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, 2018

☐ **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	**04-3321804**
(*State or other jurisdiction of incorporation or organization*)	(*I.R.S. Employer Identification No.*)

100 Campus Drive
Florham Park, New Jersey 07932
(*Address of principal executive offices*)

(608) 441-8120
(*Registrant's telephone number, including area code*)

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

Title of Class	Name of each exchange on which registered
Common stock, par value $0.00001	NASDAQ Capital Market
Warrant to purchase common stock, expiring August 20, 2019	NASDAQ Capital Market
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 every Interactive Data File required to be submitted 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 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

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, 2018 was $10,374,683.

As of February 22, 2019, there were 4,757,709 shares of the registrant's $0.00001 par value common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the Registrant's 2019 Annual Meeting of Stockholders are incorporated by reference in Part III of this annual report on Form 10-K. The definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this annual report on Form 10-K.

CELLECTAR BIOSCIENCES, INC.
FORM 10-K

TABLE OF CONTENTS

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FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K of Cellectar Biosciences, Inc. (the "Company", "Cellectar", "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 1800 series, CLR 1900 series, CLR 2000 series, CLR 2100 series, CLR 2200 series and CLR 12120 series;
- the status of the disruption in supply of CLR 131 obtained from the Centre for Probe Development and Commercialization ("CPDC");
- our ability to maintain orphan drug designation and in the U.S. for CLR 131 as a therapeutic for the treatment of multiple myeloma, neuroblastoma, osteosarcoma, rhabdomyosarcoma and Ewing's sarcoma, and the expected benefits of orphan drug status;
- the volatile market for priority review vouchers;
- our ability to pursue strategic alternatives;
- our ability to advance 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;
- 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 annual report on Form 10-K.

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.

This annual report on Form 10-K contains trademarks and service marks of Cellectar Biosciences, Inc. Unless otherwise provided in this annual report on Form 10-K, trademarks identified by ™ are trademarks of Cellectar 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 conjugate™ (PDCs™) delivery platform to develop PDCs that specifically target cancer cells to deliver improved efficacy and better safety as a result of fewer off-target effects. Our PDC platform possesses the potential for the discovery and development of the next generation of cancer-targeting treatments and we plan to develop PDCs independently and through research and development collaborations.

Our lead PDC candidate, CLR 131, provides targeted delivery of the cytotoxic (cell-killing) radioisotope iodine 131. CLR 131 is in a Phase 2 clinical study in relapsed or refractory (R/R) multiple myeloma (MM) and a range of other B-cell malignancies and Phase 1 clinical study for R/R MM and we plan to initiate a Phase 1 study in 2019 for pediatric solid tumors and lymphoma.

In order to preserve resources and extend our cash runway we have focused our early stage research efforts on projects that we believe can provide the greatest near-term value. Our pipeline includes a PDC chemotherapeutic program in drug discovery, CLR 1900. CLR 1900 is being targeted for solid tumors with a payload that inhibits mitosis (cell division) which is a validated pathway for treating cancers.

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

Our PDC platform provides selective delivery of a diverse range of oncologic payloads to cancerous cells, whether a hematologic cancer or solid tumor, the primary tumor, or a metastatic tumor and cancer stem cells. The PDC platform's mechanism of entry does not rely upon specific cell surface epitopes or antigens as are required by other targeted delivery platforms. Our PDC platform takes advantage of a metabolic pathway utilized by all tumor cell types in all stages of the tumor "cycle." Tumor cells modify regions on the cell surface due to the utilization of this metabolic pathway and our PDCs bind to these regions and directly enter the intracellular compartment. This allows the PDC molecules to accumulate over time, which enhances drug efficacy, and to avoid the specialized highly acidic cellular compartment known as lysosomes, which allows the PDC to deliver molecules that previously could not be delivered. Additionally, molecules targeting specific cell surface epitopes face challenges in completely eliminating a tumor because the targeted antigens are expressed in limited in the total numbers on the cell surface, have longer cycling time from internalization to being present on the cell surface again upon binding and are not present on all tumor cells of a particular cancer type. This means a subpopulation of tumor cells will always exist that be non-targetable by therapies targeting specific surface epitopes. 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.

On August 7, 2018, we were informed by CPDC, our sole supplier of CLR 131, that CPDC is subject to an Import Alert 66-40 (the "Import Alert") by the U.S. Food and Drug Administration (the "FDA"). While the basis for the Import Alert was not related to CLR 131, or CPDC's production facility associated with CLR 131, CPDC informed us on August 8, 2018 that CPDC would not be able to supply CLR 131 to us until the Import Alert is lifted or alternative agreements are reached with the FDA. On November 8, 2018, the FDA notified us that CLR 131 would be exempted from the Import Alert placed on CPDC in relation to our ongoing clinical studies. As a result, we have resumed patient enrollment in our CLR 131 hematology clinical studies.

We await either the lifting of the Import Alert or the granting of an exemption from the FDA for any future shipments into the U.S. in connection with our Phase 1 study of pediatric patients with neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. As a result of the supply disruption, we are experiencing delays in initiation of this clinical study. At this time, we are seeking clinical sites outside the U.S. which would allow us to begin enrollment of this clinical study.

A description of our PDC product candidates follows:

Clinical Pipeline

CLR 131 is a small-molecule, cancer-targeting radiotherapeutic PDC designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. CLR 131 is our lead therapeutic PDC product candidate and is currently being evaluated in both Phase 2 and Phase 1 clinical studies. The Investigational New Drug ("IND") application was accepted by the FDA in March 2014. Initiated in March 2017, the primary goal of the Phase 2 study is to assess the compound's efficacy in a broad range of hematologic cancers. The Phase 1 study is designed to assess the compound's safety and tolerability in patients with R/R MM and was initiated in April 2015. This clinical study is a standard three-by-three dose escalation safety study. 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. Secondary objectives include the 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 December 2014, the FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma. In 2018, the FDA granted orphan drug and rare pediatric disease designations for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. 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 plan to initiate this Phase 1 study in 2019.

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 (NCI) Fast-Track Small Business Innovation Research grant to further advance the clinical development of CLR 131. The funds are supporting the Phase 2 study initiated in March 2017 to define the clinical benefits of CLR 131 in R/R MM and other niche hematologic malignancies with 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 ("DLBCL"). The study is being conducted in approximately 10 U.S. cancer centers in patients with orphan-designated relapse or refractory hematologic cancers. The study's primary endpoint is clinical benefit response (CBR), with additional endpoints of Overall Response Rate (ORR), PFS, median OS and other markers of efficacy following a single 25.0 mCi/m^2 dose of CLR 131, with the option for a second 25.0 mCi/m^2 dose approximately 75-180 days later. Based on the performance results from Cohort 5 of our Phase 1 study in patients with R/R MM, reviewed below, we have modified the dosing regimen of this study to a fractionated dose of 15.625 mCi/m^2 administered on day 1 and day 8.

In February 2019, we announced that a single, 25mCi/m^2, 30-minute intravenous infusion of CLR 131 in the first 10 patients with R/R MM were assessed. These interim data show a 30% response rate in a patient population which have received an average of five prior lines of systemic therapy (including daratumumab), at least one stem cell transplantation with the average age being 70. The observed responses to date show overall reductions in surrogate markers of disease (M protein or free light chains, depending upon which is being used to monitor the patient's disease) between 70% and over 90%. In addition to these patients, 100% of patients achieved stable disease with 2 patients experiencing a minimal response or a minimum reduction of a 25% in the surrogate marker being used to monitor the patient's disease. Historically, patients receiving 4th line chemotherapy treatment show a 15% response rate, and patients receiving 5th line chemotherapy show an 8% response rate, whether dosed as mono-therapy or in combination. The Multiple Myeloma average treatment response rate (RR) provided by line of therapy was obtained through Decision Resource Group, a global information and technology vendor specializing in healthcare data analysis utilizing over 12.5 billion U.S. insurance claims and 90 million electronic medical records. As a result of these outcomes, we have expanded this cohort to include up to 30 additional patients.

In July 2018, we announced that after a single 25mCi/m^2 IV administration of CLR 131, patients with relapsed/refractory aggressive DLBCL were assessed for response. These interim data show a 33% ORR and a 50% CBR. In addition, the observed responses to date show overall tumor reduction ranged from 60% to greater than 90%. As a result of these favorable outcomes, we have expanded this cohort to include up to 30 additional patients. We also announced that a patient in the lymphoplasmacytic lymphoma (LPL) arm with advanced Waldenstrom macroglobulinema showed a 94% reduction in tumor burden and complete resolution in four of five targeted masses after two doses of CLR 131 separated by 123 days.

Phase 1 Study in Patients with R/R Multiple Myeloma

CLR 131 in combination with dexamethasone is currently under investigation in a Phase 1 study in adult patients with R/R MM following treatment with at least one proteasome inhibitor and an immunomodulatory agent. All patients have been heavily pretreated with an average of 5 prior lines of therapy. CLR 131 was deemed by an independent Data Monitoring Committee to be safe and tolerable up to its planned maximum single dose of 31.25 mCi/m^2. The four single dose cohorts examined were: 12.5 mCi/m^2, 18.75 mCi/m^2, 25 mCi/m^2, and 31.25 mCi/m^2, all in combination with 40 mg dexamethasone weekly. Of the five patients in the first cohort, four achieved stable disease and one patient progressed at Day 15 after administration and was taken off the study. Of the five patients that have been admitted to the second cohort, four achieved stable disease and one patient progressed at Day 41 after administration and was taken off the study. Four patients were enrolled to the third cohort and all achieved stable disease. In September 2017, we announced results for Cohort 4, showing that a single 30-minute infusion of 31.25mCi/m^2 of CLR 131 was safe and tolerated by the three patients in the cohort. Additionally, all three patients experienced clinical benefit with one patient achieving a PR. We are monitoring response rates via surrogate markers of efficacy including M protein and FLC. The International Myeloma Working Group defines a PR as a greater than or equal to 50% decrease in FLC levels (for patients in whom M protein is unmeasurable) or 50% decrease in M protein. The patient experiencing a PR had an 82% 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% reduction in M protein. For all of the patients receiving the single dose, CLR 131 was the third line of treatment or later. We have recently converted the Phase 1a clinical data (single CLR 131 dose) to pooled data for presentation of the total performance of the results to date. On January 7, 2019, we announced that the pooled median Overall Survival ("mOS") data from the first four cohorts was 22.0 months.

