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, 2020

☐ **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, including zip code*)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.00001	CLRB	NASDAQ Capital Market
Warrant to purchase common stock, expiring April 20, 2021	CLRBZ	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 (§ 232.405 of this chapter) 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 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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, 2020 was $32,346,423.

As of March 1, 2021, there were 50,504,064 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 2021 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

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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 future impacts of the COVID-19 pandemic on our business, employees, operating results, ability to obtain additional funding, product development programs, research and development programs, suppliers and third-party manufacturers;
- 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 1900 series, CLR 2000 series and CLR 12120;
- our ability to continue development plans for our Phospholipid Drug Conjugates (PDC)™;
- our ability to maintain orphan drug designation in the U.S. for CLR 131 as a therapeutic for the treatment of multiple myeloma, neuroblastoma, osteosarcoma, rhabdomyosarcoma, Ewing's sarcoma and lymphoplasmacytic lymphoma, and the expected benefits of orphan drug status;
- any disruptions at our sole supplier of CLR 131;
- our ability to pursue strategic alternatives;
- our ability to advance our technologies into product candidates;
- our enhancement and consumption of current resources along with ability to obtain additional funding;
- our current view regarding general economic and market conditions, including our competitive strengths;
- uncertainty and economic instability resulting from conflicts, military actions, terrorist attacks, natural disasters, public health crises, including the occurrence of a contagious disease or illness, including the COVID-19 pandemic, cyber-attacks and general instability;
- 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 late-stage clinical 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™ (PDC™) delivery platform to develop PDCs that are designed to specifically target cancer cells and 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 both independently and through research and development collaborations.

The COVID-19 pandemic has created uncertainties in the expected timelines for clinical stage biopharmaceutical companies such as us, and because of such uncertainties, it is difficult for us to accurately predict expected outcomes. We have not yet experienced any significant impacts as a result of the pandemic. However, COVID-19 may impact our future ability to recruit patients for clinical studies, obtain adequate supply of CLR 131 and obtain additional financing.

Our lead PDC therapeutic, CLR 131 is a small-molecule PDC designed to provide targeted delivery of iodine-131 directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates CLR 131 from many traditional on-market treatments. CLR 131 is currently being evaluated in the CLOVER-WaM Phase 2 pivotal study in patients with relapsed/refractory (r/r) Waldenstrom's macroglobulinemia (WM), a Phase 2B study in r/r multiple myeloma (MM) patients and the CLOVER-2 Phase 1 study for a variety of pediatric cancers.

The CLOVER-1 Phase 2 study met the primary efficacy endpoints from the Part A dose-finding portion, conducted in r/r B-cell malignancies. The CLOVER-WaM Study is a pivotal registration study currently evaluating CLR 131 in Bruton tyrosine kinase inhibitor (BTKi) failed or suboptimal response in WM. The CLOVER-1 Phase 2B study is ongoing where CLR 131 remains under further evaluation in highly refractory multiple myeloma (MM) patients.

The CLOVER-2 Phase 1 pediatric study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of CLR 131 in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). The study is being conducted internationally at seven leading pediatric cancer centers.

The U.S. Food and Drug Administration ("FDA") granted CLR 131 Fast Track Designation for WM patients having received two or more prior treatment regimens, as well as r/r MM and r/r diffuse large B-cell lymphoma (DLBCL). Orphan Drug Designations (ODDs) have been granted for WM, MM, neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. CLR 131 was also granted Rare Pediatric Disease Designation (RPDD) for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. The European Commission granted an ODDs for r/r MM and WM.

Our product pipeline also includes one preclinical PDC chemotherapeutic program (CLR 1900) and several partnered PDC assets. The CLR 1900 Series is being targeted for solid tumors with a payload that inhibits mitosis (cell division) a validated pathway for treating cancers.

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

Our PDC platform provides selective delivery of a diverse range of oncologic payloads to cancerous cells, whether a hematologic cancer or solid tumor, a 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 specific regions on the cell surface as a result of the utilization of this metabolic pathway. Our PDCs bind to these regions and directly enter the intracellular compartment. This mechanism allows the PDC molecules to accumulate in tumor cells over time, which can enhance drug efficacy, and to avoid the specialized highly acidic cellular compartment known as lysosomes, which allows a 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 limited in the total number on the cell surface, have longer cycling time from internalization to being present on the cell surface again and available for binding and are not present on all of the tumor cells in any cancer. This means a subpopulation of tumor cells always exist that cannot be targeted by therapies targeting specific surface epitopes. In addition to the benefits provided by the mechanism of entry, PDCs offer the ability to conjugate payload 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 types of 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 also 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.

In June 2020, the European Medicines Agency (EMA) granted us Small and Medium-Sized Enterprise (SME) status by the EMA's Micro, Small and Medium-sized Enterprise office. SME status allows us to participate in significant financial incentives that include a 90% to 100% EMA fee reduction for scientific advice, clinical study protocol design, endpoints and statistical considerations, quality inspections of facilities and fee waivers for selective EMA pre and post-authorization regulatory filings, including orphan drug and PRIME designations. We are also eligible to obtain EMA certification of quality and manufacturing data prior to review of clinical data. Other financial incentives include EMA-provided translational services of all regulatory documents required for market authorization, further reducing the financial burden of the market authorization process.

A description of our PDC product candidates follows:

Clinical Pipeline

Our lead PDC therapeutic, CLR 131 is a small-molecule PDC designed to provide targeted delivery of iodine-131 directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates CLR 131 from many traditional on-market treatments and treatments in development. CLR 131 is currently being evaluated in the CLOVER-WaM Phase 2 pivotal study in patients with r/r WM, a Phase 2B study in r/rMM patients and the CLOVER-2 Phase 1 study for a variety of pediatric cancers.

CLR 131 is currently being evaluated in a pivotal study, CLOVER-WaM, in WM patients that have failed or had a suboptimal response to a BTKi therapy after receiving first line standard of care. The CLOVER-1 Phase 2 study met the primary efficacy endpoints from the Part A dose-finding portion, conducted in r/r B-cell malignancies, and is now enrolling an MM expansion cohort (Phase 2B). The Phase 2B study will evaluate highly refractory MM patients including triple, quad and penta class refractory patients. The initial Investigational New Drug (IND) application was accepted by the FDA in March 2014 with multiple INDs submitted since that time. The Phase 1 study was designed to assess the compound's safety and tolerability in patients with r/r MM (to determine maximum tolerated dose (MTD) and was initiated in April 2015. The study completed enrollment and the final clinical study report is expected in the first half of 2021. Initiated in March 2017, the primary goal of the Phase 2A study was to assess the compound's efficacy in a broad range of hematologic cancers.

The CLOVER-2 Phase 1 pediatric study is being conducted internationally at seven leading pediatric cancer centers. The study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of CLR 131 in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). 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. This study was initiated during the first quarter of 2019. These cancer types were selected for clinical, regulatory and commercial rationales, including the radiosensitive nature and continued unmet medical need in the r/r setting, and the rare disease determinations made by the FDA based upon the current definition within the Orphan Drug Act.

In December 2014, the FDA granted ODD for CLR 131 for the treatment of MM. In 2018, the FDA granted ODD and RPDD for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. In May 2019, the FDA granted Fast Track designation for CLR 131 for the treatment of MM and in July 2019 for the treatment of DLBCL, in September 2019 CLR 131 received Orphan Drug Designation from the European Union for Multiple Myeloma, in January 2020, the FDA granted Orphan Drug Designation for CLR 131 Waldenstrom's macroglobulinemia and the European Union granted Orphan Drug Designation for CLR 131 Waldenstrom's macroglobulinemia. The FDA granted Fast Track designation for CLR 131 for the treatment of WM in May 2020.

The FDA may award priority review vouchers (PRV) to sponsors of a RPDD that meet its specified criteria. The key criteria to receiving a PRV is that the disease being treated is life-threatening and that it primarily effects individuals under the age of 18. Under this program, a sponsor who receives an approval for a drug or biologic for a rare pediatric disease can receive a PRV that can be redeemed to receive a priority review of a subsequent marketing application for a different product. Additionally, the PRV's can be exchanged or sold to other companies so that the receiving company may use the voucher.

CLOVER-WaM: Phase 2 Study Pivotal Study in: Patients with r/r Waldenstrom's Macroglobulinemia

In January 2021, we announced that a Type C guidance meeting with the FDA was conducted in September of 2020. The results of that guidance meeting provided Cellectar with an agreed upon path for conducting the CLOVER-WaM study; a single arm, pivotal study in WM patients that have received standard of care first line therapy and either failed or had a suboptimal response to BTKi therapy. The FDA agreed with the dose to be tested, our proposal for a safety and futility assessment to be conducted on the first 10 patients, the endpoint to be assessed, the statistical analysis plan and study size of 50 patients. Based upon this agreement the pivotal study was initiated. WM is a rare, indolent and incurable form of non-Hodgkin's lymphoma (NHL) that is composed of a patient population in need of new and better treatment options.

Phase 2A Study: Patients with r/r Waldenstrom's Macroglobulinemia Cohort

Current data from our Phase 2A CLOVER-1 clinical study show that six WM patients demonstrated 100% overall response rate (ORR) and an 83.3% major response rate with one patient achieving a complete response (CR), which continues at nearly 27 months post- last treatment. While median treatment free survival (TRS) also known as treatment free remission (TFR)) and duration of response (DOR) has not been reached, the average treatment TFS/TFR is currently at 330 days. This may represent an important improvement in the treatment of r/r WM as we believe no approved or late-stage development treatments for second- and third-line patients have reported a CR to date.

Phase 2A Study: Patients with r/r Multiple Myeloma Cohort

In September 2020, we announced that a 40% ORR was observed in the subset of refractory multiple myeloma patients deemed triple class refractory who received 60 mCi or greater total body dose (TBD). Triple class refractory is defined as patients that are refractory to immunomodulatory, proteasome inhibitors and anti-CD38 antibody drug classes. The 40% ORR (6/15 patients) represents triple class refractory patients enrolled in Part A of Cellectar's CLOVER-1 study and additional patients enrolled in Part B from March through May 2020 and received ≥60mCi TBD. All MM patients enrolled in the expansion cohort are required to be triple class refractory. The additional six patients enrolled in 2020 were heavily pre-treated with an average of nine prior multi-drug regimens. Three patients received a TBD of ≥ 60 mCi and three received less than 60 mCi. Consistent with the data released in February 2020, patients receiving ≥ 60 mCi typically exhibit greater responses. Based on study results to date, patients continue to tolerate CLR 131 well, with the most common and almost exclusive treatment emergent adverse events being cytopenias.

