

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, 2021

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

For the transition period from _____ to _____.

Commission File Number 333-119366

CELLECTAR BIOSCIENCES, INC.
(Exact name of Registrant as specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

04-3321804
(I.R.S. Employer Identification No.)

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

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 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, 2021, was \$65,452,004.

As of March 18, 2022, there were 61,101,263 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 2022 Annual Meeting of Stockholders are incorporated by reference in Part III of this annual report on Form 10-K. The definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this annual report on Form 10-K.

CELLECTAR BIOSCIENCES, INC.
FORM 10-K

TABLE OF CONTENTS

	Forward-Looking Statements	2
PART I		4
Item 1.	Business	4
Item 1A.	Risk Factors	29
Item 2.	Properties	54
Item 3.	Legal Proceedings	54
Item 4.	Mine Safety Disclosures	54
PART II		55
Item 5.	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	55
Item 6.	Reserved	55
Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	55
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	58
Item 8.	Financial Statements	58
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	74
Item 9A.	Controls and Procedures	74
Item 9B.	Other Information	75
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	75
PART III		75
Item 10.	Directors, Executive Officers, and Corporate Governance	75
Item 11.	Executive Compensation	75
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	75
Item 13.	Certain Relationships and Related Transactions, and Director Independence	75
Item 14.	Principal Accounting Fees and Services	75
PART IV		76
Item 15.	Exhibits, Financial Statement Schedules	76
Item 16.	Summary	77
	Signatures	78

FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K of Celectar Biosciences, Inc. (the “Company”, “Celectar”, “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 recruit patients for clinical studies, 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 iopofosine I-131 (iopofosine, also known as 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 iopofosine 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 iopofosine;
- 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;
- the future impacts of legislative and regulatory developments in the U.S. on the pricing and reimbursement of our product candidates;
- our ability to meet the continued listing standards of Nasdaq;
- 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,” “would” 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.

[Table of Contents](#)

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 Collectar Biosciences, Inc. Unless otherwise provided in this annual report on Form 10-K, trademarks identified by TM are trademarks of Collectar Biosciences, Inc. All other trademarks are the properties of their respective owners.

PART I

Item 1. Business.

Business Overview

We are a 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. We believe that 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, including variants thereof, 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. While we have commenced dosing in our CLOVER-WaM pivotal clinical study of iopofosine in Waldenström's macroglobulinemia (WM), we have experienced material delays in patient recruitment and enrollment as a result of continued resourcing issues related to COVID-19 at study sites and potentially resulting from concerns among patients about participating in clinical studies during a public health emergency. The COVID-19 pandemic is also affecting the operations of third parties upon whom we rely. We are unable to predict how the COVID-19 pandemic may affect our ability to successfully progress our CLOVER-WaM pivotal clinical study or any other clinical programs in the future. Moreover, there remains uncertainty relating to the trajectory of the pandemic and whether it may cause further delays in patient study recruitment. The impact of related responses and disruptions caused by the COVID-19 pandemic may result in difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing studies and the incurrence of unforeseen costs as a result of disruptions in clinical supply of iopofosine or preclinical study or clinical study delays and our ability to obtain additional financing. The continued impact of COVID-19 on results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease or variants thereof, the duration of the pandemic, vaccination rates, travel restrictions and social distancing in the U.S., Canada and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the U.S., Canada and other countries to contain and treat the disease. In October 2021, we announced that we are collaborating with BBK Worldwide to provide new concierge services for patients participating in our clinical studies. These services are designed to improve patients' and their caregivers' access to high quality care and innovative treatments for their cancer.

Our lead PDC therapeutic, iopofosine 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 iopofosine from many traditional on-market treatments. Iopofosine is currently being evaluated in the CLOVER-WaM Phase 2 pivotal study in patients with relapsed/refractory (r/r) 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. As with all clinical trials, adverse events, serious adverse events or fatalities may arise during a clinical trial due to medical problems that may not be related to clinical trial treatments

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 iopofosine in Bruton tyrosine kinase inhibitor (BTKi) failed or suboptimal response WM patients. The CLOVER-1 Phase 2B study, where iopofosine remains under further evaluation in highly refractory MM patients, is ongoing.

The CLOVER-2 Phase 1 pediatric study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of iopofosine in children and adolescents with relapsed or refractory malignant solid tumors (neuroblastoma, Ewing's sarcoma, osteosarcoma, rhabdomyosarcoma) and lymphoma or recurrent or refractory malignant brain tumors (high grade glioma, and glioblastoma, etc.) for which there are no standard treatments. The study is being conducted internationally at seven leading pediatric cancer centers.

The U.S. Food and Drug Administration (FDA) granted iopofosine Fast Track Designation for lymphoplasmacytic lymphoma (LPL) and 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 LPL/WM, MM, neuroblastoma, soft tissue sarcomas including rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Iopofosine was also granted Rare Pediatric Disease Designation

[Table of Contents](#)

(RPDD) for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. The European Commission granted ODD 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 developed for solid tumors with a payload that inhibit 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 is designed to provide 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 is designed not to 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 are designed to bind to these regions and directly enter the intracellular compartment. This mechanism allows the PDC molecules to accumulate in tumor cells over time, which we believe 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, iopofosine, 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 iopofosine from many traditional on-market treatments and treatments in development. Iopofosine is currently being evaluated in the CLOVER-WaM Phase 2 pivotal study in patients with r/r WM, a Phase 2B study in r/r MM patients and the CLOVER-2 Phase 1 study for a variety of pediatric cancers. Adverse events across all studies have been largely restricted to fatigue (39)% and cytopenias, specifically, thrombocytopenia (75)%, anemia (61)%, neutropenia (54)%, leukopenia (56)%, and lymphopenia (34)%. Fatalities due to infection have occurred in patient treated with iopofosine.

The CLOVER-WaM pivotal Phase 2B study is enrolling 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, and 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 2022. 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 iopofosine 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 iopofosine 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 iopofosine for the treatment of MM. In 2018, the FDA granted ODD and RPDD for iopofosine for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. In May 2019, the FDA granted Fast Track designation for iopofosine for the treatment of MM and in July 2019 for the treatment of DLBCL. In September 2019 iopofosine received ODD from the European Union for MM. In December 2019, the FDA and the European Union each granted ODD for iopofosine for the treatment of WM. The FDA granted Fast Track designation for iopofosine for the treatment of r/r LPL and WM in May 2020.