Based on the safety observed to date as well as various efficacy signals, including reductions in M protein and FLC and a pooled mOS, the study protocol was modified for cohort 5 to introduce a fractionated dose of 15.625 mCi/m^2 administered on day 1 and day 8 to further determine the optimal dose-range for CLR 131. Results from Cohort 5 indicate enhanced tolerability and safety in comparison to Cohort 4 despite an 18% increase in total average dose from 55.29 mCi to 65.15 mCi of CLR 131. Patients in Cohort 5 required less supportive care such as transfusions of platelets or packed red blood cells than seen in previous cohorts. Furthermore, a review of surrogate efficacy markers demonstrated that patients in Cohort 5 monitored by M-protein showed a nearly 50% further reduction in M-Protein than seen in Cohort 4. Based on these results and an independent Data Monitoring Committee recommendation, on December 4, 2018, we initiated a sixth cohort and the second fractionated cohort using a two dose regimen of 18.75 mCi/m^2 administered approximately one week apart.

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 study of CLR 131 will be 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 2018, the FDA granted orphan drug and a Rare Pediatric Disease Designation (RPDD) for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Should any of these indications reach approval, the RPDD would enable us to receive a priority review voucher. Priority review vouchers can be used by the sponsor to receive Priority Review for a future New Drug Application ("NDA") or Biologic License Application ("BLA") submission, which would reduce the FDA review time from 12 months to six months. Currently, these vouchers can also be transferred or sold to another entity. We plan to initiate this Phase 1 study in 2019 at 3-5 pediatric cancer centers, within and possibly outside the US.

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.

Preclinical Pipeline

- CLR 1800 Series is a collaborative PDC program with Pierre Fabre that was entered into in December 2015 and extended in October 2017 and again in 2018. Pierre Fabre is the third largest French pharmaceutical company with an extensive oncology research and development infrastructure. The objective of the collaboration is to leverage our expertise in conjugation, linker chemistry and phospholipid ether chemistry to codesign a library of PDCs employing Pierre Fabre's chemotherapeutics. The newly developed PDCs may provide enhanced therapeutic indices to otherwise highly potent, nontargeted payloads through the targeted delivery to cancer cells provided by our proprietary phospholipid ether delivery platform. Research progress has been achieved, including the demonstration of improved tolerability in animal models. Our agreement with Pierre Fabre expired in January 2019, however, the program is evaluating a number of PDC molecules for possible candidate selection and progression to IND enabling studies.

- CLR 1900 Series is an internally developed proprietary PDC program leveraging a novel small molecule cytotoxic compound as the payload. The payload inhibits mitosis (cell division) and targets a key pathway required to inhibit rapidly dividing cells that results in apoptosis. We believe that this program could produce a product candidate targeted to select solid tumors. Currently, the program is in 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 studies previously by Onconova. We would own all new intellectual property associated with the design of the new PDCs, and both companies will have the option to advance compounds.

- CLR 12120 Series is a collaborative PDC program with Orano Med for the development of novel PDCs utilizing Orano Med's unique alpha emitter, lead 212 conjugated to our phosolipid ether (PLE); the companies intend to evaluate the new PDCs in up to three oncology indications.

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 and stabilization of lipid rafts in cancer cells, including cancer stem cells, our product candidates provide selective targeting preferentially to cancer cells 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 cytotoxic radioactive I-131. Non-radioactive molecules, including many classes of small molecule chemotherapeutic 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. The objective 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 1800, 1900, 2000, 2100, 2200, and 12120 series of conjugated compounds currently being researched independently and through partnerships. Other than CLR 12120, 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* in animal models as well as in clinical studies. 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 likely results from cancer cells maintenance of an overabundance of lipid rafts and the stabilization of these microdomains within the plasma membrane as compared to normal cells. 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 (including mitochondria and the endoplasmic reticulum). The pivotal role played by lipid rafts is underscored by the fact that disruption of lipid raft architecture significantly eliminates 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 have 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 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 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 study 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 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 study established an initial dose of 12.5 mCi/m^2, for the Phase 1b escalating dose study that commenced in January 2012.

The primary objective of the multicenter Phase 1b dose-escalation study 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 study 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 study. Dose escalation in four cohorts subsequently occurred with refractory cancer patients receiving single doses of 25 mCi/m^2, 31.25 mCi/m^2 or 37.5 mCi/m^2.

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 studies 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.

In September 2017, we announced results for Cohort 4 showing that a single 30-minute infusion of 31.25mCi/m^2 of CLR 131 was safe and tolerated by the three patients in the cohort. Additionally, all three patients experienced clinical benefit with one patient achieving a partial response ("PR"). We are monitoring response rates via surrogate markers of efficacy including M protein and FLC. The IMWG defines a PR as a greater than or equal to 50% decrease in FLC levels (for patients in whom M protein is unmeasurable) or 50% decrease in M protein. The patient experiencing a PR had an 82% 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% reduction in M protein. For all of the patients receiving the single dose, CLR 131 was the third line of treatment or later. We have recently converted the Phase 1a clinical data (single CLR 131 dose) to pooled data for presentation of the total performance of the results to date. On January 7, 2019, we announced that the pooled mOS data from the first four cohorts was 22.0 months. Based on the safety observed to date as well as various efficacy signals, including reductions in M protein and FLC and a pooled median OS that has not yet been reached, the study protocol was modified for cohort 5 to introduce a fractionated dose of 15.625 mCi/m^2 administered on day 1 and day 8 to further determine the optimal dose-range for CLR 131. Results from Cohort 5 indicate enhanced tolerability and safety in comparison to Cohort 4 despite an 18% increase in total average dose from 55.29 mCi to 65.15 mCi of CLR 131. Patients in Cohort 5 required less supportive care such as transfusions of platelets or packed red blood cells than seen in previous cohorts. Furthermore, a review of surrogate efficacy markers demonstrated that patients in Cohort 5 monitored by M-protein showed a nearly 50% further reduction in M-Protein than seen in Cohort 4. Based on the results and an independent Data Monitoring Committee recommendation, on December 4, 2018 we initiated a sixth cohort using a fractionated two dose regimen of 18.75 mCi/m^2 administered one week apart.

CLR 131 is also 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/m^2 dose infused over approximately 30 minutes with the option of a second 25 mCi/m^2 dose 75-180 days later based on physician assessment. Based on the performance results from Cohort 5 of our Phase 1 study in patients with R/R MM, reviewed below, we modified the dosing regimen of this study to a fractionated dose of 15.625 mCi/m^2 administered on day 1 and day 8. This study is partially funded through a $2,000,000 Fast Track NCI SBIR award which was granted in July 2016.

In February 2019, we announced that a single, 25mCi/m^2, 30-minute intravenous infusion of CLR 131 in the first 10 patients with R/R MM were assessed. These interim data show a 30% response rate in a patient population which received an average of five prior lines of systemic therapy (including daratumumab), at least one stem cell transplantation with the average age being 70. The observed responses to date show overall reductions in surrogate markers of disease (M protein or free light chains, depending upon which is being used to monitor the patient's disease) between 70% and over 90%. In addition to these patients, 100% of patients achieved stable disease with 2 patients experiencing a minimal response or a minimum reduction of a 25% in the surrogate marker being used to monitor the patient's disease. Historically, patients receiving 4th line chemotherapy treatment show a 15% response rate, and patients receiving 5th line chemotherapy show an 8% response rate, whether dosed as mono-therapy or in combination. The Multiple Myeloma average treatment response rate (RR) provided by line of therapy was obtained through a global information and technology vendor specializing in healthcare data analysis utilizing over 12.5 billion U.S. insurance claims and 90 million electronic medical records. As a result of these outcomes, we have expanded this cohort to include up to 30 additional patients.

In July 2018, we announced that after a single 25mCi/m^2 IV administration of CLR 131, patients with relapsed/refractory aggressive DLBCL were assessed for response. These interim data show a 33% ORR and a 50% CBR. In addition, the observed responses to date show overall tumor reduction ranged from 60% to greater than 90%. As a result of these favorable outcomes, we have expanded this cohort to include up to 30 additional patients. We also announced that a patient in the lymphoplasmacytic lymphoma (LPL) arm with advanced Waldenstrom macroglobulinema showed a 94% reduction in tumor burden and complete resolution in four of five targeted masses after two doses of CLR 131 separated by 123 days.

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 study 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 2018, the FDA a granted orphan drug and a Rare Pediatric Disease Designation (RPDD) for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Should any of these indications reach approval, the RPDD may enable us to receive a priority review voucher. Priority review vouchers can be used by the sponsor to receive Priority Review for a future NDA or BLA submission, which would reduce the FDA review time from 12 months to six months. Currently, these vouchers can also be transferred or sold to another entity. We plan to initiate this Phase 1 study in 2019, at 3-5 pediatric cancer centers within and possibly outside the US.