Phase 2A: Patients with r/r non-Hodgkin's lymphoma Cohort

In February 2020, we announced positive data from our Phase 2a CLOVER-1 study in patients with relapsed/refractory non-Hodgkin lymphoma (NHL). patients were treated with three different doses (<50mCi, ~50mCi and ≥60mCi TBD. Patients with r/r NHL who received <60mCi TBD and the ≥60mCi TBD had a 42% and 43% ORR, respectively and a combined rate of 42%. These patients were also heavily pre-treated, having a median of three prior lines of treatment (range, 1 to 9) with the majority of

patients being refractory to rituximab and/or ibrutinib. The patients had a median age of 70 with a range of 51 to 86. All patients had bone marrow involvement with an average of 23%. In addition to these findings, subtype assessments were completed in the r/r B-cell NHL patients. Patients with DLBCL demonstrated a 30% ORR with one patient achieving a (CR), which continues at nearly 24 months post-treatment. The ORR for chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) and marginal zone lymphoma (MZL) patients was 33%.

Based upon the dose response observed in the Phase 2A for patients receiving TBDs of 60mCi or greater, we determined that patient dosing of CLR 131 would be ≥60mCi TBD. Therefore, patients are now grouped as receiving <60mCi or ≥60mCi TBD.

The most frequently reported adverse events in all patients were cytopenias, which followed a predictable course and timeline. The frequency of adverse events have not increased as doses were increased and the profile of cytopenias remains consistent. Importantly, these cytopenias have had a predictable pattern to initiation, nadir and recovery and are treatable. The most common grade ≥3 events at the highest dose (75mCi TBD) were hematologic toxicities including thrombocytopenia (65%), neutropenia (41%), leukopenia (30%), anemia (24%) and lymphopenia (35%). No patients experienced cardiotoxicities, neurological toxicities, infusion site reactions, peripheral neuropathy, allergic reactions, cytokine release syndrome, keratopathy, renal toxicities, or changes in liver enzymes. The safety and tolerability profile in patients with r/r NHL was similar to r/r MM patients except for fewer cytopenias of any grade. Based upon CLR 131 being well tolerated across all dose groups and the observed response rate, especially in difficult to treat patients such as high risk and triple class refractory or penta-refractory, and corroborating data showing the potential to further improve upon current ORRs and durability of those responses, the study has been expanded to test a two-cycle dosing optimization regimen with a target TBD ≥60 mCi/m^2 of CLR 131.

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 supported 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/WM and 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 secondary endpoints of ORR, progression free survival (PFS,) median Overall Survival (mOS) and other markers of efficacy following patients receiving one of three TBDs of CLR 131 (<50mCi, ~50mCi and ≥60mCi), with the option for a second cycle approximately 75-180 days later. Dosages were provided either as a single bolus or fractionated (the assigned dose level split into two doses) given day 1 and day 15.

In May 2020, we announced that the FDA granted Fast Track Designation for CLR 131 in WM in patients having received two prior treatment regimens or more.

Phase 1 Study in Patients with r/r Multiple Myeloma

In February 2020, we announced the successful completion of our Phase 1 dose escalation study. Data from the study demonstrated that CLR 131 was safe and tolerated up to a TBD of approximately 95mCi in r/r MM. The Phase 1 multicenter, open-label, dose-escalation study was designed to evaluate the safety and tolerability of CLR 131 administered in an up to 30-minute I.V. infusion, either as a single bolus dose or as fractionated doses. The r/r multiple myeloma patients in this study received single cycle doses ranging from approximately 20mCi to 95mCi TBD. An independent Data Monitoring Committee determined that all doses used were safe and well-tolerated by patients.

CLR 131 in combination with dexamethasone was under investigation in adult patients with r/r MM. Patients had to be refractory to or relapsed from at least one proteasome inhibitor and at least one immunomodulatory agent. The clinical study was a standard three-plus-three dose escalation safety study to determine the maximum tolerable dose. Multiple myeloma is an incurable cancer of the plasma cells and is the second most common form of hematologic cancers. Secondary objectives included the evaluation of therapeutic activity by assessing surrogate efficacy markers, which include M protein, free light chain (FLC), PFS and OS. All patients were heavily pretreated with an average of five prior lines of therapy. CLR 131 was deemed by an Independent Data Monitoring Committee (IDMC) to be safe and tolerable up to its planned maximum single, bolus dose of 31.25 mCi/m^2 or a TBD of ~63 mCi. The four single dose cohorts examined were: 12.5 mCi/m^2 (~25mCi TBD), 18.75 mCi/m^2 (~37.5mCi TBD), 25 mCi/m^2(~50mCi TBD), and 31.25 mCi/m^2(~62.5mCi TBD), all in combination with low dose dexamethasone (40 mg 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 admitted to the second cohort, all five achieved stable disease however 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 infusion up to 30-minutes of 31.25mCi/m^2 of CLR 131 was safe and tolerated by the three patients in the cohort. Additionally, all three patients experienced CBR with one patient achieving a partial response (PR). We use the International Myeloma Working Group (IMWG) definitions of response, which involve monitoring the surrogate markers of efficacy, 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% or greater decrease in M protein. The patient experiencing a PR had an 82% reduction in FLC. This patient did not produce M protein, had 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. In January 2019, we announced that the pooled mOS data from the first four cohorts was 22.0 months. In late 2018, we modified this study to evaluate a fractionated dosing strategy to potentially increase efficacy and decrease adverse events.

Cohort 5 and 6 were fractionated cohorts of 31.25 mCi/m^2(~62.5mCi TBD) and 37.5 mCi/m^2(~75mCi TBD), each administered on day 1 and on day 8. Following the determination that all prior dosing cohorts were safe and tolerated, we initiated a cohort 7 utilizing a 40mCi/m2 (~95mCi TBD) fractionated dose administered 20mCi/m2 (~40mCi TBD) on days 1 and day 8. Cohort 7 was the highest pre-planned dose cohort and subjects have completed the evaluation period. The study completed enrollment and the final clinical study report is expected in the first half of 2021.

In May 2019, we announced that the FDA granted Fast Track Designation for CLR 131 in fourth line or later r/r MM. CLR 131 is our small molecule radiotherapeutic PDC designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. It is currently being evaluated in our ongoing CLOVER-1 Phase 2 clinical study in patients with relapsed or refractory multiple myeloma and other select B-cell lymphomas.

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

In December 2017 the Division of Oncology at the FDA accepted our IND and study design for the Phase 1 study of CLR 131 in children and adolescents with select rare and orphan designated cancers. This study was initiated during the first quarter of 2019. In December 2017, we filed an IND application for r/r pediatric patients with select solid tumors, lymphomas and malignant brain tumors. The Phase 1 clinical study of CLR 131 is an open-label, sequential-group, dose-escalation study evaluating the safety and tolerability of intravenous administration of CLR 131 in 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 efficacious dose of CLR 131 and to determine preliminary antitumor activity (treatment response) of CLR 131 in children and adolescents. In August 2020, it was announced that four dose levels 15mCi/m^2 up to 60mCi/m^2 were deemed safe and tolerable by an independent Data Monitoring Committee and evaluation of the next higher dose cohort, 75mCi/m^2 was initiated. In November 2020, we announced that CLR 131 had been measured in tumors, confirming that systemic administration of CLR 131 crosses the blood brain barrier and is delivered into tumors and that disease control has been exhibited in heavily pretreated patients with ependymomas. In 2018, the FDA granted ODD and RPDD for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Should CLR 131 be approved for any of these pediatric indications, the first approved 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. In December 2020, the FDA extended the Priority Review Voucher Program through September 2026 for rare pediatric diseases.

Phase 1 Study in r/r Head and Neck Cancer

In August 2016, the University of Wisconsin Carbone Cancer Center ("UWCCC") was awarded a five-year Specialized Programs of Research Excellence ("SPORE") grant of $12,000,000 from the National Cancer Institute and the National Institute of Dental and Craniofacial Research to improve treatments and outcomes for head and neck cancer, HNC, patients. HNC is the sixth most common cancer across the world with approximately 56,000 new patients diagnosed every year in the U.S. As a key component of this grant, the UWCCC researchers completed testing of CLR 131 in various animal HNC models and initiated the first human clinical study enrolling up to 30 patients combining CLR 131 and external beam radiation with recurrent HNC in Q4 2019. This clinical study was suspended due to the COVID-19 pandemic over the first three quarters of 2020 but is now open and actively enrolling patients.

Preclinical Pipeline

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 below, that may result in improvements upon current standard of care ("SOC") for the treatment of a broad range of human cancers:

- 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 and if we elect to progress any molecules further, we will select preferred candidates.

- CLR 2000 Series is a collaborative PDC program with Avicenna Oncology, or Avicenna, that we entered into in July 2017. Avicenna is a 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 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. The CLR 2000 Series has demonstrated improved safety, efficacy and tissue distribution with the cytotoxic payload in animal models. A candidate molecule and a back-up have been selected for further advancement at a future time.

- 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 phospholipid ether; 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, the cytotoxic radioisotope, iodine-131 can be attached via a stable covalent bond to the PLE resulting in our lead PDC, CLR 131. Non-radioactive molecules, including many classes of small molecule chemotherapeutic compounds, peptides and other molecules can also be attached to the delivery vehicle.

In parallel to advancing the clinical development of our lead PDC, CLR 131 in both adult and pediatric orphan indications; we remain focused on exploring the creation of additional PDCs ranging from newly discovered to well-characterized anti-cancer agent 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 1900, 2000 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 PDC designed to provide targeted delivery of iodine-131 (radioisotope) directly to cancer cells, while limiting exposure to healthy cells unlike many traditional on-market treatment options. 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 NHL. 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 and a unique product profile. Selective uptake and retention have been demonstrated in cancer stem cells compared with normal cells, offering the prospect of longer lasting anti-cancer activity.

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 targeted delivery technology has the potential to achieve these goals. CLR 131 has been shown in animal models to reliably and near-universally accumulate in cancer cells, including cancer stem cells.