As the result of iopofosine's RPDD designation, we may be eligible to receive a priority review voucher (PRV) if the product receives approval for any of the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma or osteosarcoma. The FDA may award PRV to sponsors of a product application for a RPDD that meet its specified criteria. The key criteria to receiving PRV is that the drug be approved for a rare pediatric disease and treat a serious or life-threatening manifestation of the disease or condition that primarily affects individuals under the age of 18. In order to receive a PRV, a sponsor must obtain approval of a "rare pediatric disease product application," which is a human drug application for prevention or treatment of a rare pediatric disease and which contains no active ingredient, including any ester or salt thereof, that has been approved by the FDA; is deemed eligible for priority review; is submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) or section 351(a) of the Public Health Service Act (PHSA); relies on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population; does not seek approval for an adult indication in the original rare pediatric disease application; and is approved after September 30, 2016. 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. Congress has only authorized the rare pediatric disease priority review voucher program until September 30, 2024. However, if a drug candidate receives RPDD before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026.

CLOVER-WaM: Phase 2 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 2020. The results of that guidance meeting provided Cellerar 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. We believe this design is in alignment with the feedback received from the FDA during the guidance meeting held in September 2020. The FDA accepted 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.

The study is expected to enroll 50 WM patients who have received at least two prior lines of therapy, failed both lines of therapy including having failed or had a suboptimal response to a BTKi (i.e. ibrutinib). Patients in the trial will receive up to 4-doses of iopofosine over two cycles (cycle one days 1, 15, and cycle two days 57, 71) with each dose administered as a 15mCi/m² infusion. 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 total body dose (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. If three of the 10 patients experience a Clinically Significant Toxicity (CST) then the dose will be reduced to 12.5 mCi/m². 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 and international cancer centers and sites.

CLOVER-1: Phase 2 Study in Select B-Cell Malignancies

The Phase 2 CLOVER-1 study is an open-label study designed to determine the efficacy and safety of CLR 131 in select B-cell malignancies (multiple myeloma (MM), indolent chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), lymphoplasmacytic lymphoma (LPL)/Waldenstrom's macroglobulinemia (WM), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), DLBCL, and central nervous system lymphoma (CNSL) who have been previously treated with standard therapy for their underlying malignancy. As of March 2022, the study arms for CLL/SLL, LPL/WM, MZL, MCL, and DLBCL are closed. Dosing of patients varied by disease state cohort and was measured in terms of TBD.

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 iopofosine. The funds supported the Phase 2 study initiated in March 2017 to define the clinical benefits of iopofosine in r/r MM and other niche hematologic malignancies with unmet clinical need. These niche hematologic malignancies include CLL, SLL, MZL, LPL/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 planned study enrollment was up to 80 patients.

The study's primary endpoint is clinical benefit response (CBR), with secondary endpoints of overall response rate (ORR), progression free survival (PFS), time to next treatment (TtNT), median Overall Survival (mOS), duration of response (DOR) and other markers of efficacy following patients receiving one of three TBDs of iopofosine (<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. Over the course of the study the dosing regimen of iopofosine 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). Adverse events occurring in at least 25% of subjects were fatigue (39)% and cytopenias, specifically, thrombocytopenia (75)%, anemia (61)%, neutropenia (54)%, leukopenia (51)%, and lymphopenia (25)%. Serious adverse events occurring in greater than 5% of subjects were restricted to thrombocytopenia (9)% and febrile neutropenia (7.5)%.

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

Patients in the r/r WM cohort all received TBD of ≥ 60 mCi (25 mCi/m² single bolus, 31.25 mCi/m² fractionated, 37.5 mCi/m² fractionated, or two cycles of mCi/m² fractionated) either as a bolus dose or fractionated. Current data from our Phase 2a CLOVER-1 clinical study show a 100% ORR in 6 WM patients 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 (TFS), also known as treatment free remission (TFR), and DOR have not been reached, the average treatment TFS/TFR is currently at 330 days. We believe 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. Based on study results to date, patients continue to tolerate iopofosine well, with the most common adverse events being cytopenias and fatigue.

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 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 ≥ 60 mCi TBD (25 mCi/m² single bolus, 31.25 mCi/m² fractionated, 37.5 mCi/m² fractionated, or two cycles

of mCi/m² fractionated) either as a bolus dose or fractionated. Patients with MM received 40 mg of dexamethasone concurrently beginning within 24 hours of the first CLR 131 infusion. 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 iopofosine well, with the most common and almost exclusive treatment-emergent adverse events are cytopenias, such as thrombocytopenia, neutropenia, and anemia.

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 NHL patients were treated with three different doses (<50mCi, ~50mCi and ≥ 60 mCi TBD. Patients in the r/r NHL cohort received TBD of either ≥ 60 mCi or < 60 mCi (25 mCi/m² single bolus, 31.25 mCi/m² fractionated, 37.5 mCi/m² fractionated, or two cycles of mCi/m² fractionated) either as a bolus dose or fractionated. Patients with r/r NHL who received <60mCi TBD and the ≥ 60 mCi 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 CLL/SLL and MZL patients was 33%.

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

The most frequently reported adverse events in all patients were cytopenias, which followed a predictable course and timeline. The frequency of adverse events did not increase as doses were increased and the profile of cytopenias remains consistent. Importantly, our assessment is that 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 iopofosine being well tolerated across all dose groups, the observed response rate, and 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/m² of iopofosine.

In May 2020, we announced that the FDA granted Fast Track Designation for iopofosine 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 indicate that iopofosine was 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 iopofosine administered in an up to 30-minute I.V. infusion, either as a single bolus dose or as fractionated doses. The r/r MM patients in this study received single cycle doses ranging from approximately 20mCi to 95mCi TBD. An IDMC assessed the safety of all doses used with patients and deemed them to be safe and tolerated.

Iopofosine 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. 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. Multiple myeloma is an incurable cancer of the plasma cells and is the second most common form of hematologic cancer. 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. An IDMC assessed the safety of iopofosine up to its planned maximum single, bolus dose of 31.25 mCi/m² or a TBD of ~63 mCi. The four single dose cohorts examined were: 12.5 mCi/m² (~25mCi TBD), 18.75 mCi/m² (~37.5mCi TBD), 25 mCi/m² (~50mCi TBD), and 31.25 mCi/m² (~62.5mCi TBD), all in combination with low dose dexamethasone (40 mg weekly). Of the five patients in the first cohort, four were assessed as achieving 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 were assessed as achieving 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 were assessed as achieving stable disease. In September 2017, we announced safety and tolerability data for cohort 4, in which patients were treated with a single infusion up to 30-minutes of 31.25mCi/m² of iopofosine, which was tolerated by the three patients in the cohort. Additionally, all three patients experienced CBR with one patient achieving a partial response (PR). 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 cohort 6 received fractionated dosing of 31.25 mCi/m² (~62.5mCi TBD) and 37.5 mCi/m² (~75mCi TBD), each administered on day 1 and on day 8. Following the determination that all prior dosing cohorts were 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 2022. Adverse events occurring in at least 25% of subjects were fatigue (26%) and cytopenias, specifically, thrombocytopenia (90%), anemia (65%), neutropenia (55%), leukopenia (61%), and lymphopenia (58%). Serious adverse events occurring in greater than 2 subjects were restricted to febrile neutropenia n=3 (9.7%).