CLR 1800 Series

CLR 1800 Series is a collaborative PDC program with Pierre Fabre that was entered into in December 2015 and extended in October 2017 and again in 2018. Pierre Fabre is the third largest French pharmaceutical company with an extensive oncology research and development infrastructure. The objective of the collaboration is to leverage our expertise in conjugation, linker chemistry and phospholipid ether chemistry to codesign a library of PDCs employing Pierre Fabre's chemotherapeutics. The newly developed PDCs may provide enhanced therapeutic indices to otherwise highly potent, nontargeted payloads through the targeted delivery to cancer cells provided by our proprietary phospholipid ether delivery platform. Research progress has been achieved, including the demonstration of improved tolerability in animal models. Our agreement with Pierre Fabre expired in January 2019, however, the program is evaluating a number of PDC molecules for possible candidate selection and progression to IND enabling studies.

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 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

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 studies previously by Onconova. We would own all new intellectual property associated with the design of the new PDCs, and both companies will have the option to advance compounds.

CLR 12120 Series

CLR 12120 Series is a collaborative PDC program with Orano Med for the development of novel PDCs utilizing Orano Med's unique alpha emitter, lead 212 conjugated to our phosolipid ether (PLE); the companies intend to evaluate the new PDCs in up to three oncology indications.

Market Overview

Our target market is broad and represents the market for the treatment of cancer. The American Cancer Society estimated that approximately 1.76 million new cancer cases were expected to be diagnosed in the U.S. in 2019 and approximately 606,880 cancer deaths in the U.S. 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 Decision Resources Group in 2016 estimated the Multiple Myeloma dollar market size to be over $17B in 2018 and is forecasted to increase to nearly $27B 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. It is believed the largest growth will occur in patients receiving at least three lines of treatment due to the expanding elderly population, increases in treatment population and increasing rates of survival from earlier lines of treatment. According to data obtained from Decision Resource Group, over 40% of patients in later lines of therapy while eligible, refuse treatment due to higher treatment failure, severity of adverse events and difficulty of treatment dosing regimen. The average response rates for patients receiving their fourth- and fifth-line treatment are 15% and 8% response rates respectively. Additionally, the mOS for these patients also decreases by line of therapy and is less than 9 months post third-line treatment.

Based on the CLR 131 Phase 1 and Phase 2 product profile demonstrated in fifth-line patients to date with a single dose, we believe CLR 131 may meet the unmet medical need in the heavily pre-treated patient population described above.

B-Cell Lymphoma

B-cell lymphoma represents cancers of the lymphatic system. The lymphoma may be indolent or aggressive and circulates in the blood or form tumors in lymph nodes. According to the National Cancer Institute SEER data base the estimated 2018 incidence of B-Cell Lymphoma was 163,000 cases. Types of B-Cell Lymphomas include Chronic Lymphocytic Leukemia, Small Lymphocytic Leukemia, Mantel Cell Lymphoma, Marginal Zone Lymphoma, and the most common lymphoma, DLBCL.

We believe there is a significant unmet medical need in B-Cell Lymphoma due to continued high mortality and poor response rates remain in second- and third- line treatments compounded by the limited durability of responses.

Based on the CLR 131 Phase 2 product profile demonstrated in DLBCL patients to date with a single dose, we believe CLR 131 may meet the unmet medical need in the patient population described above as well.

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%.

Sarcomas

Sarcomas represent a heterogeneous disease group. Sarcomas grow in connective tissue, or cells that connect or support other kinds of tissue in the body. These tumors are most common in the bones, muscles, tendons, cartilage, nerves and blood vessels. Sarcomas represent 15% of all pediatric tumors and 21% of pediatric solid tumors. The National Cancer Institute SEER data base estimates that there were 2,060 incidences in 2019. The median age at diagnosis was 3, the median age of death was 5.

We are focused on 3 subsets of Sarcomas:

- Osteosarcoma: The tumor develops in growing bone tissues, accounts for 28% of all bone sarcomas and is the most common pediatric sarcoma (56%).
- Ewing's Sarcoma: The tumor develops in immature tissues in bone marrow
- Rhabdomyosarcoma: Tumors develop in the muscles predominately skeletal muscle.

Based on information from Market Insights, Epidemiology, and Market Forecast, the global market value of the Pediatric Sarcoma Market is expected to nearly double from $324 million in 2018 to $635 million in 2025. This growth is expected to be driven by the high rate of recurrence in pediatrics, increased incidence in select markets and new high priced therapies coming to the market.

Manufacturing

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.

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 transferred the manufacturing of CLR 131 to CPDC, a validated Current Good Manufacturing Practices ("cGMPs") manufacturing organization specializing in radiopharmaceuticals, as our exclusive source to supply drug product for our ongoing research and clinical studies, including our Phase 1 and Phase 2 studies of CLR 131. We believe that CPDC and our other third party manufactures have the ability to supply large scale clinical and commercial scale material.

On August 7, 2018, we were informed by CPDC, our sole supplier of CLR 131, that CPDC is subject to an Import Alert 66-40 (the "Import Alert") by the U.S.FDA. While the basis for the Import Alert was not related to CLR 131, or CPDC's production facility associated with CLR 131, CPDC informed us on August 8, 2018 that CPDC would not be able to supply CLR 131 to us until the Import Alert is lifted or alternative agreements are reached with the FDA.

On November 8, 2018, the FDA notified us that CLR 131 would be exempted from the Import Alert placed on CPDC in relation to our ongoing clinical studies. As a result, we have resumed patient enrollment in our CLR 131 hematology clinical studies.

We await either the lifting of the Import Alert or the granting of an exemption from the FDA for any future shipments into the U.S. in connection with our Phase 1 study of pediatric patients with neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. As a result of the supply disruption, we are experiencing delays in initiation of this clinical study. At this time, we are sourcing clinical sites outside the U.S. which would allow us to begin enrollment of this clinical study.

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 Cellectar 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 U.S. 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 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 2018, the FDA a granted orphan drug and a Rare Pediatric Disease Designation (RPDD) for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. We expect to initiate a Phase 1 study during 2019.

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 August 1, 2018, we entered into a collaboration with Orano Med for the development of novel PDCs utilizing Orano Med's alpha emitter lead-212 conjugated to our phospholipid ether; the companies intend to evaluate the new PDCs in up to three oncology indications.

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). Pierre Fabre is the third largest French pharmaceutical company with an extensive oncology research and development infrastructure. The objective of the collaboration is to leverage our expertise in conjugation, linker chemistry and phospholipid ether chemistry to codesign a library of PDCs employing Pierre Fabre's chemotherapeutics. The newly developed PDCs may provide enhanced therapeutic indices to otherwise highly potent, nontargeted payloads through the targeted delivery to cancer cells provided by our proprietary phospholipid ether delivery platform. Research progress has been achieved, including the demonstration of improved tolerability in animal models. Our agreement with Pierre Fabre expired in January 2019, however, the program is evaluating a number of PDC molecules for possible candidate selection and progression to IND enabling studies.

Research and Development

Our primary activity to date has been research and development. The research had been historically been conducted at our facility in Madison, Wisconsin and through third party laboratories and academic universities. Starting in 2018, we no longer used the facility in Madison, Wisconsin for these activities. 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 $6,835,000 and $9,466,000 for 2018 and 2017, respectively.

Regulation

The production, distribution, and marketing of products employing our technology, and our development activities, are subject to extensive governmental regulation in the U.S. and in other countries. In the U.S., 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 U.S., 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 U.S. 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 U.S. 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 studies 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 Studies

Clinical study 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 studies 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 U.S. 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.

U.S. 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 study process for a new compound can take ten years or more to complete. The FDA may prevent clinical studies from beginning or may place clinical studies 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. Studies 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 studies 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 studies, the data is analyzed to determine whether the studies successfully demonstrated safety and effectiveness and whether a product approval application may be submitted. In the U.S., 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 2019, the NDA review fee alone is $2,588,478, 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 studies, and the risks and benefits demonstrated in the clinical studies.

Other U.S. Regulatory Requirements

In the U.S., 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 U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. 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 studies, 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 U.S. 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 U.S. Pharmacopoeia Drug Information. Another commonly cited compendium, for example under Medicaid, is the DRUGDEX Information System.

Employees

As of December 31, 2018, we had seven employees, all of whom are 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 our financial statements.

Corporate Information

Cellectar Biosciences, Inc., formerly known as Novelos Therapeutics, Inc., was incorporated in Delaware in June 1996. On April 8, 2011, we entered into a business combination with Cellectar, 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, we changed our name to Cellectar Biosciences, Inc. Our common stock is listed on the Nasdaq Capital Market under the symbol "CLRB."

Our principal executive offices are located at 100 Campus Drive, Florham Park, New Jersey 07932 and our telephone number is (608) 441-8120. Our corporate website address is www.cellectar.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, 2018, our consolidated cash balance was approximately $13.3 million. We believe our cash balance at December 31, 2018, is adequate to fund operations at budgeted levels into the first quarter of 2020. We will require additional funds to conduct research and development, establish and conduct clinical and preclinical studies, establish commercial-scale manufacturing arrangements and provide for the marketing and distribution of our products. Our ability to execute our operating plan depends on our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. We plan to actively pursue financing alternatives. However, there can be no assurance that we will obtain the necessary funding in the amounts we seek or that it will be available on a timely basis or upon terms acceptable to us. If we obtain capital by issuing debt or preferred stock, the holders of such securities would likely obtain rights that are superior to those of holders of our common stock.

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

- the number of potential products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with preclinical studies and clinical studies;
- 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 study 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 and 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 biopharmaceutical 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 biopharmaceutical 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 or not we achieve profitability 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 studies. 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, 2018, we had working capital of approximately $12.3 million and stockholders' equity of approximately $13.3 million. For the period from our inception in November 2002 until the business combination with Novelos Therapeutics, Inc. on April 8, 2011, and thereafter through December 31, 2018, we incurred aggregate net losses of approximately $97.6 million. The net loss for the year ended December 31, 2018, was approximately $13.2 million. We may never achieve profitability.

Our financial statements as of December 31, 2018, were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2018 financial statements, in its 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 generate revenue.