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), along with an understanding of classical oncology drug development our initial plan was to develop CLR 131 as a monotherapy for cancer indications with significant unmet medical need. CLR 131's unique benefits such as a novel mechanism of action, ease of administration, and positive benefit/risk profile offered potential treatment benefits for a variety of high unmet cancer populations. While a number of cancer indications were evaluated as the initial target treatment, multiple myeloma was selected principally because, like many hematologic malignancies, is known to be highly radiosensitive and remained an incurable hematologic disease with significant unmet medical need in the relapse or refractory clinical setting. Additionally, MM is designated as an orphan disease and drugs granted an orphan drug designation (ODD) are provided regulatory and marketing exclusivity benefits. The IND application for MM was accepted by the FDA in September 2014. In December 2014, the FDA granted ODD for CLR 131 for the treatment of MM. We initiated our Phase 1 Study of CLR 131 for the treatment of r/r MM in April 2015. The Phase 1 study was a multicenter, open-label, dose-escalation study designed to evaluate the safety and tolerability of CLR 131 administered as a 15-20-minute IV infusion, either as a single bolus dose or as two fractionated doses, in patients with R/R MM. All cohorts dosed were deemed safe and well tolerated by an independent Data Monitoring Committee (DMC). The study was successfully completed in February 2020**.**

In February 2020, final results from a multicenter, phase 1 clinical trial of CLR 131 in r/r MM were presented. The trial was designed to evaluate the safety and potential initial efficacy of CLR 131 in heavily pretreated MM patients and enrolled a total of 26 evaluable patients at three trial sites. For the trial, which used a modified 3 + 3 dose escalation design, 15 evaluable patients were dosed in single bolus doses from 12.5mCi/m2 up to 31.25mCi/m2 (TBD 20.35-59.17 mCi) and 11 evaluable patients were dosed in fractionated dosing cohorts of 31.25mCi/m2 to 40mCi/m2 (TBD 54.915-89.107 mCi). An independent data monitoring committee determined that no dose-limiting toxicities were seen in any cohort. Of the 26 evaluable patients in the trial, a partial response was seen in 4 of 26 patients (15.4%) and stable disease or minimal response in 22 of 26 patients (84.6%), for a disease control rate of 100%. A significant decrease in M-protein and FLC was also observed, suggesting ample targeting of the tumor.

The Phase 2 A study (CLOVER-1) of CLR 131 was initiated in July 2017 and conducted in approximately 10 leading cancer centers in the United States for patients with relapsed or refractory B-cell hematologic cancers. The hematologic cancers being studied in the trial included MM, lymphoplasmacytic lymphoma (LPL) / Waldenstrom's macroglobulinemia (WM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and diffuse large B-cell lymphoma (DLBCL).

The planned study enrollment was up to 80 patients. Its primary endpoint was clinical benefit response (CBR), with additional endpoints of ORR, progression free survival (PFS), median overall survival (OS) and other markers of efficacy. Over the course of the study the dosing regimen of CLR 131 advanced from a single bolus dose to two cycles of fractionated administrations of 15 mCi/m2 per dose on days 1, 15 (cycle 1), and days 57, 71 (cycle 2).

In September 2020, we announced that a 40% ORR was observed in the subset of r/r MM deemed triple class refractory who received 60 mCi or greater TBD. Triple class refractory is defined as patients that are refractory to immunomodulatory, proteasome inhibitors and anti-CD38 antibody drug classes. The 40% ORR (6/15 patients) represents triple class refractory patients enrolled in Part A of our CLOVER-1 study and additional patients enrolled in Part B from March through May 2020 and received ≥60mCi TBD. All MM patients enrolled in the expansion cohort are required to be triple class refractory. The six patients enrolled from March through May 2020 were heavily pre-treated with an average of nine prior multi-drug regimens. Three patients received a TBD of ≥ 60 mCi and three received less than 60 mCi. Consistent with the data released in February 2020, patients receiving ≥ 60 mCi typically exhibit greater responses. Based on study results to date, patients continue to tolerate CLR 131 well, with the most common and almost exclusive treatment emergent adverse events being cytopenias. This cohort will continue to enroll and evaluate patients that are even more refractory (quad-class refractory (proteasome inhibitor, immunomodulatory drug, anti-CD-38 antibodies, nuclear export inhibitors, or BCMA antibody drug conjugates) or hepta-drug refractory) to determine if CLR 131 at the dose of ≥60mCi TBD can be effective in patients that likely have no alternative therapies.

Data from our Phase 2 CLOVER-1 clinical study show that six WM patients demonstrated 100% ORR and an 83.3% major response rate with one patient achieving a CR, which continues at nearly 27 months post- last treatment. While median treatment free survival (or treatment free remission) and duration of response has not been reached, the average treatment free survival is currently at 330 days. This may represent an important improvement in the treatment of r/r WM as we believe no approved or late-stage development treatments for second- and third-line patients have reported a CR nor do any therapies provide any significant benefit after the therapy is stopped.

In January 2021, we announced the initiation of the CLOVER-WaM pivotal study inWM. The study is designed as a global, non-comparator, single arm, study of CLR 131. We believe this design is in alignment with the feedback received from the FDA during the guidance meeting held in September 2020.

The study will enroll 50 WM patients who have failed first-line therapy and have failed or had a suboptimal response to a BTK i (i.e. ibrutinib). Patients in the trial will receive up to 4-doses of CLR 131 over two cycles (cycle one days 1, 15, and cycle two days 57, 71). The primary endpoint of the trial is major response rate (MRR) as defined as a partial response (a minimum of a 50% reduction in IgM) or better in patients that receive a minimum TBD of 60 mCi with secondary endpoints of treatment free survival (treatment free remission), duration of response and progression free survival. An independent data monitoring committee (iDMC) will perform an interim safety and futility evaluation on the first 10 patients enrolled. The assessment will occur patient by patient and will conclude after the tenth patient is evaluated; there is no planned study stoppage. The trial has been initiated at select US cancer centers and will roll out to additional US and international sites in early 2021.

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.

In December 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 pediatric study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of CLR 131 in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). The Phase 1 study was initiated in 2019 at 3 pediatric cancer centersand is currently being conducted internationally at seven leading pediatric cancer centers.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 November 2020, we announced that CLR 131 demonstrated preliminary activity in inoperable brain tumors as part of the Phase 1 study. Similar to previous CLR 131 studies in adults, this study demonstrated that 20-40% of the infused CLR 131 is delivered to cancer tumors. Additionally, the study demonstrated that systemic administration of CLR 131 results in a sufficient proportion of infused drug crossing the blood brain barrier and is delivered to different types of malignant brain tumors. CLR 131 has achieved disease control at multiple dose levels in rapidly progressing, heavily pretreated patients, including two patients at distinct dose levels with rapidly growing ependymomas. Pediatric HGGs are a collection of aggressive brain and central nervous system tumor subtypes (i.e. diffuse intrinsic pontine gliomas, glioblastomas, astrocytomas, ependymomas, etc.) with about 400 new pediatric cases diagnosed annually in the United States. Children with these tumors have a poor prognosis and limited 5-year survival.

The FDA has granted ODD's and RPDDs 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 statutory FDA review time from 12 months to six months. Currently, these vouchers can also be transferred or sold to another entity.

Market Overview

Our target market is broad and represents the market for the treatment of cancer. The American Cancer Society estimated that approximately 1.90 million new cancer cases were expected to be diagnosed in the U.S. in 2019 and approximately 608,570 cancer deaths in the U.S.1 The global market for cancer drugs reached $143 billion in annual sales (2019), and could reach $250 billion by 2024, according to a report dated September 2020 by McKinsey & Company.2 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.

Waldenstrom's macroglobulinemia

Waldenstrom's macroglobulinemia (WM) is a rare and incurable disease defined by specific genotypic subtypes that defines patient responses and long-term outcomes. The annual incidence is 6,500 with prevalence of approximately 60,000 patients globally. WM is a lymphoma, or cancer of the lymphatic system. The disease occurs in a type of white blood cell called a B-lymphocyte or B-cell, which normally matures into a plasma cell whose job is to manufacture immunoglobulins (antibodies) to help the body fight infection. In WM, there is a malignant change to the B-cell in the late stages of maturing, and it continues to proliferate into a clone of identical cells, primarily in the bone marrow but also in the lymph nodes and other tissues and organs of the lymphatic system. These clonal cells over-produce an antibody of a specific class called IgM.

WM cells have characteristics of both cancerous B-lymphocytes (NHL) and plasma cells (multiple myeloma), and they are called lymphoplasmacytic cells. For that reason, WM is classified as a type of non-Hodgkin's lymphoma called lymphoplasmacytic lymphoma (LPL). About 95% of LPL cases are WM; the remaining 5% do not secrete IgM and consequently are not classified as WM.

Several drugs have demonstrated activity either alone or in combinations but only a single drug has received regulatory approval. Treatment is mainly focused on the control of symptoms and the prevention of organ damage. Front-line treatments for WM include rituximab alone or in combination with other agents. In the salvage therapy (second line or later) setting, ibrutinib, combinations of proteosome inhibitors and immunomodulatory drugs and stem cell transplantation are considered. Ibrutinib is the only drug to receive regulatory approval (2015) as a salvage therapy; in late 2019, it was approved for front-line treatment in combination with rituximab. Factors such as long-term cytopenias, age, hyper viscosity, the need for quick disease control, lymphadenopathy, co-morbidities, and IgM-related end-organ damage are key consideration in the choice of treatment.

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. In 2019, Global Data Research Group estimated the multiple myeloma dollar market size to be over $20B in 2021 and is forecasted to increase to nearly $28B in 2027. The increase in drug sales over this period will be mainly driven by the increasing incidence of multiple myeloma 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 WHO Global Cancer Observatory database, the estimated 2020 US incidence of B-Cell Lymphoma was 66,289 cases.9 Types of B-Cell Lymphomas include Chronic Lymphocytic Lymphoma, Small Lymphocytic Lymphoma, Mantle Cell Lymphoma, Marginal Zone Lymphoma, and the most common lymphoma, DLBCL. According to a report dated June 2019 by Global Data Research Group, the B-cell Lymphoma market was valued at $5.7 billion for 2017, with a forecasted increase to $9.2 billion in 2027 at a Compound Annual Growth Rate (CAGR) of 4.9%.

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.

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.

Centre for Probe Development and Commercialization ("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.

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.

Potential Commercial Competition to Our Current and Future Clinical-Stage Compounds

Currently, many 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. There also remain a significant number of compounds being researched and developed for the treatment of cancer. We are focused on the product development and commercialization of adult and pediatric orphan designated indications with unmet clinical need. While multiple adult hematology indications for CLR 131 were evaluated, WM was selected based on CLR 131's efficacy and safety profile demonstrated to date. Other considerations such as the regulatory pathway, unmet clinical need, limited commercial competition and cost efficiencies were also assessed. We believe CLR 131 is a therapeutic option in either adult or pediatric relapse or refractory settings 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 ODD for CLR 131 by the FDA for the treatment of MM in December 2014 and for WM in January 2020. In addition, we received ODD from the European Union for MM in September 2019, and for WM in January 2021. We 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 RPDD for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. We initiated a Phase 1 study in 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

In August 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.

In July 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.

Research and Development

Our primary activity to date has been research and development. The research had 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 $10,141,000 and $8,996,000 for 2020 and 2019, 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.

U.S. 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 are 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 2020, the NDA review fee alone is $2,942,965, although we may qualify for a waiver of these FDA filing fees since we are a small business entity.

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, 2020, we had eleven employees, all of whom are full-time employees.

Legal Proceedings

We may be 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 Capital and Our Operations

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, 2020, our consolidated cash balance was approximately $57.2 million. We believe our cash balance at December 31, 2020, is adequate to fund our basic budgeted operations for at least 12 months from the filing of this annual report. 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 conflicts, military actions, terrorist attacks, natural disasters, public health crises, including the occurrence of a contagious disease or illness, such as the COVID-19 coronavirus, cyber-attacks and general instability; 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.