In May 2019, we announced that the FDA granted Fast Track Designation for iopofosine in fourth line or later r/r MM. Iopofosine is currently being evaluated in our ongoing CLOVER-1 Phase 2 clinical study in patients with r/r MM and other select B-cell lymphomas. Patients in the study received up to 4, approximately 20-minute IV infusions of iopofosine over 3 months, with doses given 14 days apart in each cycle and a maximum of 2 cycles. Low dose dexamethasone 40 mg weekly (20mg in patients \geq 75), was provided for up to 12 weeks. The planned study enrollment was up to 80 patients. Its primary endpoint was clinical benefit rate (CBR), with additional endpoints of ORR, PFS, median overall survival (OS) and other markers of efficacy. Over the course of the study the dosing regimen of iopofosine 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). Following treatment with iopofosine, approximately 91% of patients experience a reduction in tumor marker with approximately 73% experiencing greater than 37% reduction.

In December 2021, we presented data from 11 MM patients from our ongoing Phase 2 CLOVER-1 study in a poster at the American Society of Hematology (ASH) Annual Meeting and Exposition. The MM patients were at least triple class refractory (defined as refractory to an immunomodulatory agent, proteasome inhibitor and monoclonal antibody) with data current as of the end of May 2021. Patients had a median of greater than 7 prior therapies with 50% classified as high risk. Initial results in these patients showed an ORR of 45.5%, a CBR of 72.7% and a disease control rate (DCR) of 100%. Median PFS was 3.4 months. In a subset of 5 quad/penta drug refractory patients, efficacy increased, demonstrating an ORR of 80% and CBR of 100% in this highly treatment refractory group. The most commonly observed treatment emergent adverse events were cytopenias that included Grade 3 or 4 thrombocytopenia (62.5%), anemia (62.5%), neutropenia (62.5%) and decreased white blood cell count (50%). Treatment emergent adverse events were mostly limited to bone marrow suppression in line with prior observations. No patients experienced a treatment emergent adverse event of neuropathy, arrhythmia, cardiovascular event, bleeding, ocular toxicities, renal function, alterations in liver enzymes, or infusion-site reactions or adverse events.

CLOVER 2: 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 iopofosine 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 submitted an IND application for r/r pediatric patients with select solid tumors, lymphomas and malignant brain tumors. The Phase 1 clinical study of iopofosine is an open-label, sequential-group, dose-escalation study evaluating the safety and tolerability of intravenous administration of iopofosine in children and adolescents with relapsed or refractory malignant solid tumors (neuroblastoma, Ewing's sarcoma, osteosarcoma, rhabdomyosarcoma) and lymphoma or recurrent or refractory malignant brain tumors for which there are no standard treatments. Secondary objectives of the study are to identify the recommended efficacious dose of iopofosine and to determine preliminary antitumor activity (treatment response) of iopofosine in children and adolescents.

In August 2020, based on data on four dose levels from 15mCi/m² up to 60mCi/m², an DMC permitted the beginning of the evaluation of the next higher dose cohort, at 75mCi/m². The IDMC advised, based upon the initial data, to enrich the 60 mCi/m² dose level for patients over the age of 10 with HGG and Ewing sarcoma. Changes in various tumor parameters appeared to demonstrate initial response and tumor uptake. This includes patients with relapsed HGGs with over 5 months of PFS. In November 2020, we announced clinical data providing that iopofosine had been measured in pediatric brain tumors, confirming that systemic administration of iopofosine crosses the blood brain barrier and is delivered into tumors and that the data show disease control in heavily pretreated patients with ependymomas. In November 2021, we announced favorable data on changes in various tumor parameters in a Phase 1 study in children and adolescents with relapsed and refractory high-grade gliomas (HGGs) and soft tissue sarcomas. 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 U.S.. Children with these tumors have a poor prognosis and limited 5-year survival. Adverse events occurring in at least 25% of subjects were fatigue, headache, nausea and vomiting (28% respectively), and cytopenias, specifically, thrombocytopenia (67)%, anemia (67)%, neutropenia (61)%, leukopenia (56)%, and lymphopenia (33)%. There were no serious adverse events occurring in more than 2 subjects.

In 2018, the FDA granted ODD and RPDD for iopofosine for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. If iopofosine should 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 NCI 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 iopofosine in various animal HNC models and initiated the first human clinical study enrolling up to 30 patients combining iopofosine and external beam radiation treatment (EBRT) with recurrent HNC in the fourth quarter of 2019. UWCCC has completed the part A portion of a safety and tolerability study of iopofosine in combination with EBRT and preliminary data suggest safety and tolerability in relapsed or refractory HNC. The reduction in the amount or fractions (doses) of EBRT has the potential to diminish the (number and severity of) adverse events associated with EBRT. Patients with HNC typically receive approximately 60-70 Grays (Gy) of EBRT given as 2 – 3 Gy daily doses over a 6-week timeframe. Patients can experience long-term tumor control following re-irradiation in this setting; however, this approach can cause severe injury to normal tissue structures, significant adverse events and diminished quality of life. Part B of the study will further assess the safety and potential benefits of iopofosine in combination with EBRT in a cohort of up to 24 patients. Adverse events occurring in at least 25% of subjects were fatigue (46)% and cytopenias, specifically, thrombocytopenia (69)%, anemia (77)%, neutropenia (54)%, leukopenia (69)%, and lymphopenia (62)%. There were no serious adverse events occurring in more than 2 subjects.

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 an alpha emitting radio-conjugate program. A collaboration with Orano Med was initiated to validate the potential of this class of PDC radio-conjugates and for the potential development of novel PDCs utilizing Orano Med's unique alpha emitter, lead 212 conjugated to our phospholipid ether. The companies evaluated the new PDCs in three oncology indications. The collaboration successfully met its endpoints with the *in vivo* animal data demonstrating that the PDC combined with an alpha emitting radioisotope resulted in significant reduction in tumor volumes in all animal models tested.
- Expanded ongoing collaboration with biotechnology company IntoCell Inc., combining their novel linker chemistry with our validated targeting platform to create novel next generation phospholipid drug conjugate therapeutics.
- Co-development and commercialization collaboration with LegoChemBio, a clinical stage biotechnology company to utilize their proprietary drug conjugate linker-toxin platform to further enhance our portfolio of next generation PDC therapeutics.