We rely on a collaborative outsourced business model, and disruptions with these third-party collaborators, including potential disruptions at our sole source supplier of CLR 131, Centre for Probe Development and Commercialization, CPDC, may impede our ability to gain FDA approval and delay or impair commercialization of any products.

We are in the preclinical and clinical study phases of product development and commercialization. We have closed manufacturing operations located at our corporate headquarters, and have implemented a collaboration outsourcing model to more efficiently manage costs. We rely significantly on contracts with third parties to use their facilities to conduct our research, development and manufacturing.

We have engaged CPDC, which has been a validated cGMP manufacturing organization specializing in radiopharmaceuticals, as our exclusive source to supply drug product for our ongoing research and clinical studies, including our Phase 1 and Phase 2 studies of CLR 131. On August 7, 2018, we were notified by CPDC, our sole supplier of CLR 131, that it is subject to an Import Alert 66-40, the Import Alert, by the FDA. While the basis for the Import Alert was not related to CLR 131 or CPDC's production facility associated with CLR 131, CPDC informed us on August 8, 2018 that CPDC would not be able to supply CLR 131 to us until the Import Alert was lifted or alternative agreements are reached with the FDA. On November 8, 2018, the FDA notified us that it has completed its initial review concerning a possible exemption for CLR 131 from the Import Alert placed on CPDC. The FDA authorized CPDC to send shipments to the investigator sites participating in our ongoing hematology focused clinical studies, including our Phase 2 clinical study for relapsed or refractory multiple myeloma and a range of other B-cell malignancies, and our Phase 1 clinical study for relapsed or refractory multiple myeloma. As a result, we have resumed patient enrollment in those clinical studies.

We continue to await authorization from the FDA for any future shipments in connection with our Phase 1 study of pediatric patients with neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. As a result of the supply disruption, we are experiencing delays in enrollment in this clinical study. At this time, we are not able to assess the extent of the delays or what impact the supply disruption will have on us, but the inability of CPDC to supply CLR 131 for this study on a prolonged basis would result in further delayed patient enrollment. We intend to continue to work with CPDC and the FDA to resolve this issue as soon as practical.

In addition, we rely exclusively on contract research organizations to conduct research and development. Any inability of these organizations 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 exposes us to risks related to 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.

Furthermore, 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.

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. For example, we announced in November 2018 that John E. Friend II, M.D. resigned as Vice President and Chief Medical Officer and Brian Posner our Vice President and Chief Financial Officer resigned effective March 2019.Our success will depend on our ability to attract and retain 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.

We cannot assure the successful development and commercialization of our compounds in development.

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 the treatment of pediatric solid tumors and lymphomas; the development of new PDCs, specifically new products developed from our 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, the delivery of a significant increase in targeted oncologic payload, 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 increase 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 study 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 study 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, approved by all necessary regulatory authorities, and commercially produced, there is no guarantee that there will be market acceptance of our products.

- Our competitors may develop therapeutics or other treatments that 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 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 studies, manufacturing and marketing o 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 studies and regulatory approval can take many years to accomplish and require the expenditure of substantial financial, managerial and other resources.

In addition to the required regulatory approval described above, in order to be commercially viable, we must successfully research, develop, 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 preclinical and clinical studies that each drug is safe and effective; and
- demonstrating that we have established viable FDA cGMPs 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 studies 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 studies. The FDA can halt clinical studies at any time for safety reasons or because we or our clinical investigators do not follow the FDA's requirements for conducting clinical studies. If any of our studies 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 studies for a product, we will not be able to achieve any revenue from that 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 studies involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

In order to obtain regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive clinical studies 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 study process.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical studies will begin on time, need to be redesigned, or be completed on schedule, if at all. Clinical studies can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, reaching agreement on acceptable clinical study terms with prospective sites, obtaining institutional review board approval to conduct a study at a prospective site, recruiting patients to participate in a study, or obtaining sufficient supplies of clinical study 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 study, competing clinical studies, 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 studies. Any delays in completing our clinical studies will increase our costs, slow down our product development and approval process, and delay our ability to generate revenue.

In addition, the results of preclinical studies and early clinical studies of our product candidates do not necessarily predict the results of later-stage clinical studies. Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. The data collected from clinical studies of our product candidates may not be sufficient to support the submission of an NDA or to obtain regulatory approval in the U.S. 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 studies 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 studies due to unexpected side effects or other safety risks that could preclude approval of our product candidates.

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

Administering any product candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical studies 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 studies.

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

We and our third-party collaborators are subject to federal, state and local laws and regulations governing the storage, use and disposal of hazardous materials and waste products. Current or future regulations may impair our research, development, manufacturing and commercialization efforts. The inability of our third-party collaborators to maintain the required licenses and permits for any reason 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 the suspension or termination of clinical studies, 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 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 U.S., 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 U.S. for CLR 131 as a therapeutic for the treatment of multiple myeloma, neuroblastoma, rhabdomyosarcoma and Ewing's sarcoma. While we have been granted this orphan designation, we will not be able to rely on it 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 were 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 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 other indications if not for our patent portfolio, or for the use of other types of products in the same indications as our orphan product. 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.

The FDA has granted rare pediatric disease designation, RPDD, to CLR 131 for treatment of neuroblastoma and rhabdomyosarcoma; however, we may not be able to realize any value from such designation.

Our CLR 131 compound has received RPDD designation from the FDA for the treatment of neuroblastoma and rhabdomyosarcoma. The FDA defines a "rare pediatric disease" as a disease that affects fewer than 200,000 individuals in the U.S. primarily under the age of 18 years old. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, upon the approval of an NDA or a BLA for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a Rare Pediatric Disease Priority Review Voucher that can be used to obtain priority review for a subsequent NDA or BLA. There is no assurance we will receive a Rare Pediatric Disease Priority Review Voucher or that it will result in a faster development process, review or approval for a subsequent marketing application. Further, this program has been subject to criticism, including by the FDA, and it is possible that even if we obtain approval for CLR 131 and qualify for such a Priority Review Voucher, the program may no longer be in effect at the time of approval. Also, although Priority Review Vouchers may be sold or transferred to third parties, there is no guaranty that we will be able to realize any value if we were to sell a Priority Review Voucher.

We are exposed to product, clinical and preclinical 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 studies 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 for 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;
- attracting corporate partners, including pharmaceutical companies, to assist in commercializing our intended products; and
- marketing 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, drugs and treatments that may be developed by others could impair our ability to 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 noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and 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 our 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 widespread acceptance of our technologies and products if commercialized.

We may face litigation from third parties claiming 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, place a significant strain on our financial and managerial resources, and 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 adequately protect or enforce our rights to intellectual property 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, for products 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 nonpatented technology.

We may have to resort to litigation to protect our rights for certain intellectual property or to determine the scope, validity or enforceability of our intellectual property rights. Enforcing or defending our rights would be 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 that inventions conceived by them 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 U.S. 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 sufficient numbers, in a timely manner regarding our intended proposed products to achieve our marketing plans and 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 the commercial success of our product candidates.

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 the 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, contract research organizations 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 study data from ongoing or planned clinical studies 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, inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, lack of 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 or other malfeasance by hackers. This type of breach of our cybersecurity may compromise our confidential and financial information, 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 to assess that our internal controls over financial reporting are effective are evolving and complex, require significant documentation and testing, and may require remediation if they are not met. 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 noncompliance with its listing rules, and delisting with Nasdaq could impact the price of our common stock and our ability to raise funds.

The failure to meet continuing compliance standards subjects our common stock to delisting. We have not received any other notices of noncompliance with Nasdaq listing rules, but we have received such notices as recently as 2016. 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, by-laws, 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 by-laws 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 its 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 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 by-laws.

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 occur only if our stock price appreciates.

Item 2. Properties.

We lease administrative office space in Florham Park, New Jersey and Madison, Wisconsin. The space in New Jersey consists of approximately 4,000 square feet and is rented for approximately $12,500 per month under an agreement that expires on February 29, 2024, subject to one five- year extension. The space in Wisconsin consists of approximately 300 square feet and is rented for approximately $3,300 per month under an agreement that expires on August 31, 2019.

We previously occupied 19,500 square feet of office, laboratory, and manufacturing space in Madison, Wisconsin. This space was vacated in 2018 due to our decision to outsource our manufacturing. We extended our lease in this space to February 2019 to accommodate certain alterations required under the lease agreement.

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

Our common stock is listed on the NASDAQ Capital Market under the ticker symbol CLRB.

On February 22, 2019 there were 220 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 3,750 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 7,500 options to our Chief Business Officer 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, 2018 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 and rights (#) (a)		Weighted-average exercise price of outstanding options and rights ($) (b)	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a)) (#) (c)
Equity compensation plans approved by stockholders	239,761	$	14.37	44,473
Equity compensation plans not approved by stockholders	11,250	$	107.53	—
Total	251,011	$	18.67	44,473

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 discovery, development and commercialization of drugs for the treatment of cancer. Our core objective is to leverage our proprietary phospholipid drug conjugate™ (PDCs™) delivery platform to develop PDCs that specifically target cancer cells to deliver improved efficacy and better safety as a result of fewer off-target effects. Our PDC platform possesses the potential for the discovery and development of the next generation of cancer-targeting treatments and we plan to develop PDCs independently and through research and development collaborations.

Our lead PDC candidate, CLR 131, provides targeted delivery of the cytotoxic (cell-killing) radioisotope iodine 131. CLR 131 is in a Phase 2 clinical study in relapsed or refractory (R/R) multiple myeloma (MM) and a range of other B-cell malignancies and Phase 1 clinical study for R/R MM and we plan to initiate a Phase 1 study in 2019 for pediatric solid tumors and lymphoma.

Our pipeline includes a PDC chemotherapeutic program in drug discovery, CLR 1900. CLR 1900 is being targeted for solid tumors with a payload that inhibits mitosis (cell division) which is a validated pathway for treating cancers.