The COVID-19 pandemic could materially and adversely affect our business.

The COVID-19 pandemic could significantly disrupt our business and may prevent us from conducting business activities due to spread of the disease, or due to shutdowns that may be requested or mandated by federal, state and local governmental authorities. Business disruptions have included restrictions on our ability to travel, as well as temporary closures. While we have not yet experienced any significant impacts as a result of the pandemic, it is not possible at this time to estimate the ultimate impact that it could have on our business. The continued rapid spread of COVID-19 including new virus strains and the measures taken by government authorities has created uncertainties and could delay our ongoing clinical studies or the manufacture or shipment of CLR 131 for clinical studies.

We continue to evaluate the impact COVID-19 may have on our ability to effectively conduct our business. Our clinical trial sites may be affected by travel or quarantine restrictions imposed by federal, state or local governments. We may in the future need to update or suspend our clinical studies as a result of the pandemic. In addition, we have made and we (and our CROs) may need to make certain adjustments to the operation of clinical studies in an effort to ensure the monitoring and safety of patients and minimize risks to trial data integrity during the pandemic in accordance with the guidance issued by the FDA in 2020, which describes a number of considerations for sponsors of clinical studies impacted by the pandemic, including, among other requirements, the requirements to include in the clinical trial report contingency measures implemented to manage the clinical trial, any disruption of the clinical trial as a result of the COVID-19 pandemic, and analyses and corresponding discussions that address the impact of implemented contingency measures on the safety and efficacy results reported for the clinical trial. To the extent we (or our third-party suppliers and manufacturers) are required to implement additional or to modify existing policies and procedures for our clinical studies and/or manufacturing functions, or if the pandemic significantly impacts recruitment of patients or the conduct of our clinical studies, our anticipated timelines for initiating or completing clinical studies and seeking regulatory approval may be substantially delayed, and we may incur additional costs. Also, to the extent FDA and other regulatory authorities experience any delays or limited resources in reviewing our regulatory applications or requests for meetings and/or guidance, and inspection of manufacturing facilities prior to regulatory approval due to the COVID-19 pandemic or other reasons, we may experience significant delays in our anticipated timelines for our clinical studies and/or seeking regulatory approvals, which could adversely affect our business.

Although we expect no material impact on the supply of CLR 131 for our current clinical studies, should our third-party manufacturers experience extended disruptions, we could experience delays in future trials. Further, in June 2020, FDA issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs. Such guidance and any future guidance or regulatory requirements impacting drug product manufacturing, including delays associated with complying with new requirements, could impact the operations of our contract manufacturers, our business, and our ability to obtain sufficient supplies for our clinical development on a timely basis.

The COVID-19 pandemic continues to rapidly evolve. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis could have a material negative impact on our business, financial condition and operating results. To the extent that COVID-19 pandemic impacts our business in any way, it may also have the effect of heightening the impact of other risk factors disclosed herein.

Conflicts, military actions, terrorist attacks, natural disasters. public health crises, including the occurrence of a contagious disease or illness, such as the COVID-19 coronavirus, cyber-attacks and general instability could adversely affect our business.

Conflicts, military actions, terrorist attacks, natural disasters, public health crises and cyber-attacks have precipitated economic instability and turmoil in financial markets. Instability and turmoil may result in raw material cost increases. The uncertainty and economic disruption resulting from hostilities, military action, acts of terrorism, public health crises or cyber-attacks may impact our operations or those of our suppliers. Accordingly, any conflict, military action, terrorist attack, public health crises or cyber-attack that impacts us or any of our suppliers, could have a material adverse effect on our business, liquidity, prospects, financial condition and results of operations.

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, phishing attempts, 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.

Risks Related to Manufacturing and Supply

We rely on a collaborative outsourced business model, and disruptions with our 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.

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.

Risks Related to Research and Development and the FDA

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 Waldenstrom's macroglobulinemia, 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 late-stage clinical 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 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 of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug, and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacturing, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, clinical 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.

The FDA has granted rare pediatric disease designation, RPDD, to CLR 131 for treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma; 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, rhabdomyosarcoma, osteosarcoma and Ewing's sarcoma. 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 could 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. 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. In December 2020, the Priority Review Voucher Program was extended by the FDA permitting additional grants through September 2026 for rare pediatric diseases. It is possible that even if we obtain approval for CLR 131 and qualify for a priority review voucher, the program may no longer be in effect at the time of such approval.

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.

Risks Related to Legal Compliance and Litigation

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 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.

Risks Related to Intellectual Property

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 ODD 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 ODD in the U.S. for CLR 131 as a therapeutic for the treatment of multiple myeloma, neuroblastoma, osteosarcoma, rhabdomyosarcoma, Ewing's sarcoma and lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia. Additionally, we have been granted ODD in Europe for CLR 131 as a therapeutic for the treatment of multiple myeloma and Waldenstrom's macroglobulinemia. 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 ODD in a particular indication, it is possible that another company also holding ODD 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 ODD, 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 ODD and exclusivity are in effect right now, the FDA has the authority to modify this assessment at any time.

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.

Risks Related to Our Employees

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. 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.

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 current or former employers.

As is common in the biotechnology and pharmaceutical industry, we engage individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors or who are employed by academic research institutions. 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 current or 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.

Risks Related to Commercialization of our Products

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.

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.

Risks Related to Internal Controls

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

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.

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 $12,900 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 $3,100 per month under an agreement that expires on August 31, 2021.

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 25, 2021 there were 181 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 vested 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 vested annually over three years and expire ten years after the date of grant. During 2019, we issued 90,000 options to our Chief Financial Officer that were not issued pursuant to our 2015 Stock Incentive Plan. During 2020, we issued 100,000 options to our Chief Medical 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, 2020 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 (#)	Weighted-average exercise price of outstanding options and rights ($)	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a)) (#)
	(a)	(b)	(c)
Equity compensation plans approved by stockholders	983,214	$ 3.65	675,685
Equity compensation plans not approved by stockholders	201,250	$ 7.71	n/a
Total	1,184,464	$ 4.34	675,685

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 late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer. Our core objective is to leverage our proprietary PDC delivery platform to develop PDCs that are designed to specifically target cancer cells and 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 both independently and through research and development collaborations.

Our lead PDC therapeutic, CLR 131 is a small-molecule PDC designed to provide targeted delivery of iodine-131 directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates CLR 131 from many traditional on-market treatments. CLR 131 is currently being evaluated in the multi cohort CLOVER-1 Phase 2 study in adult B-cell malignancies and the CLOVER-2 Phase 1 study for a variety of pediatric cancers. Our product pipeline also includes one preclinical PDC chemotherapeutic program (CLR 1900) and several partnered PDC assets. The CLR 1900 Series is being targeted for solid tumors with a payload that inhibits mitosis (cell division) a validated pathway for treating cancers.

Results of Operations

Research and development expense. Research and development expense consists of costs incurred in identifying, developing and testing, and manufacturing product candidates, which primarily include 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, 2020 and 2019

Research and Development. Research and development expense for the year ended December 31, 2020 was approximately $10,141,000 compared to approximately $8,996,000 for the year ended December 31, 2019.

The following table is a comparison summary of research and development costs for the years ended December 31, 2020 and December 31, 2019:

	Year Ended December 31,		
	2020	2019	Variance
Clinical project costs	$ 3,794,000	$ 3,629,000	$ 165,000
Manufacturing and related costs	2,322,000	2,772,000	(450,000)
Pre-clinical project costs	213,000	323,000	(100,000)
General research and development costs	3,812,000	2,272,000	1,540,000
	$ 10,141,000	$ 8,996,000	$ 1,145,000

The overall increase in research and development expense of approximately $1,145,000, or 13%, was primarily attributable to an increase in general research and development costs of approximately $1,540,000 largely related to an increase in research and development personnel. Manufacturing and related costs decreased by approximately $450,000 due to a reduction in materials production processes and related costs. The clinical and pre-clinical project costs were relatively consistent.

General and Administrative. General and administrative expense for the year ended December 31, 2020 was approximately $5,150,000 compared to approximately $5,183,000 in 2019. The decrease of $18,000, or less than 1%, in general and administrative costs was primarily related to a decrease of approximately $42,000 in personnel costs and an approximate $158,000 decrease related to public company expenses. These costs were offset by an increase in legal fees and business insurance of approximately $185,000.

Gain on Revaluation of Derivative Warrants. We recorded a gain on the revaluation of derivative warrants of approximately $43,000 in 2019. These amounts, which are non-cash in nature, represent the change in fair value (resulting primarily from changes in our stock price, and reduced remaining time over which the warrants will remain outstanding), during the respective period, of outstanding warrants which were 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. For the year ended December 31, 2020, there was no gain or loss on derivatives as they expired on August 20, 2019.

Other income (expense), net. Other income for the year ended December 31, 2020 was approximately $185,000 due a gain on extinguishment of debt related to the forgiveness of our loan and accrued interest obtained under the Paycheck Protection Program ("PPP"). The PPP was established as part of the Coronavirus Aid, Relief and Economic Security Act which provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loans and accrued interest are forgivable after 24 weeks as long as the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels. The amount of loan forgiveness will be reduced if the borrower terminates employees or reduces salaries during the 24-week period. Interest income, net, for the year ended December 31, 2020 was approximately $11,000, as compared to approximately $43,000 for the year ended December 31, 2019. The decrease is a result of decreased returns on investments.

Liquidity and Capital Resources

Year ended December 31, 2020 Compared to Year Ended December 31, 2019

As of December 31, 2020, we had cash, cash equivalents and restricted cash of $57.2 million compared to $10.6 million at December 31, 2019. The increase was largely attributable to net cash received from financing activities of approximately $60.5 million, offset by cash used in operating activities of $13.9 million and cash used in investing activities of approximately $62,000.

Cash provided from financing activities of approximately $60.5 million was due to the net proceeds we received from the sale of our common stock, preferred stock and pre-funded warrants. On June 5, 2020, we issued and sold 14,601,628 shares of common stock, 2,789,700 pre-funded warrants exercisable for one share of our common stock at an exercise price of $0.00001 per share and 8,695,664 Series H warrants to purchase 8,695,664 shares of common stock. The public offering price of a share of common stock together with one-half of a Series H warrant to purchase one share of common stock was $1.15. The public offering price of a pre-funded warrant together with one-half of a Series H Warrant was $1.1499. The Series H warrants have an exercise price of $1.2075 per share and are exercisable for five years from the date of issuance. Gross offering proceeds were $20.0 million, with net proceeds of approximately $18.3 million after deducting placement agent fees and related offering expenses. On December 23, 2020, we entered into an underwriting agreement where we agreed to sell 18,148,136 shares of common stock at a public offering price of $1.35 per share of common stock, prior to deducting underwriting discounts and commissions and estimated offering expenses. On December 23, 2020, in a separate concurrent private placement, we entered into a Securities Purchase Agreement with certain purchasers named therein, pursuant to which we agreed to issue and sell, 1,518.5180 shares of Series D convertible preferred stock (the "Preferred Shares"). The Preferred Shares are convertible into a number of shares of common stock equal to $13,500 divided by $1.35 (or 10,000 shares of common stock for each share of Series D Preferred Stock converted) and were issued at a price of $13,500 per share of Series D Preferred Stock. The net proceeds of the offerings, after deducting the underwriting discounts and commissions, placement agency fees and estimated offering expenses payable by us were approximately $41.4 million.