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, iopofosine. 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, iopofosine 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 iopofosine (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 iopofosine 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, iopofosine 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

Iopofosine

Iopofosine 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. Iopofosine is comprised of our proprietary PLE, 18-(p-[I-131]iodophenyl) octadecyl phosphocholine, acting as a cancer-targeting delivery and retention vehicle, covalently labeled with iodine-131, a cytotoxic (cell-killing) radioisotope with a half-life of eight days that is already in common use to treat thyroid, 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 iopofosine 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.

Collectar conducted early dosimetry studies to determine whole body uptake and distribution. 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 iopofosine. 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/m², 31.25 mCi/m² or 37.5 mCi/m².

Tumor treatment with radioactive isotopes has been used as a fundamental cancer therapeutic for decades. The goals of targeted cancer therapy — selective delivery of effective doses of isotopes that destroy tumor tissue, sparing of surrounding normal tissue, and non-accumulation in vital organs such as the liver and kidneys — remain goals of new therapies as well. We believe our targeted delivery technology has the potential to achieve these goals. Iopofosine has been shown in animal models to reliably and near-universally accumulate in cancer cells, including cancer stem cells.

In view of preclinical data suggesting selective uptake and retention of iopofosine in a wide range of solid tumors and in cancer stem cells, its single-agent activity 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 iopofosine as a monotherapy for cancer indications with significant unmet medical need. Iopofosine’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, MM was selected principally because, like many hematologic malignancies, is known to be highly radiosensitive and remains 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 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 iopofosine for the treatment of MM. We initiated our Phase 1 Study of iopofosine 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 iopofosine 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. The safety of doses used for all cohorts dosed was as assessed by an IDMC. The study was successfully completed in February 2020.

In February 2020, final results from a multicenter, Phase 1 clinical trial of iopofosine in r/r MM were presented. The trial was designed to evaluate the safety and potential initial efficacy of iopofosine 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 IDMC did not identify dose-limiting toxicities in any cohort. Of the 26 evaluable patients in the trial, a partial response was observed 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, which may suggest targeting of the tumor.

The Phase 2a study (CLOVER-1) of iopofosine was initiated in July 2017 and conducted in approximately 10 leading cancer centers in the U.S. for patients with relapsed or refractory B-cell hematologic cancers. The hematologic cancers studied in the trial included MM, LPL/WM, CLL/SLL, MZL, MCL, and DLBCL.

In July 2018, we announced that data collected after a single 25mCi/m² IV administration of iopofosine, in patients with r/r aggressive DLBCL. 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 LPL arm with advanced WM showed a 94% reduction in tumor burden and complete resolution in four of five targeted masses after two doses of iopofosine separated by 123 days.

The FDA has granted ODD's and RPDDs for iopofosine 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's review target from 10 months from filing 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 estimates 1 in 3 people will develop cancer in their lifetime. Approximately 1.92 million new cancer cases will be diagnosed in the U.S. in 2022 and approximately 609,360 cancer deaths in the U.S. The global market for cancer drugs reached \$135 billion in annual sales (2020), and with a compound annual growth rate (CAGR) of 7.5% could reach \$275 billion by 2030, according to a report dated November 2021 by Allied Market Research. This growth will be driven by emerging targeted therapies, which are expected to change the cancer treatment landscape (Cowen Report 2020), and an increased use of cancer drug combination regimens.

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 11,000 with prevalence of approximately 110,000 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 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 class of BTKi's, in the form of two drugs (ibrutinib and zanubrutinib), have 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, including ibrutinib. In the salvage therapy (second line or later) setting, BTKi's, and other combinations are considered (bendamustine, proteasome inhibitors, etc.). Ibrutinib and zanubrutinib are the only drugs to receive regulatory approval (in 2015 and 2020, respectively) as a salvage therapy; in late 2019, ibrutinib 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 2020, Global Data Research Group estimated the MM 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 MM 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

[Table of Contents](#)

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 iopofosine Phase 1 and Phase 2 product profile demonstrated in fifth-line patients to date, we believe iopofosine 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 circulate 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. Nine types of B-cell lymphomas include CLL, SLL, MCL, MZL, 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 \$7.6 billion for 2022, with a forecasted increase to \$11.7 billion in 2032 at a 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 iopofosine Phase 2 product profile demonstrated in DLBCL patients to date treated with a single dose, we believe iopofosine 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 NCI 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: The 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 \$490 million in 2022 to \$1.01 billion in 2029. 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

Iopofosine drug product is made via a five-step synthetic process. The release specifications for the drug product have been established and validated. Through process improvements, we have been able to achieve 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 EMA. 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.

The Centre for Probe Development and Commercialization (CPDC), a validated Current Good Manufacturing Practices (cGMPs) manufacturing organization specializing in radiopharmaceuticals, is our exclusive source to supply drug product for our ongoing research and clinical studies, including our Phase 1 and Phase 2 studies of iopofosine. We believe that CPDC and our other third-party manufacturers 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 either entering into an agreement for a contract sales organization (CSO), or a partnering arrangement with one or more biotechnology or pharmaceutical companies 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 our approach 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 iopofosine were evaluated, WM was selected based on iopofosine'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 iopofosine 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 iopofosine.

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 Celleract 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 iopofosine 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.

Iopofosine

We have taken a broad approach to creating market exclusivity for iopofosine 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 iopofosine includes all 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 iopofosine by the FDA for the treatment of MM in December 2014 and for WM in January 2020. Furthermore, 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 iopofosine in additional hematologic and solid tumor orphan designated indications. Our patents have a variety of expected expiration dates with some potentially being extended on a country-by-country basis. In 2018, the FDA granted orphan drug and a RPDD for iopofosine 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 iopofosine 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 iopofosine 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. The collaboration successfully met its endpoints. The *in vivo* animal data demonstrated that the PDC combined with an alpha emitting radioisotope resulted in significant reduction in tumor volumes in all animal models tested. However due to the limited half-life and associated logistical challenges associated with lead-212, Cellectar has elected to advance with an alternative alpha emitting radioisotope.

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.

In July 2021, we expanded our ongoing collaboration with biotechnology company IntoCell Inc., combining their novel linker chemistry with our validated targeting platform to create novel next generation phospholipid drug conjugate therapeutics.