Supply of CLR 131

On August 7, 2018, we were informed by CPDC, our sole supplier of CLR 131 that CPDC is subject to an Import Alert 66-40, the Import Alert, by the U.S.FDA. While the basis for the Import Alert was not related to CLR 131, or CPDC's production facility associated with CLR 131, CPDC informed us on August 8, 2018 that CPDC would not be able to supply CLR 131 to us until the Import Alert is lifted or alternative agreements are reached with the FDA.

On November 8, 2018, the FDA notified us that CLR 131 would be exempted from the Import Alert placed on CPDC in relation to our ongoing clinical studies. As a result, we have resumed patient enrollment in our CLR 131 hematology clinical studies.

We await either the lifting of the Import Alert or the granting of an exemption from the FDA for any future shipments into the U.S. in connection with our Phase 1 study of pediatric patients with neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. As a result of the supply disruption, we are experiencing delays in initiation of this clinical study. At this time, we are sourcing clinical sites outside the U.S. which would allow us to begin enrollment of this clinical study.

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, cost of manufacturing materials, fees paid to contract research organizations, fees paid to medical institutions for clinical studies, and costs to secure intellectual property. We analyze our research and development expenses based on four categories as follows: clinical projects, manufacturing and related, preclinical projects, 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, 2018 and 2017

Research and Development. Research and development expense for the year ended December 31, 2018 was approximately $6,835,000 compared to approximately $9,466,000 for the year ended December 31, 2017.

The following table is a comparison summary of research and development costs for the years ended December 31, 2018 and December 31, 2017:

	Year Ended December 31,		
	2018	**2017**	**Variance**
Clinical project costs	$ 1,220,000	$ 1,769,000	$ (549,000)
Manufacturing and related costs	1,419,000	2,649,000	(1,230,0000)
Pre-clinical project costs	1,926,000	1,107,000	819,000
General research and development costs	2,270,000	3,941,000	(1,671,000)
	$ 6,835,000	$ 9,466,000	$ (2,631,000)

The overall decrease in research and development expense of approximately $2,631,000, or 28%, was due primarily to a decrease in general research and development costs related to the accelerated depreciation expense to the reassessed estimated useful life of the leasehold improvements and laboratory equipment in 2017. The reassessment of the useful lives for these assets was due to our decision to close our manufacturing facility and outsource all our manufacturing. Pre-clinical project costs increased due to additional expenditures for outsourced services in connection with research related to our PDC platform and other preclinical programs. Clinical project costs decreased as a result of increased National Cancer Institute contract reimbursements, which are recorded as an offset against expense.

General and Administrative. General and administrative expense for the year ended December 31, 2018 was approximately $4,820,000 compared to approximately $4,135,000 in 2017. The increase of $685,000, or 17%, in general and administrative costs was primarily related to an increase of approximately $229,000 in purchased services related to accounting, investor relations and public company costs offset by a decrease in legal fees of approximately $157,000; and an increase of approximately $510,000 in personnel related costs.

Impairment of Goodwill. During the year ended December 31, 2018, we recorded an impairment charge of approximately $1,675,000. We decided to bypass the qualitative assessment and proceeded to the first step of the goodwill impairment test. The first step of the goodwill impairment test compares the fair value of the reporting unit with its carrying amount. We used our market capitalization as of December 31, 2018 to assess our fair value. Enterprise market capitalization was determined based on stock price and taking into consideration recent stock price trends.

As of December 31, 2018, the carrying value of our net assets exceeded our market capitalization. We adopted ASU No. 2017-04 during the year ended December 31, 2018, therefore, no additional calculation was necessary.

Gain on Revaluation of Derivative Warrants. We recorded a gain on the revaluation of derivative warrants of approximately $62,000 in 2018 and $22,000 in 2017. These amounts, which are non-cash in nature, represent the change in fair value (resulting primarily 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, 2018 was approximately $30,000, as compared to approximately $17,000 for the year ended December 31, 2017. The increase is due to an increase in the average balance of our cash equivalents and higher yields in 2018. In 2017, we had approximately $1,000 of interest expense related to our outstanding debt owed to the Wisconsin Department of Commerce. There were no such costs during the year ended December 31, 2018.

Deemed Dividend on Preferred Stock. During the years ended December 31, 2018, and 2017, we 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 $2,242,000 or $0.76 per share, and approximately $1,449,000 or $1.03 per share, for the years ended December 31, 2018 and 2017, respectively, have been included in the calculation of net loss attributable to common stockholders of approximately $15,481,000 and $15,011,000 for the years ended December 31, 2018 and 2017, respectively.

Liquidity and Capital Resources

Year ended December 31, 2018 Compared to Year Ended December 31, 2017

As of December 31, 2018, we had cash, cash equivalents and restricted cash of $13.3 million compared to $10.1 million at December 31, 2017. The increase was largely attributable to cash received from financing activities of approximately $15.0 million, offset by cash used in operating activities of $11.4 million and cash used in investing activities of approximately $330,000.

Cash provided from financing activities of approximately $15.0 million was due to the net proceeds we received from our sale in July 2018 of 1,355,000 shares of common stock, 1,114 shares of Series C Convertible Preferred Stock (the "Series C Preferred Stock") convertible into 2,785,000 shares of common stock and Series E warrants to purchase 4,140,000 shares of common stock. The public offering price of a share of common stock together with a Series E warrant to purchase one share of common stock was $4.00. The public offering price of a share of Series C Preferred Stock, each of which is convertible into 2,500 shares of common stock, together with a Series E warrant to purchase 2,500 shares of common stock was $10,000. The Series E warrants have an exercise price of $4.00 per share and are exercisable until July 31, 2023.

Cash used in operating activities of approximately $11.4 million was largely due to funding of our research and development programs and general and administrative expenses.

Cash used in investing activities of $330,000 was due to leasehold improvements and furniture and fixtures in connection with our new corporate headquarters.

Liquidity Outlook

Because we have had recurring losses and negative cash flows from operating activities, and in light of our expected expenditures, the report of our independent auditors with respect to the financial statements as of December 31, 2018 and for the year ended December 31, 2018 contains an explanatory paragraph as to the potential inability to continue as a going concern. The opinion indicates that substantial doubt exists regarding our ability to remain in business.

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 financed our operations since inception primarily through the sale of equity securities and securities convertible into equity securities. To date we have raised capital aggregating approximately $191 million.

We have incurred losses since inception in devoting substantially all of our efforts toward research and development and have an accumulated deficit of approximately $97.6 million at December 31, 2018. During the year ended December 31, 2018, we generated a net loss of approximately $13.2 million, and used approximately $11.4 million in cash from operations. We expect that we will continue to generate operating losses for the foreseeable future. At December 31, 2018, our consolidated cash balance was approximately $13.3 million. We believe this cash balance is adequate to fund budgeted operations into first quarter 2020. Our ability to execute our operating plan beyond that time depends on our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. We plan to actively pursue all available financing alternatives; however, there can be no assurance that we will obtain the necessary funding. Other than the uncertainties regarding our ability to obtain additional funding, there are currently no known trends, demands, commitments, events or uncertainties that are likely to materially affect our liquidity.

Critical Accounting Policies and Estimates

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the U.S., 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 studies; 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. 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.

For the December 31, 2018 goodwill impairment test we decided to bypass the qualitative assessment and proceeded to the first step of the goodwill impairment test. The first step of the goodwill impairment test compares the fair value of the reporting unit with its carrying amount. We used our market capitalization as of December 31, 2018 to assess our fair value. Enterprise market capitalization was determined based on stock price and taking into consideration recent stock price trends.

As of December 31, 2018, the carrying value of our net assets exceeded our market capitalization. We adopted ASU No, 2017-04 during the year ended December 31, 2018, therefore, no additional calculation was necessary.

As a result of this test, our total goodwill was determined to be impaired and an impairment charge of $1,675,462 was recorded for the year ended December 31, 2018. No impairment was deemed to exist at December 31, 2017.

Long-Lived Assets. With the exception of goodwill, our only long-lived assets are property and equipment. We periodically evaluate long-lived assets for potential impairment. Whenever events or circumstances change, an assessment is made as to whether there has been impairment to the value of long-lived assets by determining whether projected undiscounted cash flows generated by the applicable asset exceed its net book value as of the assessment date. There were no long-lived asset impairment charges recorded during the years ended December 31, 2018 or 2017.

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 2018 and 2017, 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

INDEX TO FINANCIAL STATEMENTS FOR CELLECTAR BIOSCIENCES, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors
Cellectar Biosciences, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cellectar Biosciences, Inc. and Subsidiary (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, 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
February 26, 2019

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 13,255,616	$ 10,006,421
Restricted cash	55,000	55,000
Prepaid expenses and other current assets	641,218	412,173
Total current assets	13,951,834	10,473,594
Fixed assets, net	543,339	244,713
Goodwill	—	1,675,462
Long-term assets	540,823	465,823
Other assets	18,086	11,872
TOTAL ASSETS	$ 15,054,082	$ 12,871,464
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 1,543,819	$ 1,867,758
Derivative liability	43,000	105,050
Capital lease obligations, current portion	2,213	3,036
Deferred rent	33,090	138,944
Total current liabilities	1,622,122	2,114,788
LONG-TERM LIABILITIES:		
Capital lease obligation, less current portion	—	2,213
Deferred rent, less current portion	170,999	—
Total long-term liabilities	170,999	2,213
TOTAL LIABILITIES	1,793,121	2,117,001
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.00001 par value; 7,000 shares authorized; Series B preferred stock: none and 18 issued and outstanding as of December 31, 2018 and 2017, respectively	—	995,782
Series C preferred stock: 473 and none issued and outstanding as of December 31, 2018 and 2017, respectively	2,526,049	—
Common stock, $0.00001 par value; 80,000,000 shares authorized; 4,732,387 and 1,666,144 shares issued and outstanding at December 31, 2018 and 2017, respectively	47	16
Additional paid-in capital	108,323,208	94,107,981
Accumulated deficit	(97,588,343)	(84,349,316)
Total stockholders' equity	13,260,961	10,754,463
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 15,054,082	$ 12,871,464