Cash used in operating activities of approximately $13.9 million was largely due to funding of our research and development programs and general and administrative expenses.

Cash used in investing activities of $62,000 was due to the purchase of computer hardware.

Liquidity Outlook

We have incurred losses since inception in devoting substantially all of our efforts toward research and development and have an accumulated deficit of approximately $126.8 million at December 31, 2020. During the year ended December 31, 2020, we generated a net loss of approximately $15.1 million, and used approximately $13.9 million in cash from operations. We expect that we will continue to generate operating losses for the foreseeable future. At December 31, 2020, our consolidated cash balance was approximately $57.2 million. We believe our cash balance at December 31, 2020, is adequate to fund our basic budgeted operations for at least 12 months from the filing of these financial statements. 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. To date we have raised capital aggregating approximately $267 million.

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.

Long-Lived Assets. Long-lived assets include property, equipment and right-of-use assets. 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, 2020 or 2019.

Right-Of-Use Asset and Lease Liability. 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.

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, had been 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 had been 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 was the change in fair value of the underlying common stock. Such financial instruments were 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 outstanding derivative warrants was 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. No derivative warrants existed on December 31, 2020 or December 31, 2019.

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 our financing in 2019 we allocated the common stock and warrants separately based on the respective estimated relative fair value. In conjunction with our financing in June 2020, we allocated the common stock, warrants and pre-funded warrants separately based on the respective estimated relative fair value. In conjunction with our financing in December 2020, we allocated the common stock and preferred stock separately based on the respective estimated relative fair value. If management made different assumptions or judgments, material differences in measurements of fair value could occur.

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

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

Not applicable.

Item 8. Financial Statements.

FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Cellectar Biosciences, Inc. and Subsidiary

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, 2020 and 2019, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Complex Equity Instruments

As described in Note 6 to the consolidated financial statements, the Company issued $20.5 million of Series D Convertible Preferred Stock (“Preferred Stock”) in December 2020. The Preferred Stock is redeemable and convertible upon the occurrence of certain events. The Preferred Stock was evaluated to determine whether or not it (i) was mandatorily redeemable or (ii) represented an unconditional obligation of the Company to be settled in a variable number of shares of common stock. The Company determined that the Preferred Stock was neither mandatorily redeemable nor did it require settlement in a variable number of shares of common stock.

The embedded conversion features were evaluated for bifurcation as an embedded derivative instrument. This evaluation included determining whether or not the economic characteristics and risks of the embedded conversion features were clearly and closely related to the economic characteristics of the Preferred Stock. Based on its terms, the Company determined that the Preferred Stock was akin to an equity-like host. As a result, the Company concluded that the embedded conversion features were clearly and closely related to the Preferred Stock.

The embedded conversion features were further evaluated for the presence of a beneficial conversion feature and the Preferred Stock for classification as mezzanine, or temporary, equity. As the Preferred Stock is contingently convertible at the commitment date and requires shareholder approval, a beneficial conversion feature was not recognized in 2020.

Mezzanine equity classification is required when preferred stock is redeemable upon the occurrence of an event that is not solely within the control of the Company. There is a limited exception provided to this requirement. The Company determined that this exception was applicable based upon the terms of the Preferred Stock. The Company concluded that the Preferred Stock should be classified in stockholders’ equity.

Also as described in Note 6 to the consolidated financial statements, the Company issued $20.0 million of common stock, pre-funded warrants, which are exercisable for one share of common stock, and Series H warrants to purchase additional shares of common stock in June 2020. The Company determined the pre-funded warrants and the Series H warrants are freestanding financial instruments because both the pre-funded warrants and the Series H warrants are separately exercisable and legally detachable from each other and from the common stock. The Company evaluated the pre-funded warrants and Series H warrants pursuant to ASC 480, *Distinguishing Liabilities from Equity*, and concluded they are not liabilities. The pre-funded warrants and Series H warrants were further evaluated to determine whether or not they were derivative financial instruments. The Company concluded that both the pre-funded warrants and the Series H warrants should be classified in stockholders’ equity, as they meet both the indexation guidance and the equity classification guidance included in ASC 815-40. The Company allocated the proceeds to the common stock, pre-funded warrants and the Series H warrants based on their relative fair values.

The principal considerations for our determination that the accounting for complex equity instruments constituted a critical audit matter included the significant complexity of the relevant accounting guidance, as well as extent of management judgments involved in the application of that guidance. In addition, the audit effort included the use of firm personnel with relevant expertise to assist in auditing these transactions.

The primary procedures we performed to address this critical audit matter included:

- We assessed the design and implementation of management's controls over the accounting for complex equity instruments
- We read the agreements and compared the relevant terms to management's analysis of the transactions
- With the assistance of firm personnel having expertise in the accounting for complex equity instruments, we evaluated management's conclusions regarding the balance sheet classification and valuation of the complex equity instruments
- We tested the Company's determination of the fair value for the transactions, as well as the respective relative fair value allocations. Our testing included assessing the reasonableness of certain assumptions used by the Company, as well as, the completeness and accuracy of the data utilized
- We assessed the required financial statement disclosures related to the transactions

/s/ Baker Tilly US, LLP (formerly known as Baker Tilly Virchow Krause, LLP)

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

Madison, Wisconsin
March 2, 2021

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 57,165,377	$ 10,614,722
Prepaid expenses and other current assets	774,432	770,951
Total current assets	57,939,809	11,385,673
Fixed assets, net	355,982	435,083
Right-of-use asset, net	282,365	348,841
Long-term assets	75,000	75,000
Other assets	6,214	6,214
TOTAL ASSETS	$ 58,659,370	$ 12,250,811
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 3,443,197	$ 2,663,873
Lease liability	119,904	105,885
Total current liabilities	3,563,101	2,769,758
LONG-TERM LIABILITIES:		
Lease liability	301,740	421,644
Total long-term liabilities	301,740	421,644
TOTAL LIABILITIES	3,864,841	3,191,402
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.00001 par value; 7,000 shares authorized;		
Series C preferred stock: 215 issued and outstanding as of both December 31, 2020 and 2019	1,148,204	1,148,204
Series D preferred stock: 1,519 and 0 issued and outstanding as of December 31, 2020 and 2019, respectively	18,887,645	—
Common stock, $0.00001 par value; 80,000,000 shares authorized; 45,442,729 and 9,386,689 shares issued and outstanding at December 31, 2020 and 2019, respectively	454	94
Additional paid-in capital	161,533,653	119,592,366
Accumulated deficit	(126,775,427)	(111,681,255)
Total stockholders' equity	54,794,529	9,059,409
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 58,659,370	$ 12,250,811

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,	
	2020	2019
COSTS AND EXPENSES:		
Research and development	$ 10,140,681	$ 8,996,058

General and administrative	5,149,668	5,182,566
Total costs and expenses	15,290,349	14,178,624
LOSS FROM OPERATIONS	(15,290,349)	(14,178,624)
OTHER INCOME:		
Gain on revaluation of derivative warrants	—	43,000
Gain on extinguishment of debt	185,280	—
Interest income, net	10,897	42,712
Total other income, net	196,177	85,712
NET LOSS	$ (15,094,172)	$ (14,092,912)
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	$ (0.76)	$ (1.84)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	19,812,659	7,675,092

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				
	Shares	Amount	Shares	Par Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
BALANCE AT DECEMBER 31, 2018	473	$ 2,526,049	4,732,387	$ 47	$ 108,323,208	$ (97,588,343)	$ 13,260,961
Issuance of common stock, warrants and preferred stock, net of issuance costs	—	—	4,000,000	40	9,024,529	—	9,024,569
Stock-based compensation	—	—	—	—	866,791	—	866,791
Vested restricted stock	—	—	9,334	—	—	—	—
Retired shares	—	—	(32)	—	—	—	—
Conversion of preferred shares into common shares	(258)	(1,377,845)	645,000	7	1,377,838	—	-
Net loss	—	—	—	—	—	(14,092,912)	(14,092,912)
BALANCE AT DECEMBER 31, 2019	215	$ 1,148,204	9,386,689	$ 94	$ 119,592,366	$ (111,681,255)	$ 9,059,409
Issuance of common stock, preferred stock, pre-funded warrants and warrants, net of issuance costs	1,519	18,887,645	32,749,764	327	40,831,284	—	59,719,256
Stock-based compensation	—	—	—	—	467,541	—	467,541
Vested restricted stock	—	—	9,334	—	—	—	—
Retired shares	—	—	(133)	—	—	—	—
Conversion of warrants into common shares	—	—	3,297,075	33	642,462	—	642,495
Net loss	—	—	—	—	—	(15,094,172)	(15,094,172)
BALANCE AT DECEMBER 31, 2020	1,734	$ 20,035,849	45,442,729	$ 454	$ 161,533,653	$ (126,775,427)	$ 54,794,529

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,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (15,094,172)	$ (14,092,912)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	141,453	132,798
Stock-based compensation	467,541	866,791
Gain on extinguishment of debt	(185,280)	—
Noncash lease expense	66,476	56,562
Gain on revaluation of derivative warrants	—	(43,000)
Changes in:		
Prepaid expenses and other current assets	(3,480)	(129,733)
Other assets	—	477,695
Accounts payable and accrued liabilities	780,604	1,120,054
Lease liability	(105,885)	(81,963)
Cash used in operating activities	(13,932,743)	(11,693,708)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(62,353)	(24,542)
Cash used in investing activities	(62,353)	(24,542)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on capital lease obligations	—	(2,213)

Proceeds from long-term obligations	184,000	—
Proceeds from issuance of common stock and preferred stock, net of underwriting issuance costs	59,719,256	9,024,569
Proceeds from exercise of warrants	642,495	—
Cash provided by financing activities	60,545,751	9,022,356
INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	46,550,655	(2,695,894)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF PERIOD	10,614,722	13,310,616
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF PERIOD	$ 57,165,377	$ 10,614,722
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest expense	$ 1,584	$ 880
Gain on extinguishment of debt	$ 185,280	$ —
Conversion of preferred stock to common stock	$ —	$ 1,377,845

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

CELLECTAR BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS AND ORGANIZATION

Cellectar Biosciences, Inc. (the Company) is a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer leveraging our proprietary phospholipid drug conjugate™ (PDCs™) delivery platform that specifically targets cancer cells, delivering improved efficacy and better safety as a result of fewer off-target effects.