In July 2021, we entered into a co-development and commercialization collaboration with LegoChemBio, a clinical stage biotechnology company to utilize their proprietary drug conjugate linker-toxin platform to further enhance our portfolio of next generation PDC therapeutics.

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 \$17,586,000 and \$10,141,000 for 2021 and 2020, 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, research and development, manufacture, quality control, safety, effectiveness, approval, labeling, distribution, sale, import, export, storage, record-keeping, reporting, advertising and promotion, sampling, and tracking and tracing 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

In the US, the FDA approves and regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and implementing regulations. The failure to comply with requirements under the FDCA and other applicable laws at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties.

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, and formulation studies, performed under the FDA's Good Laboratory Practices regulations, referred to herein as GLP;
- submission to the FDA of an IND, which must become effective before human clinical studies may commence;
- approval by an independent institutional review board (IRB) for each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical studies performed under the FDA's Good Clinical Practices regulations, to evaluate the drug's safety and effectiveness for its intended uses;
- submission of a marketing application to the FDA for one or more proposed indications;
- review by an FDA advisory committee, if requested by the FDA;
- Satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities in which the drug is manufactured, processed, packed, or held complies with current Good Manufacturing Practices (cGMP), requirements and standards designed to that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

[Table of Contents](#)

- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and potentially post-market requirement, or PMR, and commitment, or PMC, studies.

Pre-Clinical Testing

During pre-clinical testing, studies are performed with respect to the chemical and physical properties of candidate formulations. Preclinical studies include laboratory evaluation as well as in vitro and animal studies to assess product chemistry, formulation, and toxicity, and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. These studies are subject to applicable 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. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, including but not limited to animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

Submission of IND

An IND must be submitted to the FDA and become effective before studies in humans may commence. An IND is an exemption from the FDCA that allows an unapproved new drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. In support of the IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the submission of each IND before clinical trials may begin. At any time during this 30-day period, or thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin or resume. An IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB can suspend or terminate approval of a clinical trial.

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. During Phase 1, sufficient information about the drug's safety and tolerability, pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. In Phase 2, controlled clinical studies are generally conducted in larger groups of patients having the target disease or condition in order to determine the common short-term side effects and risks associated with the drug, and to obtain preliminary data on the safety and 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 of effectiveness and safety of the product candidate that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling, 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.

[Table of Contents](#)

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 an active reference control, however, if testing in a patient population that does not have an approved treatment and where it would be unethical to only provide a placebo, single-arm, open label studies may be acceptable in coordination with the FDA. 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.

At any time during this 30-day period, or thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. 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. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin or resume. 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, the termination of ongoing clinical trials and 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 support an application for product approval. 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, among other things, a substantial amount of data and other information concerning the safety and effectiveness of the compound from preclinical, laboratory, animal, toxicology 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. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease or condition to be treated by the drug, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity.

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 2022, the application fee for an application requiring clinical data alone is \$ 3,117,218, although we may qualify for a waiver of these FDA filing fees since we are a small business entity. In addition, the sponsor of an approved NDA is also subject to annual program fees. Application and program fees are typically increased annually.

Each NDA submitted for FDA approval is usually reviewed for administrative completeness to permit a substantive review within 60 days following receipt of the application. If deemed complete, the FDA will “file” the NDA, thereby triggering substantive review of the application. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has established performance goals for the review of NDAs— six months from the filing date for applications subject to priority review and ten months from the filing date for applications subject to standard review. However, the FDA is not legally required to complete its review within these periods, and these performance goals may change over time.

The FDA’s review of an application may involve review and recommendations by an independent FDA advisory committee. The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is

not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA intends to review such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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, including Phase 4 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 REMS, or otherwise limit the scope of any approval. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and submission to the FDA of a supplemental NDA (sNDA), which may require FDA review and approval prior to implementation. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Expedited Approval Pathways

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as Fast Track designation, Breakthrough Therapy designation and Priority Review designation. In addition, accelerated approval offers the potential for approval based on a surrogate or intermediate clinical endpoint. In May 2014, the FDA published a final Guidance for Industry titled "Expedited Programs for Serious Conditions Drugs and Biologics," which provides guidance on the FDA programs that are intended to facilitate and expedite development and review of new drug candidates as well as threshold criteria generally applicable to concluding that a drug candidate is a candidate for these expedited development and review programs.

The FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and nonclinical or clinical data demonstrate the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's review clock for a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing available therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross disciplinary project lead for the review team; rolling review; and, taking other steps to design the clinical trials in an efficient manner.

The FDA intends to review applications for standard review drug products within ten months of the 60-day filing date; and applications for priority review drugs within six months. Priority review can be applied to drugs that the FDA determines treat a serious condition, and if approved, would offer a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or

[Table of Contents](#)

substantial reduction of a treatment limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation.

RPDD by the FDA enables priority review voucher (PRV) eligibility upon U.S. market approval of a designated drug for rare pediatric diseases. The RPDD-PRV program is intended to encourage development of therapies to prevent and treat rare pediatric diseases. The voucher, which is awarded upon NDA or BLA approval to the sponsor of a designated RPDD can be sold or transferred to another entity and used by the holder to receive priority review for a future NDA or BLA submission, which reduces the FDA review time of such future submission from ten to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides a meaningful therapeutic advantage to patients over available treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such drug for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality (IMM) and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. In addition, all promotional materials for drugs approved under accelerated regulations are subject to prior review by the FDA.

Post NDA Regulation

Significant and pervasive continuing 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 and its implementing regulations which, among other things, impose various requirements in connection with the distribution of product samples to physicians. The FDA also enforces the Drug Supply Chain Security Act, or DSCSA, which regulates the distribution and tracing of prescription drugs and prescription drug samples at the federal level, sets minimum standards for the regulation of drug distributors by the states, and imposes requirements to track and trace drug products, ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and

these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and consistent with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

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 the 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.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition, generally meaning that it affects fewer than 200,000 individuals in the US, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the US for treatment of the disease or condition will be recovered from sales of the product. A company must request ODD before submitting an NDA for the drug and rare disease or condition. ODD does not shorten the goal dates for the regulatory review and approval process, although it does convey certain advantages such as tax benefits and exemption from the application fee. After the FDA grants ODD, the name of the drug and its potential orphan-designated use are disclosed publicly by the FDA.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same drug for the same indication for seven years, except in certain limited circumstances. Orphan exclusivity does not block the approval of a different drug for the same rare disease or condition, nor does it block the approval of the same drug for different indications. If a drug designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same drug for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act of 2012 (the FDASIA), sponsors must also submit pediatric study plans prior to the assessment data.