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,	
	2018	**2017**
COSTS AND EXPENSES:		
Research and development	$ 6,835,229	$ 9,465,666
General and administrative	4,820,073	4,135,304
Impairment of goodwill	1,675,462	—
Total costs and expenses	13,330,764	13,600,970
LOSS FROM OPERATIONS	(13,330,764)	(13,600,970)
OTHER INCOME:		
Gain on revaluation of derivative warrants	62,050	22,075
Interest income, net	29,687	16,605
Total other income, net	91,737	38,680
NET LOSS	(13,239,027)	(13,562,290)
DEEMED DIVIDEND ON PREFERRED STOCK	(2,241,795)	(1,448,945)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	(15,480,822)	(15,011,235)
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	$ (5.23)	$ (10.70)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	2,961,972	1,403,132

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, 2016	17	$ 865,136	1,036,832	$ 10	$ 83,461,752	$ (70,787,026)	$ 13,539,872
Issuance of common stock, warrants and preferred stock, net of issuance costs	41	2,265,257	195,438	2	4,789,606	—	7,054,865
Warrant exercises	—	—	197,550	2	2,963,257	—	2,963,259
Stock-based compensation	—	—	—	—	758,757	—	758,757
Cashless option exercise	—	—	240	—	—	—	—
Conversion of preferred shares into common shares	(40)	(2,134,611)	236,084	2	2,134,609	—	—
Net loss	—	—	—	—	—	(13,562,290)	(13,562,290)
BALANCE AT DECEMBER 31, 2017	18	$ 995,782	1,666,144	$ 16	$ 94,107,981	$ (84,349,316)	$ 10,754,463
Issuance of common stock, warrants and preferred stock, net of issuance costs	1,114	5,949,301	1,355,000	14	9,075,763	—	15,025,078
Stock-based compensation	—	—	—	—	721,209	—	721,209
Vested restricted stock	—	—	12,667	—	—	—	—
Reverse stock split fractional shares	—	—	(105)	—	(762)	—	(762)
Retired shares	—	—	(104)	—	—	—	—
Conversion of preferred shares into common shares	(659)	(4,419,034)	1,698,785	17	4,419,017	—	-
Net loss	—	—	—	—	—	(13,239,027)	(13,239,027)
BALANCE AT DECEMBER 31, 2018	473	$ 2,526,049	4,732,387	$ 47	$ 108,323,208	$ (97,588,343)	$ 13,260,961

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, 2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (13,239,027)	$ (13,562,290)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	82,265	1,546,048
Stock-based compensation	721,209	758,757
Impairment of goodwill	1,675,462	—
Gain on revaluation of derivative warrants	(62,050)	(22,075)
Gain on disposal of fixed assets	(50,898)	—
Changes in:		
Prepaid expenses and other current assets	(229,045)	281,396
Accounts payable and accrued liabilities	(258,794)	451,325
Other assets	(81,214)	(473,462)
Cash used in operating activities	(11,442,092)	(11,020,301)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(384,993)	(346,703)
Proceeds from sale of fixed assets	55,000	—
Cash used in investing activities	(329,993)	(346,703)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on capital lease obligations	(3,036)	(2,727)
Reverse stock split fractional shares	(762)	—
Proceeds from issuance of common stock, net of underwriting issuance costs	9,075,777	4,905,945
Proceeds from issuance of preferred stock	5,949,301	2,265,257
Change in deferred issuance costs	—	(116,337)
Proceeds from conversion of warrants	—	2,963,259
Payments on long-term obligations	—	(86,591)
Cash provided by financing activities	15,021,280	9,928,806
INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	3,249,195	(1,438,198)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF PERIOD	10,061,421	11,499,619
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF PERIOD	$ 13,310,616	$ 10,061,421
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest expense	$ —	$ 364
Beneficial conversion feature and related deemed dividend on preferred stock	$ 2,241,795	$ 1,448,945

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

1. NATURE OF BUSINESS, ORGANIZATION AND GOING CONCERN

Cellectar 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.

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 $97,588,000 at December 31, 2018. During the year ended December 31, 2018 the Company generated a net loss of approximately $13,239,000 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, 2018 is adequate to fund operations at budgeted levels into first quarter 2020. The Company's ability to execute its operating plan beyond first quarter 2020 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, 2018 are presented on a consolidated basis.

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and the accounts of its wholly-owned subsidiary. All 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 U.S. 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.

Reclassifications— Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations. An adjustment has been made to the Consolidated Statements of Cash Flows for fiscal year ended December 31, 2017, to identify the long-term other assets of approximately $466,000. This change in classification does not affect previously reported cash flows from operating activities in the Consolidated Statements of Cash Flows.

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, 2018 and 2017 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, leasehold improvements are depreciated over 64 months (their estimated useful life), which represents the full term of the lease. Our only long-lived assets are property and equipment. The Company periodically evaluates long-lived assets for potential impairment. Whenever events or circumstances change, an assessment is made as to whether there has been impairment to the value of long-lived assets by determining whether projected undiscounted cash flows generated by the applicable asset exceed its net book value as of the assessment date. There were no long-lived asset impairment charges recorded during the years ended December 31, 2018 or 2017. (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.

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 adopted ASU No. 2017-04 during the year ended December 31, 2018.

Stock-Based Compensation — The Company uses the Black-Scholes option-pricing model to calculate the grant-date fair value of stock option awards. The resulting compensation expense, net of expected forfeitures, for awards that are not performance-based is recognized on a straight-line basis over the service period of the award, which for grants issued in 2018 ranged from seven months to three years for stock options. For stock options with performance-based vesting provisions, recognition of compensation expense, net of expected forfeitures, commences if and when the achievement of the performance criteria is deemed probable. The compensation expense, net of expected forfeitures, for performance-based stock options is recognized over the relevant performance period. Non-employee stock-based compensation is accounted for in accordance with the guidance of FASB 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, 2018 and 2017.

Fair Value of Financial Instruments — The guidance under FASB ASC Topic 825, *Financial Instruments*, requires disclosure of the fair value of certain financial instruments. Financial instruments in the accompanying financial statements consist of cash equivalents, prepaid expenses and other assets, accounts payable and long-term obligations. The carrying amount of cash equivalents, and accounts payable approximate their fair value 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 49,425 at December 31, 2018 and 2017, respectively. The primary underlying risk exposures pertaining to the warrants and their related fair value is the change in fair value of the underlying common stock, the market price of traded warrants, and estimated timing and probability of future financings. Such financial instruments are initially recorded at fair value with subsequent changes in fair value recorded as a component of gain or loss on derivatives on the consolidated statements of operations in each reporting period. If these instruments subsequently meet the requirements for equity classification, the Company reclassifies the fair value to equity. At December 31, 2018 and 2017, 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, 2018 and 2017 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, 2018, uninsured cash balances totaled approximately $12,800,000.

Leases — In February 2016, the FASB issued Accounting Standards Update ("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 will elect the transition method to initially apply ASU 2016-02 transition provisions at the effective date (i.e., 1 January 2019) recognizing any adjustment that results from applying the ASU 2016-02 transition requirements as a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption and not restating comparative periods presented. The Company believes the impact on its balance sheet of adopting ASU 2016-02 on January 1, 2019, the date of transition, will be to record a right-of use asset and a lease liability.

Recent Accounting Pronouncements - I*n* July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815). The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company believes the impact of adopting ASU 2017-11 will not have a material impact 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 8,250 shares of common stock in a February 2013 public offering (the "February 2013 Public Offering Warrants"). On February 20, 2014, warrants to purchase 2,750 of common stock expired. On May 20, 2016, warrants to purchase 1,625 shares of common stock were exercised. The remaining warrants to purchase 3,875 expired on February 20, 2018.

In August 2014, as part of an underwritten public offering, the Company issued warrants to purchase 49,425 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.

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, 2018 and 2017:

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

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

In order to estimate the value of the February 2013 Public Offering Warrants considered to be derivative instruments, the Company used 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 were 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 were classified within the Level 3 hierarchy and expired in February 2018.

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

	Year Ended December 31,	
	2018	2017
Volatility	N/A	76-118%
Risk-free interest rate	N/A	1.03-1.39%
Expected life (years)	N/A	0.14-0.89
Dividend	N/A	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,	
	2018	2017
Beginning fair value of warrants	$ 5,050	$ 27,125
Gain on derivatives resulting from change in fair value or extinguishment	(5,050)	(22,075)
Ending fair value of warrants	$ —	$ 5,050

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

Goodwill represents the excess of the purchase price of an acquired business over the fair value of the underlying net tangible and intangible assets.

As of December 31, 2017, the Company had recorded goodwill of $1,675,462 associated with the acquisition of Cellectar, Inc. on April 8, 2011. The acquisition was accounted for using the purchase method of accounting as a reverse acquisition whereby Cellectar was the accounting acquirer and Novelos was the acquired company. 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.

For the December 31, 2018 goodwill impairment test the Company decided to bypass the qualitative assessment and proceeded to the first step of the goodwill impairment test. The first step of the goodwill impairment test compares the fair value of the reporting unit with its carrying amount. We used the Company's market capitalization as of December 31, 2018 (Level 1 Input) to assess its fair value. Enterprise market capitalization was determined based on stock price and taking into consideration recent stock price trends.

As of December 31, 2018, the Company's carrying value of its net assets exceeded its market capitalization. The Company adopted ASU No, 2017-04 during the year ended December 31, 2018, therefore, no additional calculation was necessary.

