary action of such party, do not require any approval which has not been obtained, do not contravene the organizational documents of such party or any law, regulation, rule, or order binding on such party, and do not contravene the provisions of or constitute a default under any indentures, mortgage, contract, or other agreement or instrument to which it is a party.

2.2. Sponsor's Representations. Sponsor represents and warrants to INC Research that:

2.2.1. Sponsor shall be solely responsible for the use of the Licensed Software pursuant to the terms of this Appendix.

2.2.2. Sponsor shall comply with all applicable laws and regulations and obtain all appropriate government approvals pertaining to the use of the Licensed Software.

3 . INDEMNIFICATION. Sponsor agrees to defend, indemnify, and hold INC Research, and its officers, directors, shareholders, agents and employees, harmless against all costs, expenses, and losses (including reasonable attorney fees and costs) incurred as a result: of (i) claims of a third party against INC Research based on Sponsor's use of the Licensed Software pursuant to this Appendix; and/or (ii) a breach by Sponsor of any of the representations set forth in Section 2 of this Appendix.

4. **TERMINATION.**

4.1. **Term.** The terms of this Appendix, shall commence on the Effective Date of the Agreement and shall continue in perpetuity.

4.2. **Early Termination.** The terms of this Appendix shall be terminable at the option of either party upon written notice to the other party if:

4.2.1. the other party is in material breach or default with respect to any material term or provision of this Appendix and fails to cure the same within fourteen (14) days after written notice thereof, which notice shall specify the breach or default in reasonable detail;

4.2.2. the other party has made a material representation or warranty in this Appendix that is materially false or misleading;

4.2.3. either party is adjudged bankrupt, files or has filed against it any petition under bankruptcy, insolvency, or similar laws, has a receiver appointed for its business property, or makes a general assignment for the benefit of creditors, and such condition is not remedied or removed within thirty (30) days; or

4.2.4. a court of final jurisdiction determines that either party's exercise of its rights hereunder or the use of the Licensed Software infringes or contravenes any valid and outstanding right or license of a third party based upon a patent or copyright or any similar proprietary rights.

4.3. **Effect of Termination.** Within ten (10) days after the date of termination of the terms of this Appendix for any reason, Sponsor shall return all original copies of the Licensed Software and give INC Research written notice certifying that the original copies of the Licensed Software and any other material received from INC Research in connection with this Appendix have been returned to INC Research, and that the Licensed Software has been erased from all computer memories and storage devices within Sponsor's control and that Sponsor has not retained any copies of the Licensed Software. In addition to all other remedies available to INC Research under the Agreement and the terms of this Appendix, INC Research shall be entitled to specific performance of Sponsor's obligations to return and erase the Licensed Software pursuant to this Section.

4.4. **Survival of Certain Terms.** The following shall survive any termination of this Appendix for any reason: Sections 1.3, 2, 3, 4.4, 5, and 6.

5. WARRANTY EXCLUSION.

THE LICENSED SOFTWARE IS PROVIDED BY INC RESEARCH “AS-IS” AND “AS AVAILABLE” AND INC RESEARCH MAKES NO WARRANTIES WHATSOEVER WITH RESPECT TO THE LICENSED SOFTWARE, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, AND NON-INFRINGEMENT. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, INC RESEARCH MAKES NO WARRANTY WITH RESPECT TO, AND SPONSOR ACCEPTS SOLE RESPONSIBILITY FOR, THE INSTALLATION AND USE OF THE LICENSED SOFTWARE, ANY RESULTS OBTAINED FROM SUCH USE, AND THE SELECTION, USE OF AND RESULTS OBTAINED FROM ANY OTHER PROGRAM, PROGRAMMING EQUIPMENT OR SERVICES OPERATED OR APPLIED IN CONNECTION WITH THE LICENSED SOFTWARE. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, INC RESEARCH ALSO MAKES NO WARRANTY THAT THE LICENSED SOFTWARE WILL MEET SPONSOR’S TECHNICAL OR OTHER REQUIREMENTS. INC RESEARCH DOES NOT REPRESENT OR WARRANT THAT THE LICENSED SOFTWARE WILL BE UNINTERRUPTED OR THAT THE LICENSED SOFTWARE IS ERROR-FREE, PROBLEM-FREE, OR WITHOUT OTHER LIMITATIONS. NO REPRESENTATIONS, WARRANTIES OR GUARANTEES WHATSOEVER ARE MADE AS TO THE ACCURACY, ADEQUACY, AVAILABILITY, RELIABILITY, TIMELINESS, COMPLETENESS, SUITABILITY OR APPLICABILITY OF THE LICENSED SOFTWARE. IF APPLICABLE LAW REQUIRES ANY WARRANTIES WITH RESPECT TO THE LICENSED SOFTWARE, ALL SUCH WARRANTIES ARE LIMITED IN DURATION TO THE SHORTEST PERIOD OF TIME REQUIRED BY LAW. NO ORAL OR WRITTEN INFORMATION OR ADVICE GIVEN BY INC RESEARCH, ITS DEALERS, DISTRIBUTORS, AGENTS OR EMPLOYEES SHALL CREATE A WARRANTY OR IN ANY WAY INCREASE THE SCOPE OF ANY WARRANTY PROVIDED HEREIN.