[Table of Contents](#)

Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the U.S. and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress established an abbreviated regulatory scheme allowing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application (ANDA) to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug (RLD).

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form and the strength of the drug. An applicant may submit an ANDA suitability petition to request the FDA's prior permission to submit an abbreviated application for a drug that differs from the RLD in route of administration, dosage form, or strength, or for a drug that has one different active ingredient in a fixed combination drug product (i.e., a drug product with multiple active ingredients). At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists may consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

505(b)(2) New Drug Applications

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA pursuant to an NDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant, and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous findings of safety and effectiveness is scientifically and legally appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional bridging studies or measurements, including clinical trials, to support the change from the previously approved reference drug. The FDA may then approve the new drug candidate for all, or some, of the label indications for which the reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Hatch-Waxman Patent Certification and the 30-month Stay

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Orange Book.

When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Specifically, the applicant must certify that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a statement certifying that its proposed ANDA label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent, known as a Section VIII statement. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory process. The allowable patent term extension is typically calculated as one-half the time between the effective date of an IND application and the submission date of a NDA, plus the time between NDA submission date and the NDA approval date up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years from the date of product approval. Only one patent applicable to an approved drug is eligible for extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent in question. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements.

Exclusivity Under the Hatch-Waxman Amendments

In addition, under the Hatch-Waxman Amendments, the FDA may not approve an ANDA or 505(b)(2) NDA referencing a particular drug until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity (NCE). For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be submitted to the FDA until the expiration of five years from the date the NDA is approved, unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs or 505(b)(2) NDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; it does, however, block the

FDA from approving ANDAs or 505(b)(2) NDAs during the period of exclusivity. The FDA typically makes decisions about awards of data exclusivity shortly before a product is approved.

Other U.S. Regulatory Requirements

In the U.S., the research, manufacturing, distribution, marketing, sale, and promotion of drug and biological products are subject to regulation by various federal, state, and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (CMS), other agencies of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General of the Department of Health and Human Services), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. Restrictions under applicable healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which is a criminal law that prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. The intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (the Affordable Care Act) to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other, including, for example, consulting/speaking arrangements, discount and rebate offers, grants, charitable contributions, and patient support offerings, among others. A conviction for violation of the federal Anti-Kickback Statute can result in criminal fines and/or imprisonment and requires mandatory exclusion from participation in federal health care programs. Exclusion may also be imposed if the government determines that an entity has committed acts that are prohibited by the federal Anti-Kickback Statute. Although there are a number of statutory exceptions and regulatory safe harbors to the federal Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, or engaging such individuals as speakers or consultants, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor;
- the federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act (FCA), which prohibits, among other things, (i) knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent; (ii) knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim; (iii) knowingly making, using or causing to be made or used a false record or statement material to an obligation to pay money to the government; or (iv) knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Private individuals, commonly known as “whistleblowers,” can bring FCA *qui tam* actions, on behalf of the government and may share in amounts paid by the entity to the government in recovery or settlement. Pharmaceutical companies have been investigated and/or subject to government enforcement actions asserting liability under the FCA in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Moreover, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false or fraudulent claim or statement for violations. Such per-claim penalties are currently set at \$11,803 to \$23,607 per false claim or statement for penalties assessed after December 13, 2021, with respect to violations occurring after November 2, 2015. Criminal penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program,

[Table of Contents](#)

including any third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements or representations, or making false statements relating to healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, including protected health information (PHI). HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, implemented as the Open Payments Program, which requires certain manufacturers of drugs, devices, biologics and medical supplies, among others, to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services (HHS), information related to payments and other transfers of value made by that entity to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, individual imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, possible exclusion from participation in federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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.

Pursuant to the Medicaid Drug Rebate Statute (42 U.S.C. § 1396r-8(a)(1)), we will be required to participate in the Medicaid Drug Rebate Program (MDRP) in order for federal payment to be available for our products under Medicaid and Medicare Part B. Medicaid is a government health insurance program for eligible low-income adults, children, families, pregnant women, and people with certain disabilities. It is jointly funded by the federal and state governments, and it is administered by individual states within parameters established by the federal government. As a result, coverage and reimbursement requirements for drugs and biologics vary by state. For example, drugs and biologics may be covered under the medical or pharmacy benefit, and state Medicaid programs may impose different utilization management controls, such as prior authorization, step therapy, or quantity limits on drugs and biologics, subject to federal limitations for such controls. But all states must generally provide coverage and reimbursement for a manufacturer's covered outpatient drugs, as that term is defined by applicable law, if a manufacturer participates in the MDRP.

Under the MDRP, we will be required to, among other things, pay a rebate to each state Medicaid program for quantities of our products utilized on an outpatient basis (with some exceptions) that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. MDRP rebates are calculated using a statutory formula, state-reported utilization data, and pricing data that are calculated and reported by us on a monthly and quarterly basis to CMS. These data include the average manufacturer price and, in the case of single source and innovator multiple source products, the best price for each drug.

In addition to participating in the MDRP, federal law requires manufacturers to participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities only include health care organizations that have certain federal designations or receive funding from specific federal programs, including Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and certain types of hospitals and specialized clinics, as well as certain hospitals that serve a disproportionate share of low-income patients. The Affordable Care Act expanded the 340B program to include additional types of covered entities: certain children's hospitals, certain free-standing cancer hospitals, critical access hospitals, certain rural referral centers and certain sole community hospitals, each as defined by the Affordable Care Act. However, "orphan drugs" i.e., those designated under section 526 of the federal Food, Drug, and Cosmetic Act (FDCA) are exempted from the ceiling price requirements for these eligible entities added by the Affordable Care Act (except for certain children's hospitals). The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the MDRP, and in general, products subject to the MDRP are also subject to the 340B ceiling price calculation and discount requirement. In addition, after multiple delays, the final rule implementing civil monetary penalties against manufacturers for instances of overcharging 340B covered entities became effective on January 1, 2019. Accordingly, we could be subject to such penalties if the government were to find that we knowingly and intentionally overcharged a 340B covered entity.