As a result of this test the Company's total goodwill was determined to be impaired and an impairment charge of $1,675,462 was recorded for the year ended December 31, 2018. No impairment was deemed to exist at December 31, 2017.

5. FIXED ASSETS

Fixed assets consisted of the following at December 31:

	2018	2017
Office and laboratory equipment	$ 410,634	$ 3,751,059
Computer software	4,000	4,000
Leasehold improvements	309,897	2,333,443
Total fixed assets	724,531	6,088,502
Less– accumulated depreciation and amortization	(181,192)	(5,843,789)
Fixed assets, net	$ 543,339	$ 244,713

For the years ended December 31, 2018 and 2017, the Company incurred approximately $82,000 and $1,546,000 of depreciation and amortization expense, respectively.

6. NOTES PAYABLE

During the three months ended March 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.

7. ACCRUED EXPENSES

Supply of CLR 131

Accounts payable and accrued liabilities approximately consist of the following:

	2018	2017
Incentive compensation	$ 408,000	$ 341,000
Accounts payable	612,000	933,000
Clinical study costs	332,000	329,000
Professional fees	64,000	178,000
Insurance	69,000	—
Other	59,000	87,000
	$ 1,544,000	$ 1,868,000

8. STOCKHOLDERS' EQUITY

July 2018 Public Offering

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

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

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

Reverse Stock Split

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

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 195,438 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 5,337 shares of common stock for a total of 219,037 shares upon conversion at a price of $18.7375 per share. The common stock was offered at $18.7375 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 310,856 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 $17.80 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.

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 122,751 shares of common stock. During the twelve months ended December 31, 2018 the remaining 18 shares of Series B Preferred Stock were converted into 96,284 shares of common stock.

Common Stock Warrants

The following table summarizes information with regard to outstanding warrants to purchase common stock as of December 31, 2018.

Offering	Number of Shares Issuable Upon Exercise of Outstanding Warrants		Exercise Price	Expiration Date
July 2018 Series E Warrants	4,140,000	$	4.00	July 31, 2023
October 2017 Series D Warrants	310,856	$	17.80	October 14, 2024
November 2016 Public Offering Series C	415,785	$	15.00	November 29, 2021
April 2016 Underwritten Registered Series A	362,694	$	30.40	April 20,2021
October 2015 Incremental Series A	30,006	$	21.30	October 20,2021
October 2015 Private Placement Series A	8,636	$	21.30	April 1, 2021
October 2015 Offering – Placement Agent	375	$	283.00	October 1, 2020
August 2014 Public Offering [(1)]	50,395	$	468.00	August 20, 2019
Total	5,318,747			

(1) These warrants have a certain type of cash settlement feature and they have been accounted for as derivative instruments as described in Note 1, with the exception of 970 warrants issued in August 2014.

9. STOCK-BASED COMPENSATION

Accounting for Stock-Based Compensation

Increase in 2015 Stock Incentive Plan. At the 2018 annual meeting of stockholders held on May 31, 2018, 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 120,000 shares.

2015 Stock Incentive Plan. The 2015 Stock Incentive Plan was adopted on June 9, 2015 authorizing an aggregate of 42,000 shares for issuance (after taking into account the 2018 and 2016 10:1 reverse stock splits). On May 31, 2017, our stockholders approved the Amended and Restated 2015 Stock Incentive Plan (the "2015 Plan") to increase the authorized shares by 120,000 shares. On May 31, 2018, our stockholders approved the Amended and Restated 2015 Stock Incentive Plan to increase the authorized shares by 120,000. A total of 282,000 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, 2018, there are an aggregate of 44,473 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 7,000 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 Grant*s. During 2017, the Company issued 46,000 shares under the 2015 Plan of restricted common stock with a weighted average grant date fair value of $20.96. The shares vest annually over a three year period. The following table summarizes the restricted stock grants:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share	Total Grant Date Fair Value
Outstanding at December 31, 2016	—	—	—
Granted	46,000	$ 20.96	$ 964,000
Vested	—	—	—
Forfeited	(8,000)	21.00	(168,000)
Outstanding at December 31, 2017	38,000	20.95	796,000
Granted	—	—	—
Vested	(12,665)	20.95	(265,000)
Forfeited	(6,667)	20.80	(139,000)
Outstanding at December 31, 2018	18,668	$ 21.00	$ 392,000

The following table summarizes amounts charged to expense for stock-based compensation related to employee and director stock option grants:

	Year Ended December 31,	
	2018	2017
Employee and director stock options and stock grants:		
Research and development	$ 94,865	$ 147,821
General and administrative	626,344	610,936
Total stock-based compensation	$ 721,209	$ 758,757

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, 2018 and 2017. 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,	
	2018	2017
Volatility	91-106%	107-110%
Risk-free interest rate	2.64-3.05%	1.89-2.18%
Expected life (years)	6	6
Dividend	0%	0%
Weighted-average exercise price	$ 2.99	$ 1.91
Weighted-average grant-date fair value	$ 2.30	$ 1.58

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, 2016	47,133	$ 75.90		
Granted	11,230	$ 19.10		
Exercised	(2,083)	$ 14.80		
Expired	(201)	$ 1,166.10		
Forfeited	(2,914)	$ 14.80		
Outstanding at December 31, 2017	53,165	$ 73.82		
Granted	184,129	$ 2.99		
Expired	(2,344)	$ 463.16		
Forfeited	(2,607)	$ 19.46		
Outstanding at December 31, 2018	232,343	$ 14.37		
Exercisable, December 31, 2018	45,448	$ 51.97	7.85	$ —
Unvested, December 31, 2018	186,895	$ 5.23	9.65	$ —

Exercise prices for all grants made during the twelve months ended December 31, 2018 and 2017 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, 2018 and 2017 was $2.30 and $15.80, respectively. The total fair value of shares vested during the years ended December 31, 2018 and 2017 was $416,734 and $636,071, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2018 was $42.42 and $4.10, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2017 was $77.40 and $29.10, respectively.

The weighted average grant date fair value of options expired during the years ended December 31, 2018 and December 31, 2017 was $191.38 and $611.20, respectively. The weighted average grant date fair value of options forfeited during the years ended December 31, 2018 and December 31, 2017 was $15.91 and $11.90, respectively. The number of options vested during the years ended December 31, 2018 and December 31, 2017 was 22,345 and 20,360, respectively. The number of options unvested at January 1, 2018 and January 1, 2017 was 27,718 and 39,742, respectively. The weighted average grant date fair value of options unvested at January 1, 2018 and January 1, 2017 was $29.13 and $32.70, respectively.

As of December 31, 2018, there was $1,111,887 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, the Company expects to recognize $761,369, $233,413, and $117,105 during 2019, 2020, and 2021 respectively. The Company expects options to purchase 186,505 shares to vest in the future.

10. INCOME TAXES

	2018	2017
Tax provision (benefit)		
Current		
Federal	$ —	$ —
State	—	—
Total current	—	—
Deferred		
Federal	(2,688,003)	13,626,404
State	(45,138)	1,969,262
Total deferred	(2,733,141)	15,595,666
Change in valuation allowance	2,733,141	(15,595,666)
Total	$ —	$ —

Deferred tax assets consisted of the following at December 31:

	2018	2017
Deferred tax assets		
Federal net operating loss	$ 26,562,715	$ 24,353,504
Federal research and development tax credit carryforwards	5,439,062	4,947,879
State net operating losses and tax credit carryforwards	1,589,926	1,589,927
Capitalized research and development expenses	5,959,275	5,772,165
Stock-based compensation expense	1,565,130	1,445,078
Depreciable assets	—	166,793
Other	103,189	121,680
Total deferred tax assets	41,219,297	38,397,026
Deferred tax liabilities		
Depreciable assets	(89,129)	—
Total deferred tax liabilities	(89,129)	—
Net deferred tax assets	41,130,168	38,397,026
Less– valuation allowance	(41,130,168)	(38,397,026)
Total deferred tax assets	$ —	$ —

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

	Year ended December 31,	
	2018	2017
Income tax benefit using U.S. federal statutory rate	(21.00)%	34.00%
State income taxes	(0.27)%	(9.58)%
Permanent items	2.56%	(2.55)%
Federal tax credits	(3.44)%	8.43%
Change in valuation allowance	20.65%	115%
Federal rate change	—%	(143.50)%
Other	1.50%	(1.80)%
Total	0.00%	0.00%

As of December 31, 2018, the Company had federal and state net operating loss carryforwards ("NOLs") of approximately $126,489,000 and $15,862,000 respectively. Federal net operating loss generated as of December 31, 2017 will expire in 2019 through 2037, net operating loss generated during 2018 and later will be carried forward indefinitely until utilized. State net operating loss will expire in 2028 through 2031. In addition, the Company has federal and state research and development and orphan drug credits of approximately $5,403,000 and $805,000, respectively, which expire in 2019 through 2038 and in 2024 through 2033, 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, 2018 or 2017 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, 2015. Additionally, the Company may be subject to examination by the IRS for years beginning prior to January 1, 2015 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. In addition to the rate reduction, the Act requires companies with foreign subsidiaries to pay a one-time transition tax on earnings that were previously tax deferred, and also imposes a current taxation on income earned during the year. As of December 31, 2018, 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, 2018 and 2017, 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,	
	2018	2017
Warrants	5,318,747	1,183,007
Stock options	232,343	53,165
Non-vested restricted stock	18,668	38,000
Preferred shares convertible to common	1,182,500	1,020,006
Total potentially dilutive shares	6,752,258	2,294,178

12. COMMITMENTS AND CONTINGENCIES

Real Property Leases

Florham Park, New Jersey

On June 4, 2018, the Company entered in an Agreement of Lease for 3,893 square feet for its new corporate headquarters in Florham Park, New Jersey. The lease commencement date was October 19, 2018 and terminates on February 29, 2024. The Company has an option to extend the term of the lease for one additional 60-month period.