6. MISCELLANEOUS.

6.1. **No Implied Rights.** Except as expressly provided for in this Appendix, nothing contained herein shall be construed as conferring any license or other rights, by implication, estoppel, or otherwise, under any patents or patent applications, trade secrets, proprietary information, copyrights, trademarks, trade names, or trade dress of either party.

6.2. **Injunctive Relief.** Sponsor acknowledges that any breach of Sponsor’s obligations under this Appendix may result in irreparable injury for which INC Research shall not have an adequate remedy at law. Accordingly, if Sponsor breaches or threatens to breach any of Sponsor’s obligations under this Appendix, INC Research shall be entitled, without showing or proving any actual damage sustained, to a temporary restraining order, preliminary injunction, permanent injunction, and/or order compelling specific performance, to prevent the breach of Sponsor’s obligations under this Appendix. Nothing in this Appendix shall be interpreted as prohibiting INC Research from pursuing or obtaining any other remedies otherwise available to it for such actual or threatened breach, including recovery of damages.

6.3. Assignment. The terms of this Appendix shall bind and inure to the benefit of the parties and their respective permitted successors and assigns. INC Research shall have the right to assign or otherwise transfer its rights or obligations under this Appendix whether by contract or operation of law without Sponsor's consent. Sponsor shall not have the right to assign, by contract, operation of law or otherwise, the terms of this Appendix or any of the rights, interests, or obligations hereunder without the prior written consent of INC Research. A successor in interest by merger, operation of law or purchase of the assets or entire business of Sponsor or otherwise shall not acquire all or any portion of Sponsor's interests hereunder without the prior written consent of INC Research.

6.4. Informed Review. Each party acknowledges that it has received and reviewed this Appendix and that normal rules of construction, to the effect that ambiguities are to be resolved against the drafting party, shall not apply to this Appendix or to any amendments, modification, schedules, or attachments to this Appendix.

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

Set forth below is a list of the subsidiaries of Collectar Biosciences, Inc. as of December 31, 2017:

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

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Forms S-1 (File Nos. 333-221468, 333-214310, 333-214198 and 333-208638), Form S-3 (File No. 333-218514) and Forms S-8 (File Nos. 333-221469, 333-195255 and 333-164398) of our report dated March 21, 2018, relating to our audit of the consolidated financial statements of Collectar Biosciences, Inc. and Subsidiary as of and for the years ended December 31, 2017 and 2016, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern and appears in this Annual Report on Form 10-K for the years ended December 31, 2017 and 2016.

/s/ BAKER TILLY VIRCHOW KRAUSE, LLP

Madison, Wisconsin
March 21, 2018

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

I, James V. Caruso, President and 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 21, 2018

/s/ James V. Caruso

James V. Caruso

President and Chief Executive Officer

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

I, John P. Hamill, Interim 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 21, 2018

/s/ John P. Hamill

John P. Hamill
Interim Chief Financial Officer

**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, 2017, 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, John P. Hamill, Interim 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
President and Chief Executive Officer

/s/ John P. Hamill

John P. Hamill
Interim Chief Financial Officer

Dated: March 21, 2018

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.