Federal law requires that for a company to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and grantees, it also must participate in the Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. To participate, we will be required to enter into an FSS contract and other agreements with the VA for our products, which may qualify as "covered drugs." Under these agreements, we would need to make our products available to the "Big Four" federal agencies—the VA, the Department of Defense (DoD), the Public Health Service (including the Indian Health Service), and the Coast Guard—at pricing that is capped pursuant to a

[Table of Contents](#)

statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992 (VHCA). The FCP is based on a weighted average non-federal average manufacturer price (Non-FAMP), which manufacturers are required to report on a quarterly and annual basis to the VA. Pursuant to the VHCA, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to a penalty for each item of false information and could result in other potential liability as well, including liability under the False Claims Act.

FSS contracts are federal procurement contracts that include standard government terms and conditions, separate pricing for each product, and extensive disclosure and certification requirements. All items on FSS contracts are subject to a standard FSS contract clause that requires FSS contract price reductions under certain circumstances where pricing is reduced to an agreed “tracking customer.” Further, in addition to the “Big Four” agencies, all other federal agencies and some non-federal entities are authorized to purchase off FSS contracts. FSS contractors are permitted to charge FSS purchasers other than the Big Four agencies “negotiated pricing” for covered drugs that is not capped by the FCP; instead, such pricing is negotiated based on a mandatory disclosure of the contractor’s commercial “most favored customer” pricing.

In addition, pursuant to regulations issued by the DoD to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, each of our covered drugs will be listed on an agreement with the Defense Health Agency (DHA) under which we will agree to honor the “Big Four” pricing for our products when they are dispensed to TRICARE beneficiaries by TRICARE retail network pharmacies. More specifically, we will agree to provide rebates (or refunds) on such utilization. Companies are required to enter into a DHA Agreement for “covered drug” products in order for the covered drug to be eligible for DoD formulary inclusion and available to TRICARE beneficiaries without preauthorization. The formula for determining the rebate is established in the regulations and our DHA agreement and is based on the difference between the annual Non-FAMP and the FCP (as described above, these price points are required to be calculated by us under the VHCA).

Significant uncertainty exists as to the pricing and reimbursement of products approved by the FDA and other government authorities. For example, there have been several recent US Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. In the US, some of these proposals at the federal level have included directing Medicare to negotiate directly with manufacturers for the costliest drugs; various Medicare Part D and Medicaid reforms; price reporting transparency; importation rulemaking; an international pricing index proposal to require additional discounts to Medicare, as well as a proposal requiring manufacturers to pay a rebate to the federal government if the price of a Medicare Part B or Part D drug increases more than the rate of inflation. For example, included in the Consolidated Appropriations Act of 2021 were several drug price reporting and transparency measures, such as a new requirement for certain Medicare plans to develop tools to display Medicare Part D prescription drug benefit information in real time and for group and health insurance issuers to report information on pharmacy benefit and drug costs to the Secretaries of the Departments of Health and Human Services, Labor and the Treasury. Additionally, on March 11, 2021, Congress enacted the American Rescue Plan Act of 2021, which included among its provisions a sunset of the Affordable Care Act’s cap on pharmaceutical manufacturers’ rebate liability under the MDRP. Under the Affordable Care Act, manufacturers’ rebate liability was capped at 100% of the average manufacturer price for a covered outpatient drug. Effective January 1, 2024, manufacturers’ MDRP rebate liability will no longer be capped, potentially resulting in a manufacturer paying more in MDRP rebates than it receives on the sale of certain covered outpatient drugs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing, cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for the product. It is likely that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for a pharmaceutical manufacturer’s products or additional pricing pressure.

Employees and Human Capital

As of December 31, 2021, we had twelve employees, all of whom are full-time employees. Of these twelve employees, six employees were engaged in research and development. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purpose of our equity incentive plans is to attract, retain and reward personnel through the granting of stock-based compensation awards in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Legal Proceedings

On October 15, 2021, the Company filed a lawsuit against Dr. Jamey Weichert, a former director and executive officer of the Company (“Dr. Weichert”) and Dr. Anatoly Pinchuk, a former employee and consultant of the Company (“Dr. Pinchuk”) in the U.S. District Court for the Western District of Wisconsin. The Company is alleging, among other claims, that Dr. Weichert and Dr. Pinchuk breached their contractual and fiduciary duties to the Company by diverting intellectual property that rightfully belonged to the Company to a company controlled by Dr. Weichert. Although the disputed intellectual property does not directly affect the clinical studies of iopofosine or other compounds in the Company’s clinical pipeline, the disputed intellectual property may potentially enhance future areas of research, development and commercialization. The Company is seeking monetary damages, injunctive relief, and reasonable attorneys’ fees and expenses in conjunction with this lawsuit.

Corporate Information

Cellectar Biosciences, Inc., formerly known as Novelos Therapeutics, Inc., was incorporated in Delaware in June 1996. On April 8, 2011, the Company entered into a business combination with 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.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained elsewhere in this Annual Report on Form 10-K, including Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Part II, Item 8. “Financial Statements,” as well as our other filings with the Securities and Exchange Commission, or SEC, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations, cash flows and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Summary of Risk Factors

Investing in our securities involves a high degree of risk. You should carefully consider all of the risks discussed in Part I, Item 1A. “Risk Factors” of this Annual Report on Form 10-K, not just those discussed under this “Summary of Risk Factors” before making a decision to invest in our securities. The following is a list of some of these risks:

- We will require additional capital in order to continue our operations and may have difficulty raising additional capital.
- We rely on a collaborative outsourced business model, and disruptions with our third-party collaborators, including potential disruptions at our sole source supplier of iopofosine, Centre for Probe Development and Commercialization may impede our ability to gain FDA approval and delay or impair commercialization of any products.
- We cannot assure the successful development and commercialization of our compounds in development.
- 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.

[Table of Contents](#)

- The FDA has granted rare pediatric disease designation, RPDD, to iopofosine for treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma; however, we may not be able to realize any value from such designation.
- 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.
- 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.
- Controls we or our third-party collaborators have in place to ensure compliance with all applicable laws and regulations may not be effective.
- 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.
- Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of our product candidates.
- 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.
- Acceptance of our products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues.
- Regulatory approval for any approved product is limited by the FDA, the European Commission and other regulators to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and we may incur significant liability if it is determined that we are promoting the "off-label" use of any of our future product candidates if approved.
- Any product for which we have obtained regulatory approval, or for which we obtain approval in the future, is subject to, or will be subject to, extensive ongoing regulatory requirements by the FDA, EMA and other comparable regulatory authorities, and if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, we may be subject to penalties, we may be unable to generate revenue from the sale of such products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased.
- The COVID-19 pandemic as well as conflicts, military actions, terrorist attacks, natural disasters, public health crises, cyber-attacks and general instability could materially adversely affect our business.
- Failure to meet Nasdaq's continued listing requirements could result in the delisting of our common stock, negatively impact the price of our common stock and negatively impact our ability to raise additional capital.
- Our stock price has experienced price fluctuations.