During the year ended December 31, 2018, the landlord made certain improvements to the facility. As of December 31, 2018, the Company recorded a deferred lease liability of approximately $176,000 for the improvements funded by the landlord in deferred rent current and deferred rent, long-term on the consolidated balance sheet. The Company amortizes the deferred liability as a reduction to rent expense in the consolidated statement of operations over the term of the lease.

Under the terms of the lease, the Company paid a security deposit of $75,000 and the aggregate rent due over the term of the lease is approximately $828,000, which will be reduced to approximately $783,000 after certain rent abatements. The Company will also be required to pay its proportionate share of certain operating expenses and real estate taxes applicable to the leased premises. After certain rent abatements the rent is approximately $12,500 per month for the first year and then escalates thereafter by 2% per year for the duration of the term. 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 current and deferred rent, long-term of each balance sheet date on the consolidated balance sheet.

Madison, Wisconsin

On September 5, 2007, the Company 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.

This space was vacated in 2018 due to our decision to outsource our manufacturing. The company additionally extended the lease on a month by month basis through February 6, 2019 to accommodate certain alterations required under the lease agreement. As of December 31, 2018, the Company has recorded a liability of approximately $55,000, in connection with its remaining obligations under the lease.

The Company presently rents office space in Madison consists of approximately 300 square feet and is rented for approximately $3,300 per month under an agreement that expires on August 31, 2019.

Future minimum lease payments, excluding reimbursements under noncancelable operating leases at December 31, 2018 are as follows:

Years ending December 31,		
2019	$	138,619
2020		152,626
2021		155,403
2022		158,235
2023		161,123
Thereafter		13,610
	$	779,616

Total rent expense was approximately $29,000 and $130,000 for the years ended December 31, 2018 and 2017, respectively.

Supply of CLR 131

On August 7, 2018, the Company was informed by Centre for Probe Development and Commercialization ("CPDC"), its sole supplier of CLR 131, that CPDC is subject to an Import Alert 66-40 (the "Import Alert") by the U.S.FDA. While the basis for the Import Alert was not related to CLR 131, or CPDC's production facility associated with CLR 131, CPDC informed the Company on August 8, 2018 that CPDC would not be able to supply CLR 131 to it until the Import Alert is lifted or alternative agreements are reached with the FDA.

On November 8, 2018, the FDA notified the Company that CLR 131 would be exempted from the Import Alert placed on CPDC in relation to our ongoing clinical studies. As a result, the Company has resumed patient enrollment in its CLR 131 hematology studies.

The Company awaits either the lifting of the Import Alert or the granting of an exemption from the FDA for any future shipments into the U.S. in connection with its Phase 1 study of pediatric patients with neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. As a result of the supply disruption, the Company is experiencing delays in initiation of this clinical study. At this time, the Company is sourcing clinical sites outside the U.S. which would allow it to begin enrollment of this clinical study.

Legal

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.

13. 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.

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, 2018, 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, 2018. 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 2019 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 2019 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.cellectar.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 2019 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 2019 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 annual report on 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 2019 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 2019 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 2019 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, Financial Statement Schedules.

(a) Documents filed with this report.

(1) Financial Statements

i. All financial statements of the Company as set forth under Item 8 of this annual report on Form 10-K

(2) Exhibits – The exhibits to this report are listed on the Exhibit Index below.

Exhibit Index

Exhibit No.	Description	Incorporated by Reference		
		Form	Filing Date	Exhibit No.
2.1	Agreement and Plan of Merger by and among Novelos Therapeutics, Inc., Cell Acquisition Corp. and Cellectar, 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 Cellectar 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	Certificate of Amendment of Second Amended and Restated Certificate of Incorporation	8-K	July 13, 2018	3.1
3.8	Amended and Restated By-laws	8-K	June 1, 2011	3.1
3.9	Form of Certificate of Designation of Series A Preferred Stock	S-1/A	November 18, 2016	3.7
3.10	Form of Certificate of Designation of Series B Preferred Stock	8-K	October 11, 2017	3.1
3.11	Form of Certificate of Designation of Series C Preferred Stock	S-1/A	July 18, 2018	3.11
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 B Preferred Stock certificate	8-K	October 11, 2017	4.2
4.4	Form of Series C Preferred Stock certificate	S-1/A	July 18, 2018	4.7
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	Form of Convertible Debenture	8-K	February 10, 2014	4.1
10.4	Form of Warrant Agreement between Cellectar Biosciences, Inc. and American Stock Transfer and Trust Company	S-1/A	July 7, 2014	10.31
10.5	Employment Agreement between the Company and James Caruso, dated June 15, 2015**	10-Q	August 12, 2015	10.2

10.6	Form of Series B Pre-Funded Warrant	8-K	September 30, 2015	4.1
10.7	Registration Rights Agreement dated September 28, 2015	8-K	September 30, 2015	10.2
10.8	Amendment and Exchange Agreement dated April 13, 2016	S-1/A	April 14, 2016	10.43
10.9	Form of Series A Warrant	S-1/A	April 14, 2016	4.2
10.10	Form of Series B Pre-Funded Warrant	S-1/A	April 14, 2016	4.3
10.11	Form of Warrant Agency Agreement	S-1/A	April 14, 2016	4.4
10.12	Form of Series C Warrant	S-1/A	November 18, 2016	4.3
10.13	Form of Warrant Agency Agreement	S-1/A	November 18, 2016	4.4
10.14	Form of Restricted Common Stock Agreement**	10-Q	August 14, 2017	10.1
10.15	Securities Purchase Agreement, dated as of October 10, 2017, by and among Cellectar Biosciences, Inc. Inc. and the Purchasers	8-K	October 11, 2017	10.1
10.16	Form of Series D Common Stock Purchase Warrant	8-K	October 11, 2017	4.1
10.17	Registration Rights Agreement, dated as of October 10, 2017, by and among Cellectar Biosciences, Inc. Inc. and the Purchasers	8-K	October 11, 2017	10.2
10.18	Employment Agreement between the Company and Jarrod Longcor dated July 14, 2016**	10-Q	November 9, 2017	10.3
10.19	Form of Non-Statutory Stock Option**	S-8	November 9, 2017	10.2
10.20	Stock Option Agreement with James V. Caruso**	S-8	November 9, 2017	10.4
10.21	Stock Option Agreement with Jarrod Longcor**	S-8	November 9, 2017	10.5
10.22	Master Services Agreement for Clinical Research and Related Services between the Company and INC Research, LLC dated October 6, 2016*			
10.23	Cellectar Biosciences, Inc. Amended and Restated 2015 Stock Incentive Plan**	8-K	June 1, 2018	10.1
10.24	Form of Underwriting Agreement	S-1/A	July 18, 2018	1.1
10.25	Series E Common Stock Purchase Warrant	S-1/A	July 18, 2018	4.5
10.26	Form of Warrant Agency Agreement	S-1/A	July 18, 2018	4.7
10.27	Agreement of Lease between the Company and KBS II 100-200 Campus Drive, LLC	S-1/A	July 18, 2018	10.35
10.28	Form of Non-Statutory Stock Option (Definitive/Contingent – Employees)**	10-Q	November 13, 2018	10.3
10.29	Form of Non-Statutory Stock Option (Definitive/Contingent – Directors)**	10-Q	November 13, 2018	10.4
10.30	Employment Agreement between the Company and Brian Posner dated November 9, 2018**	10-Q	November 13, 2018	10.5
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

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CELLECTAR BIOSCIENCES, INC.

By: /s/ James V. Caruso
James V. Caruso
Title: Chief Executive Officer
February 26, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, 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)
February 26, 2019

By: /s/ Brian M. Posner
Brian M. Posner
Title: Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)
February 26, 2019

By: /s/ Frederick W. Driscoll
Frederick W. Driscoll
Title: Director
February 26, 2019

By: /s/ Stephen A. Hill
Stephen A. Hill
Title: Director
February 26, 2019

By: /s/ Stefan D. Loren
Stefan D. Loren
Title: Director
February 26, 2019

By: /s/ John L. Neis
John L. Neis
Title: Director
February 26, 2019

By: /s/ Douglas J. Swirsky
Douglas J. Swirsky
Title: Director
February 26, 2019

EXHIBIT 21.1

CELLECTAR BIOSCIENCES, INC.
LIST OF SUBSIDIARIES

Set forth below is a list of the subsidiaries of Cellectar Biosciences, Inc. as of December 31, 2018:

Subsidiary Name	Jurisdiction of Organization
Cellectar, Inc.	Wisconsin

EXHIBIT 23.1

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, 333-208638 and 333-225675), Form S-3 (File No. 333-218514) and Forms S-8 (File Nos. 333-221469, 333-195255 and 333-164398) of our report dated February 26, 2019, relating to our audit of the consolidated financial statements of Cellectar Biosciences, Inc. and Subsidiary as of and for the years ended December 31, 2018 and 2017, 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, 2018 and 2017.

/s/ BAKER TILLY VIRCHOW KRAUSE, LLP

Madison, Wisconsin
February 26, 2019

EXHIBIT 31.1

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

I, James V. Caruso, President and Chief Executive Officer, Cellectar Biosciences, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Cellectar 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: February 26, 2019

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

EXHIBIT 31.2

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

I, Brian M. Posner, Chief Financial Officer, Cellectar Biosciences, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Cellectar 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: February 26, 2019

/s/ Brian M. Posner
Brian M. Posner
Chief Financial Officer

EXHIBIT 32.1

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

In connection with the Annual Report on Form 10-K of Cellectar Biosciences, Inc. (the "Company") for the year ended December 31, 2018, 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, Brian M. Posner, 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	/s/ Brian M. Posner
James V. Caruso	Brian M. Posner
President and Chief Executive Officer	Chief Financial Officer

Dated: February 26, 2019

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 Cellectar Biosciences, Inc. and will be retained by Cellectar Biosciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

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