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 $126,775,000 at December 31, 2020. During the year ended December 31, 2020 the Company generated a net loss of approximately $15,094,000 and the Company expects that it will continue to generate operating losses for the foreseeable future. However, the Company believes that its cash balance at December 31, 2020 is adequate to fund our basic budgeted operations for at least 12 months from the filing of these financial statements. The Company's ability to execute its current operating plan 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.

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, 2020 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.

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

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 fixed asset impairment charges recorded during the years ended December 31, 2020 or 2019.

Right-of-Use Asset and Lease Liabilities — In February 2016, the Financial Accounting Standard Board ("FASB") issued Accounting Standard Update ("ASU") 2016-02, Leases (ASC 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires lessees to recognize Right-Of-Use ("ROU") Asset and Lease Liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). On January 1, 2019, the Company adopted FASB Accounting Standards Codification ("ASC") Topic 842 using the modified retrospective method for all material leases that existed at or commenced after January 1, 2019. ROU Assets are amortized over their estimated useful life, which represents the full term of the lease. See ***Leases*** below for additional details.

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 2019 ranged from seven months to three years and for grants issued in 2020 was over three years. 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.* The Company recognizes an 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.

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, 2020 and 2019.

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. At December 31, 2018, these warrants represented the only outstanding derivative instruments issued or held by the Company and expired on August 20, 2019.

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, 2020 and 2019 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, 2020, uninsured cash balances totaled approximately $56,700,000.

Leases — In February 2016, the FASB issued ASU 2016-02, Leases (ASC 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires lessees to recognize Right-Of-Use Asset and Lease Liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). Lessor accounting remains largely unchanged except for changes in the definition and classification of leases. ASU 2016-02 allows a modified retrospective approach for all leases existing at, or entered into after the date of initial adoption, with an option to elect to use certain transition relief. The FASB also proposed a transition method to allow entities to not apply the new leases standard in the comparative periods they present in their financial statements in the year of adoption. Because of the immaterial financial impact, the Company will not apply ASC 842 to leases that individually have total lease payments of less than $100,000 over their life of service to the Company.

On January 1, 2019, the Company adopted ASC 842 using the modified retrospective method for all material leases that existed at or commenced after January 1, 2019. See Note 11 for additional details. The Company elected to apply the practical expedients in ASC 842-10-65-1 (f) and (gg) and therefore:

1. did not reassess expired contracts for presence of lease components therein and if it was already concluded that such contracts had lease components then the classification of the respective lease components therein was not re-assessed.

2. did not re-assess initial direct costs for any existing leases.

3. will not separate the lease and non-lease components.

4. will continue applying its current policy for accounting for land easements that existed as of, or expired before effective date.

Recently Adopted Accounting Pronouncements - In 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 that its adoption of ASU 2017-11 has not had a material impact on its results of operations, cash flows and financial position.

For the fiscal year beginning January 1, 2021, management early adopted ASU 2020-06 using the modified retrospective method. ASU 2020-06 simplifies entities' accounting for convertible instruments by eliminating the cash conversion and BCF models outlined in ASC 470-20. Under ASU 2020-06, convertible instruments that would have previously been subject to the BCF or cash conversion guidance no longer require separate accounting for the conversion feature. Entities may elect to early adopt ASU 2020-06 for fiscal years beginning after December 15, 2020. Since the Company early adopted ASU 2020-06 beginning January 1, 2021, the Company would no longer be required to recognize a BCF even when shareholder approval is received. In December 2020, the Company completed a private placement where we issued Series D convertible preferred stock. The preferred shares are convertible into shares of common stock upon receipt of stockholder approval of the issuance of the underlying shares of common stock as required by Nasdaq Marketplace Rule 5635(d) at a special stockholder meeting. As such, management will continue to account for the Series D Preferred Stock in equity without any separate accounting for the conversion options.

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.

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 were listed on the NASDAQ Capital Market under the symbol "CLRBW," however, there are certain periods where trading volume is low; therefore, they were classified as Level 2 within the hierarchy. On August 20, 2019, these warrants expired.

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

4. FIXED ASSETS

Fixed assets consisted of the following at December 31:

	2020	2019
Office and laboratory equipment	$ 445,758	$ 430,591
Computer software	4,000	4,000
Leasehold improvements	309,897	309,897
Total fixed assets	759,655	744,488
Less– accumulated depreciation and amortization	(403,673)	(309,405)
Fixed assets, net	$ 355,982	$ 435,083

For the years ended December 31, 2020 and 2019, the Company incurred approximately $141,000 and $133,000 of depreciation and amortization expense, respectively.

5. ACCRUED EXPENSES

Accounts payable and accrued liabilities approximately consist of the following:

	2020	2019
Incentive compensation	$ 850,000	$ 395,000
Accounts payable	1,429,000	1,278,000
Clinical study costs	787,000	720,000
Professional fees	221,000	157,000
Insurance	—	111,000
Other	156,000	3,000
	$ 3,443,000	$ 2,664,000

6. STOCKHOLDERS' EQUITY

December 2020 Public Offering and Private Placement

On December 23, 2020, the Company issued and sold 18,148,136 shares of common stock, par value $0.00001 per share, of the at a public offering price of $1.35 per share of common stock, prior to deducting underwriting discounts and commissions and estimated offering expenses.

In a concurrent private placement, we issued and sold 1,518.5180 shares of Series D convertible preferred stock. The preferred shares are convertible into a number of shares of common stock equal to $13,500 divided by $1.35 (or 10,000 shares of common stock for each share of Series D preferred stock converted) and were issued at a price of $13,500 per share of Series D preferred stock. The preferred shares will only be convertible into common stock upon receipt of stockholder approval of the issuance of the underlying shares of common stock as required by Nasdaq Marketplace Rule 5635(d) at a special stockholder meeting to be called for that purpose.

In accordance with the concept of ASC 820 regarding the December 2020 public offering, the Company allocated value of the proceeds to the common stock and preferred stock utilizing a relative fair value basis. Using the Nasdaq closing trading price for our stock on December 28, 2020, the Company computed the fair value of the shares sold. The fair value of the preferred stock was estimated on a relative fair value basis. This valuation did not impact total Stockholders' Equity of $45.0 million, but is an internal proportionate calculation allocating the gross proceeds of approximately $24.5 million to common stock and $20.5 million to preferred stock.

The net proceeds of the offerings to the Company, after deducting the underwriting discounts and commissions, placement agency fees and estimated offering expenses payable by the Company were approximately $41.4 million.

The common stock were offered by the Company pursuant to a registration statement on Form S-3, which was declared effective by the Securities and Exchange Commission on February 1, 2021.The preferred shares are only convertible upon stockholder approval.

June 2020 Public Offering

On June 5, 2020, the Company issued and sold 14,601,628 shares of common stock, 2,789,700 pre-funded warrants exercisable for one share of our common stock at an exercise price of $0.00001 per share and 8,695,664 Series H warrants to purchase 8,695,664 shares of common stock. The public offering price of a share of common stock together with one-half of a Series H warrant to purchase one share of common stock was $1.15. The public offering price of a pre-funded warrant together with one-half of a Series H Warrant was $1.1499. The Series H warrants have an exercise price of $1.2075 per share and are exercisable for five years from the date of issuance. As of December 31, 2020, all 2,789,700 pre-funded warrants and 482,375 Series H warrants have been exercised.

In accordance with the concept of ASC 820 regarding the June 2020 public offering, the Company allocated value of the proceeds to the common stock and warrants utilizing a relative fair value basis. Using the Nasdaq closing trading price for our stock on June 5, 2020, the Company computed the fair value of the shares sold. The fair value of the warrants was estimated using the Black-Scholes option-pricing model at that same date. This valuation did not impact total Stockholders' Equity of $20.0 million, but is an internal proportionate calculation allocating the gross proceeds of approximately $12.1 million to common stock and $7.9 million to warrants.

Gross offering proceeds to the Company were $20.0 million, with net proceeds to the Company of approximately $18.3 million after deducting placement agent fees and related offering expenses. The Company intends to use the net proceeds from the offering for research and development, funding clinical studies, working capital and general corporate purposes.

The common stock, pre-funded warrants and Series H warrants were offered by the Company pursuant to a registration statement on Form S-1 filed on May 8, 2020 with the SEC under the Act and an additional registration statement filed on June 2, 2020 pursuant to Rule 462(b) under the Act.

May 2019 Public Offering

On May 20, 2019, the Company issued and sold 1,982,000 shares of common stock at an offering price of $2.50 per share. In a concurrent private placement, we issued to the purchasers of our common stock, Series F warrants to purchase an aggregate of 1,982,000 shares of common stock. The Series F warrants were immediately exercisable, expire five years after the date of issuance, and have an exercise price of $2.40. As of December 31, 2020, 25,000 Series F warrants have been exercised.

In a separate concurrent private placement transaction, the Company sold 2,018,000 shares of common stock together with Series G warrants to purchase an aggregate of up to 2,018,000 shares of common stock. The shares of common stock and Series G warrants were priced at $2.50 per fixed combination. The warrants sold in the private placement were immediately exercisable, expire five years after the date of issuance, and have an exercise price of $2.40.

In accordance with the concept of ASC 820 regarding the May 2019 public offering, the Company allocated value to the proceeds to the common stock and warrants utilizing a relative fair value basis. Using the Nasdaq closing trading price for our stock on May 20, 2019, we computed the fair value of the shares sold. The fair value of the warrants was estimated using the Black-Scholes option-pricing model at that same date. This valuation did not impact total Stockholders' Equity of $10.0 million, but is an internal proportionate calculation allocating the gross proceeds of approximately $6 million to common stock and $4.0 million to warrants.

Gross offering proceeds to the Company were $10.0 million, with net proceeds to the Company of approximately $9.0 million after deducting placement agent fees and related offering expenses. The Company intends to use the net proceeds from the offering for research and development, funding clinical studies, working capital and general corporate purposes.

The registered direct offering described above was made pursuant to a registration statement on Form S-3 previously filed with and subsequently declared effective by the SEC. The unregistered common shares and warrants were offered pursuant to the exemption from registration afforded by Section 4(a)(2) under the Act, and Regulation D promulgated thereunder. The offerings' unregistered common shares and warrants were ultimately registered through our May 31, 2019 filing of Form S-1 and acceptance of this Registration Statement by the SEC.

Common Stock Warrants

The following table summarizes information with regard to outstanding warrants to purchase common stock as of December 31, 2020:

Offering	Number of Shares Issuable Upon Exercise of Outstanding Warrants		Exercise Price	Expiration Date
June 2020 Series H Warrants	8,213,289	$	1.21	June 5, 2025
May 2019 Series F Warrants	1,957,000	$	2.40	May 20, 2024
May 2019 Series G Warrants	2,018,000	$	2.40	May 20, 2024
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
Total	17,456,266			

7. STOCK-BASED COMPENSATION

Accounting for Stock-Based Compensation

Increase in 2015 Stock Incentive Plan. At the 2020 annual meeting of stockholders held on June 24, 2020, 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 700,000 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. On June 13, 2019, 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 700,000 shares. On June 24, 2020, 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 700,000 shares. A total of 1,682,000 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, 2020, there are an aggregate of 675,685 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.

During the twelve-months ended December 31, 2020 and 2019, stock options granted were 653,750 and 411,930, respectfully. The following table summarizes amounts charged to expense for stock-based compensation related to employee and director stock option grants:

	Twelve Months Ended December 31,	
	2020	2019
Employee and director stock option grants:		
Research and development	$ 72,579	$ 62,932
General and administrative	394,962	803,859
Total stock-based compensation	$ 467,541	$ 866,791

On October 12, 2018, the Company granted 167,430 contingent non-statutory stock options, net of forfeitures, at an exercise price of $2.61 per share to current non-employee directors and employees, and on January 17, 2019, the Company granted 118,750 contingent non-statutory stock options, net of forfeitures, at an exercise price of $1.99 per share to employees. Each of these grants was contingent on approval by the Company's stockholders of the amendment to the 2015 Stock Incentive Plan at the 2019 Annual Meeting of Stockholders, and stockholders approved the amendment on June 13, 2019**.** In accordance with the timing of the stockholder approval, all related expenses were recognized by the Company in June 2019, including the catch-up for compensation expenses for recognition of contingent non-statutory stock options from October 2018.

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 the Company's historical volatility since its common stock has been publicly traded.

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 no forfeiture rate to directors for the twelve months ended December 31, 2020 and 2019. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest.

Dividends. The Company has not historically recorded dividends related to stock options.

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

	Year Ended December 31,	
	2020	2019
Volatility	96-106%	91-93%
Risk-free interest rate	0.42-1.67%	1.62-3.05%
Expected life (years)	6	6
Dividend	0%	0%
Weighted-average exercise price	$ 1.84	$ 2.33
Weighted-average grant-date fair value	$ 1.42	$ 1.76

Exercise prices for all grants made during the twelve months ended December 31, 2020 and 2019 were equal to the market value of the Company's common stock on the date of grant. There were 653,750 stock option grants during the twelve months ended December 31, 2020.

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, 2018	232,343	$ 14.37		
Granted	411,930	$ 2.33		
Forfeited	(33,559)	$ 4.78		
Outstanding at December 31, 2019	610,714	$ 6.78		$ 34,650
Granted	653,750	$ 1.84		
Forfeited	80,000	$ 2.46		
Outstanding at December 31, 2020	1,184,464	$ 4.34	8.57	$ 316,688
Exercisable, December 31, 2020	458,325	$ 8.26	7.70	$ 6,828
Unvested, December 31, 2020	726,139	$ 1.87	9.12	$ 309,859

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, 2020 and 2019 was $1.42 and $1.76, respectively. The total fair value of shares vested during the years ended December 31, 2020 and 2019 was $389,398 and $715,587, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2020 was $6.62 and $1.44, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2019 was $10.62 and $1.82, respectively.

The weighted average grant date fair value of options forfeited during the years ended December 31, 2020 and 2019 was $1.90 and $3.80 respectively. The number of options vested during the years ended December 31, 2020 and December 31, 2019 was 209,354 and 203,523, respectively. The number of options unvested at January 1, 2020 and January 1, 2019 was 361,743 and 186,895, respectively. The weighted average grant date fair value of options unvested at January 1, 2020 and January 1, 2019 was $1.82 and $4.14, respectively.

As of December 31, 2020, there was approximately $790,035 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, the Company expects to recognize approximately $424,673, $292,129 and $73,233 during 2021, 2022 and 2023, respectively. The Company's expense estimates are based upon the expectation that all unvested options will vest in the future, less the forfeiture rate discussed above. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2020 was $6.62 and $1.44, respectively.

*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. In 2017, 8,000 shares were forfeited. 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, 2018	18,668	$ 21.00	$ 392,000
Granted	—	—	—
Vested	(9,334)	21.00	(196,000)
Forfeited	—	—	—
Outstanding at December 31, 2019	9,334	21.00	196,000
Granted	—	—	—
Vested	(9,334)	21.00	(196,000)
Forfeited	—	—	—
Outstanding at December 31, 2020	—	$ —	$ —

8. INCOME TAXES

	2020	2019
Tax provision (benefit)		
Current		
Federal	$ —	$ —
State	—	—
Total current	—	—
Deferred		
Federal	(3,481,6764)	(2,141,153)
State	(1,416,877)	(6,146,506)
Total deferred	(4,898,641)	(8,287,659)
Change in valuation allowance	4,898,641	8,287,659
Total	$ —	$ —

Deferred tax assets consisted of the following at December 31:

	2020	2019

Deferred tax assets		
Federal net operating loss	$ 30,179,562	$ 28,261,717
Federal research and development tax credit carryforwards	7,063,702	6,137,842
State net operating losses and tax credit carryforwards	4,393,526	3,590,961
Capitalized research and development expenses	9,911,446	8,955,425
Stock-based compensation expense	2,459,336	2,333,551
Depreciable assets	—	—
Other	419,597	292,259
Total deferred tax assets	54,427,169	49,571,755
Deferred tax liabilities		
Depreciable assets	(110,705)	(153,928)
Total deferred tax liabilities	(110,705)	(153,928)
Net deferred tax assets	54,316,463	49,417,827
Less– valuation allowance	(54,316,463)	(49,417,827)
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,	
	2020	2019
Income tax benefit using U.S. federal statutory rate	(21.00)%	(21.00)%
State income taxes	(7.42)%	(34.46)%
Permanent items	0.00%	0.01%
Federal tax credits	(6.13)%	(5.21)%
Change in valuation allowance	34.81%	58.81%
Other	(0. 26)%	1.85%
Total	0.00%	0.00%

As of December 31, 2020, the Company had federal net operating loss carryforwards of approximately $143,722,000. Federal net operating loss generated as of December 31, 2017 will expire in 2021 through 2037, net operating loss generated during 2018 and later will be carried forward indefinitely until utilized. As of December 31, 2020,the Company also had state net operating loss carryforwards of approximately $54,283,000. State net operating loss will expire in 2028 through 2040.

As of December 31, 2020, the Company had federal research and development and orphan drug credit carryforwards of approximately $7,064,000 which will expire in 2021 through 2040. As of December 31, 2020, the Company also had state credit carryforwards of approximately $850,000which will expire in 2024 through 2035.

As of December 31, 2020, the company had federal NOLs and research and development credit carryforwards of $1,690,848 and $65,675, respectively, that expired in 2020.

The amount of NOLs and tax credit carryforwards which may be utilized annually in future periods will be limited pursuant to Section 382 and 383 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.

During 2019, the Company changed its state tax rate applied to the deferred tax assets and liabilities based on the expected reversal of the deferred tax assets and liabilities. This state deferred tax benefit is offset by a corresponding increase valuation allowance.

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 CARES Act lifts certain deduction limitations originally imposed by the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). Under the Tax Act, federal net operating losses generated after 2017 could not be carried back and utilization was limited to 80% of taxable income. The CARES Act allows for a five-year carryback of federal net operating losses generated in 2018 through 2020 and eliminates the 80% taxable income limitation by allowing entities to fully utilize net operating loss carryforwards to offset taxable income in 2018 through 2020. In addition, the CARES Act generally allows taxpayers to deduct interest up to 50% of adjusted taxable income (30% limit under the Tax Act) for tax years 2019 and 2020.

The enactment of the CARES Act did not result in any material adjustments to the Company's income tax provision for the year ended December 31, 2020, or to its deferred taxes and related allowance as of December 31, 2020.

Effective January 1, 2019, the Company adopted ASU 2016-02, which resulted in the recognition of lease liabilities and right-of-use assets. The Company's deferred tax balances have been adjusted to reflect the adoption of ASU2016-02.

The Company did not have unrecognized tax benefits or accrued interest and penalties at any time during the years ended December 31, 2020 or 2019 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, 2017. Additionally, the Company may be subject to examination by the IRS for years beginning prior to January 1, 2017 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.

9. 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, 2020 and 2019, 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,	
	2020	2019
Warrants	17,456,266	9,268,352
Stock options	1,184,464	610,714
Non-vested restricted stock	—	9,334
Preferred shares convertible to common	15,722,680	537,500
Total potentially dilutive shares	34,363,410	10,425,900

10. COMMITMENTS AND CONTINGENCIES

Legal

The Company may be 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.

11. LEASES

Operating Lease Liability

In June 2018, the Company executed an agreement for office space in the Borough of Florham Park, Morris County, New Jersey to be used as its headquarters ("HQ Lease"). The HQ Lease commenced upon completion of certain improvements in October 2018 and terminates in February 2024 with an option to extend the term of the lease for one additional 60-month period. During 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 for which we amortized the deferred liability as a reduction to rent expense in the consolidated statement of operations over the term of the lease.

Under the HQ Lease, the Company will pay monthly fixed rent based on approximate rate per rentable square foot which ranges between approximately $12,400 to $13,600 over the lease period. In addition, the Company received certain rent abatements and lease incentives subject to the limitations in the HQ Lease. The HQ Lease's net ROU asset and ROU lease liability are approximately $282,000 and ($422,000), respectively, as of December 31, 2020 and rental expense for the twelve months ended December 31, 2020 was approximately $113,000. The Company has not entered into any leases with related parties.

On January 1, 2019, the Company adopted ASC 842 using the modified retrospective method for all material leases that existed at or commenced after January 1, 2019 and elected to apply the practical expedients in ASC 842-10-65-1 (f) and (gg) to the HQ Lease. The Company accounts for short-term leases (i.e., lease term of 12 months or less) by making the short-term lease policy election and will not apply the recognition and measurement requirements of ASC 842. As a result of the immaterial financial impact, the Company will not apply ASC 842's extensive calculation and reporting requirement against the leases that individually have total lease payments of less than $100,000 over their life of service to the Company. The adoption of ASC 842 did not have a material net impact on the Company's Condensed Consolidated Statements of Operations as of the effective date. See **Note 1** for additional details.

Discount Rate

The Company has determined the interest rate implicit in the lease consideringfactors such as the Company's credit rating, borrowing terms offered by the U.S. Small Business Administration, amount of lease payments, quality of collateral and alignment of the borrowing term and lease term. The Company considers 10% per annum as reasonable to use as the incremental borrowing rate for purposes of the calculation of lease liabilities.

Maturity Analysis of Short-Term and Operating Leases

The following table approximates the dollar maturity of the Company's undiscounted payments for its short-term leases and operating lease liabilities as of December 31, 2020:

Years ending December 31,		
2021	$	155,000
2022		158,000
2023		161,000
2024		14,000
Total undiscounted lease payments		488,000
Less: Imputed interest		(66,000)
Present value of lease liabilities	$	422,000

12. 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.

13. LOAN PAYABLE

On April 21, 2020, the Company received loan proceeds in the amount of approximately $184,000 under the Paycheck Protection Program ("PPP"). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loans and accrued interest are forgivable after 24 weeks as long as the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels. The amount of loan forgiveness will be reduced if the borrower terminates employees or reduces salaries during the 24-week period.

The unforgiven portion of the PPP loan is payable over two years at an interest rate of 1%, with a deferral of payments for the first six months. The Company intends to use the proceeds for purposes consistent with the PPP requirements. On December 30, 2020, the principal loan amount of $184,000 and accrued interest of $1,280 were forgiven.

14. SUBSEQUENT EVENTS

In January and February 2021, the Company received proceeds of $1,213,924 upon the exercise of 1,005,320 Series H warrants.

In February 2021, a holder of 215 shares of our Series C Preferred Stock converted them into 537,500 shares of Common Stock at a conversion rate of 1 to 2,500 shares.

Special Meeting of Stockholders

At a special meeting of stockholders held on February 25, 2021, the Company's stockholders approved the amendment of the Company's Second Amended and Restated Certificate of Incorporation, as amended, to increase the authorized common stock from 80,000,000 shares to 160,000,000 shares. In addition, the stockholders approved, in accordance with Nasdaq Listing Rule 5635(d), the issuance of shares of the Company's common stock upon the conversion of the Series D Preferred Stock issued in a private placement on December 28, 2020. In February 2021, 351.8515 shares of our Series D Preferred Stock were converted into 3,518,515 shares of Common Stock at a conversion rate of 1 to 10,000 shares.

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, 2020, 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, 2020. 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 2021 Annual Meeting of Stockholders under the captions "Proposal No. 1 — Election of Directors," "Officers and Directors" and "Corporate Governance."

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 2021 Annual Meeting of Stockholders under the caption "Compensation of Executive Officers and Directors ¾Executive 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 2021 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 2021 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 2021 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 2021 Annual Meeting of Stockholders under the captions "Proposal No. 4 — Ratification of Appointment of our Independent Registered Public Accounting Firm" and "Audit Committee Matters — Audit and Other Fees."

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed with this annual report on Form 10-K.

(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 annual report on Form 10-K 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 to Second Amended and Restated Certificate of Incorporation	8-K	July 13, 2018	3.1
3.8	Certificate of Amendment of Second Amended and Restated Certificate of Incorporation	8-K	February 25, 2021	3.1
3.9	Amended and Restated By-laws	8-K	June 1, 2011	3.1
3.10	Form of Certificate of Designation of Series C Preferred Stock	S-1/A	July 18, 2018	3.11
3.11	Form of Certificate of Designation of Series D Preferred Stock certificate	8-K	December 28, 2020	3.1
4.1	Form of common stock certificate	S-1/A	November 9, 2011	4.1
4.2	Form of Series C Preferred Stock certificate	S-1/A	July 18, 2018	4.6
4.3	Form of Series D Preferred Stock certificate	8-K	December 28, 2020	4.1
4.4*	Description of Securities Registered under Section 12(b) of the Securities Exchange Act of 1934			
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	Registration Rights Agreement dated September 28, 2015	8-K	September 30, 2015	10.2

10.4	Form of Series A Warrant	S-1/A	April 14, 2016	4.2
10.5	Form of Warrant Agency Agreement	S-1/A	April 14, 2016	4.4

10.6	Form of Series C Warrant	S-1/A	November 18, 2016	4.3
10.7	Form of Warrant Agency Agreement	S-1/A	November 18, 2016	4.4
10.8	Form of Restricted Common Stock Agreement**	10-Q	August 14, 2017	10.1
10.9	Form of Series D Common Stock Purchase Warrant	8-K	October 11, 2017	4.1
10.10	Registration Rights Agreement, dated as of October 10, 2017, by and among Cellectar Biosciences, Inc. and the Purchasers	8-K	October 11, 2017	10.2
10.11	Form of Non-Statutory Stock Option**	S-8	November 9, 2017	10.2
10.12	Stock Option Agreement with James V. Caruso**	S-8	November 9, 2017	10.4
10.13	Stock Option Agreement with Jarrod Longcor**	S-8	November 9, 2017	10.5
10.14	Master Services Agreement for Clinical Research and Related Services between the Company and INC Research, LLC dated October 6, 2016	10-K	March 21, 2018	10.33
10.15	Series E Common Stock Purchase Warrant	S-1/A	July 18, 2018	4.5
10.16	Form of Warrant Agency Agreement	S-1/A	July 18, 2018	4.7
10.17	Agreement of Lease between the Company and KBS II 100-200 Campus Drive, LLC	S-1/A	July 18, 2018	10.35
10.18	Form of Non-Statutory Stock Option (Definitive/Contingent – Employees)**	10-Q	November 13, 2018	10.3
10.19	Form of Non-Statutory Stock Option (Definitive/Contingent – Directors)**	10-Q	November 13, 2018	10.4
10.20	Amended and Restated Employment Agreement between the Company and James Caruso, dated April 15, 2019**	8-K	April 19, 2019	10.1
10.21	Amended and Restated Employment Agreement between the Company and Jared Longcor, dated April 15, 2019**	8-K	April 19, 2019	10.2
10.22	Form of Series F Common Stock Purchase Warrant	8-K	May 20, 2019	4.1
10.23	Form of Series G Common Stock Purchase Warrant	8-K	May 20, 2019	4.2
10.24	Securities Purchase Agreement, dated as of May 16, 2019, by and among Cellectar Biosciences, Inc. and the Purchasers	8-K	May 20, 2019	10.1
10.25	Private Placement Securities Purchase Agreement, dated as of May 16, 2019, by and among Cellectar Biosciences, Inc. and the Purchasers	8-K	May 20, 2019	10.2

10.26	Registration Rights Agreement, dated as of May 16, 2019, by and among Cellectar Biosciences, Inc. and the Purchasers	8-K	May 20, 2019	10.3
10.27	Cellectar Biosciences, Inc. Amended and Restated 2015 Stock Incentive Plan**	8-K	June 14, 2019	10.1
10.28	Employment Agreement between the Company and Dov Elefant dated August 15, 2019**	8-K	August 19, 2019	10.1
10.29	Amendment to Amended and Restated Employment Agreement between the Company and Jarrod Longcor dated November 10, 2019**	10-Q	November 12, 2019	10.2
10.30	Stock Option Agreement with Dov Elefant**	10-K	March 9, 2020	10.36
10.31	Stock Option Agreement with Igor Grachev**	10-K	March 9, 2020	10.37
10.32	Form of Underwriting Agreement	S-1/A	May 20, 2020	1.1
10.33	Form of Series H Warrant	S-1/A	May 20, 2020	4.3
10.34	Form of Warrant Agency Agreement	8-K	June 5, 2020	4.3
10.35	Equity Distribution Agreement between Cellectar Biosciences, Inc. and Oppenheimer & Co. Inc., dated August 11, 2020	8-K	August 11, 2020	10.1
10.36	Form of Securities Purchase Agreement	8-K	December 28, 2020	10.1
10.37	Form of Registration Rights Agreement	8-K	December 28, 2020	10.2
21.1*	List of Subsidiaries			
23.1*	Consent of Independent Registered Public Accounting Firm			
24.1*	Power of Attorney (included on the Signatures page of this Annual Report on Form 10-K)			
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
March 2, 2021

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.

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints James V. Caruso and Dov Elefant, jointly and severally, as his attorneys-in-fact, each with the power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

By: /s/ James V. Caruso
James V. Caruso
Title: Chief Executive Officer and Director (Principal Executive Officer)
March 2, 2021

By: /s/ Dov Elefant
Dov Elefant
Title: Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
March 2, 2021

By: /s/ Frederick W. Driscoll
Frederick W. Driscoll
Title: Director
March 2, 2021

By: /s/ Stephen A. Hill
Stephen A. Hill
Title: Director
March 2, 2021

By: /s/ Stefan D. Loren
Stefan D. Loren
Title: Director
March 2, 2021

By: /s/ John L. Neis
John L. Neis
Title: Director
March 2, 2021

By: /s/ Douglas J. Swirsky
Douglas J. Swirsky
Title: Director
March 2, 2021

EXHIBIT 4.4

DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12(B) OF THE SECURITIES EXCHANGE ACT OF 1934

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

Authorized and Outstanding Capital Stock

Our authorized capital stock consists of 80,000,000 shares of common stock, $0.00001 par value per share and 7,000 shares of preferred stock, $0.00001 par value per share. Our certificate of incorporation authorizes us to issue shares of our preferred stock from time to time in one or more series without stockholder approval, each such series to have rights and preferences, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences as our board of directors may determine. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of holders of any preferred stock that we may issue in the future. The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for others to acquire, or of discouraging others from attempting to acquire, a majority of our outstanding voting stock.

Common Stock

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

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

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

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

April 2016 Underwritten Registered Series A

The Series A Warrants were issued on April 20, 2016 and are exercisable for five years. The Series A Warrants are listed on the NASDAQ Capital Market under the symbol CLRBZ. No fractional shares of common stock will be issued in connection with the exercise of a Series A Warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the market value of a share of common stock. A Series A Warrant may be transferred by a holder, upon surrender of the warrant, properly endorsed (by the holder executing an assignment in the form attached to the warrant). The holder of a Series A warrant does not possess any stockholder rights until the holder exercise the warrant.

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

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

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

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

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

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

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

calling of a special meeting of stockholders.

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

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, 2020:

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, 333-225675, 333-231888, and 333-238132), Form S-3 (File Nos. 333-218514, 333-244362, and 333-252309) and Forms S-8 (File Nos. 333-221469, 333-195255, 333-164398, and 333-233460) of Cellectar Biosciences, Inc. and Subsidiary of our report dated March 2, 2021, relating to the consolidated financial statements which appears in this annual report on Form 10-K for the years ended December 31, 2020 and 2019.

/s/ BAKER TILLY US, LLP (formerly known as BAKER TILLY VIRCHOW KRAUSE, LLP

Madison, Wisconsin
March 2, 2021

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: March 2, 2021

/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, Dov Elefant, 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: March 2, 2021

/s/ Dov Elefant
Dov Elefant
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, 2020, 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, Dov Elefant, 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/ Dov Elefant
James V. Caruso President and Chief Executive Officer	Dov Elefant Chief Financial Officer

Dated: March 2, 2021

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.