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. As of December 31, 2021, our consolidated cash balance was approximately \$35.7 million. We believe our cash balance as of December 31, 2021, 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

[Table of Contents](#)

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

[Table of Contents](#)

could have on our business. The continued impacts 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 iopofosine 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. We cannot currently fully forecast the scope of impact that the COVID-19 pandemic may have overall on clinical study results, including the timing thereof, or our ability to continue to treat patients enrolled in our trials, enroll and assess new patients, supply study drug and obtain complete data points in accordance with study protocol.

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. Due to the ongoing COVID-19 pandemic, it is also possible that we could experience delays in the timing of our interactions with regulatory authorities due to absenteeism by governmental employees or the diversion of regulatory authority efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay or limit our ability to make planned regulatory submissions or develop and commercialize our product candidates on anticipated timelines. Health regulatory agencies globally may experience prolonged disruptions in their operations as a result of the COVID-19 pandemic. For example, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products inspections of domestic manufacturing facilities through April 2020. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. On July 10, 2020, the FDA announced that it is working toward the goal of restarting on-site inspections it deems to be “mission critical.” On August 19, 2020, the FDA published guidance clarifying how it intends to conduct inspections during the COVID-19 pandemic, including how it plans to determine which inspections are “mission critical.” The Agency published an updated form of this guidance on May 17, 2021. Additionally, on April 14, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. It is unclear how the FDA’s policies and guidance will impact any inspections of our facilities, including our clinical trial sites. Regulatory authorities outside the US may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. It is unknown how long these disruptions could continue. Any de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the completion of our clinical trials.

Although we expect no material impact on the supply of iopofosine for our current clinical studies, should our third-party manufacturers experience extended disruptions, we could experience delays in future trials. Further, in June 2020, the 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. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical manufacturing and distribution industry in particular are unclear, and changes in the supply, demand or available sources of energy and the regulatory and other costs associated with energy production and delivery may affect the availability or cost of goods and services, including raw materials and other natural resources, necessary to run our businesses. The uncertainty and economic disruption resulting from hostilities, military action, acts of terrorism, natural disasters, public health crises or cyber-attacks may impact our operations or those of our suppliers. Accordingly, any conflict, military action, terrorist attack, natural disasters, 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.

War, terrorism, other acts of violence, or natural or manmade disasters may affect the markets in which we operate, our patients and resources required in our research and development activities.

Our business may be adversely affected by political instability, disruption or destruction in a geographic region in which we operate, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest, and natural or manmade disasters, including famine, flood, fire, earthquake, storm or pandemic events and spread of disease, such as the COVID-19 pandemic and the significant military action against Ukraine by Russia. Such events may affect our business by increasing prices for resources required in our research and development activities or limiting our access to patients for our clinical trials which may delay our progress on one or more of our clinical or preclinical drug product candidates.

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.

Failure to meet investor and stakeholder expectations regarding environmental, social and corporate governance, or “ESG” matters may damage our reputation.

There is an increasing focus from certain investors, employees and other stakeholders concerning ESG matters. Additionally, public interest and legislative pressure related to public companies’ ESG practices continue to grow. If our ESG practices fail to meet investor, employee or other stakeholders’ evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, Board of Directors and employee diversity, human capital management, corporate governance and transparency, our reputation, brand, appeal to investors and employee retention may be negatively impacted, which could have a material adverse effect on our business or financial condition.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Our ability to utilize our federal net operating loss and tax credit carryforwards may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code). The limitations apply if we experience an “ownership change”, generally defined as a greater than 50 percentage point change in the ownership of our equity by certain stockholders over a rolling three-year period. Similar provisions of state tax law may also apply. We have not evaluated whether such an ownership change has occurred previously. If we have experienced an ownership change at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change and, consequently, the limitations under Sections 382 and 383 of the Code. As a result, if or when we earn net taxable income, our ability to use our net operating loss carryforwards and other tax attributes to offset such taxable income may be subject to limitations, which could adversely affect our future cash flows.

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 iopofosine, 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 former corporate headquarters in Wisconsin 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 iopofosine.

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. This may lead to the stopping or delay of our clinical trials or commercial manufacturing activity. For example, in 2018, our CMO, CPDC, was placed on import alert following an FDA inspection, which resulted in our studies being placed on a clinical hold, until we received an FDA exception allowing us to import our study drug for use in clinical trials. The import alert on CPDC was removed in 2019. 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.

Our current and anticipated future dependence upon these third-party manufacturers may adversely affect our ability to develop and commercialize product candidates on a timely and competitive basis, which could have an adverse effect on sales, results of operations and financial condition. If we were required to transfer manufacturing processes to other third-party manufacturers and we were able to identify an alternative manufacturer, we would still need to satisfy various regulatory requirements. Satisfaction of these requirements could cause us to experience significant delays in receiving an adequate supply of our products and products in development and could be costly. Moreover, we may not be able to transfer processes that are proprietary to the manufacturer, if any. These manufacturers may not be able to produce material on a timely basis or manufacture material at the quality level or in the quantity required to meet our development timelines and applicable regulatory requirements and may also experience a shortage in qualified personnel, including due to the impacts of the COVID-19 pandemic. We may not be able to maintain or renew our existing third-party manufacturing arrangements, or enter into new arrangements, on acceptable terms, or at all. Our third-party manufacturers could terminate or decline to renew our manufacturing arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for the production of materials in sufficient quantity and of sufficient quality on

acceptable terms, our planned clinical trials may be significantly delayed. Manufacturing delays could postpone the filing of our IND applications and/or the initiation or completion of clinical trials that we have currently planned or may plan in the future.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, the EMA, national competent authorities in the EU and UK and other federal and state government and regulatory agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards and they may not be able to comply. Switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly on acceptable terms, or at all. Additionally, if we are required to enter into new supply arrangements, we may not be able to obtain approval from the FDA of any alternate supplier in a timely manner, or at all, which could delay or prevent the clinical development and commercialization of any related product candidates. Failure of our third-party manufacturers or us to comply with applicable regulations, whether due to the impacts of the ongoing COVID-19 pandemic or otherwise, could result in sanctions being imposed on us, including fines, civil penalties, delays in or failure to grant marketing approval of our product candidates, injunctions, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products and compounds, operating restrictions and criminal prosecutions, warning or similar letters or civil, criminal or administrative sanctions against the company, any of which could adversely affect our business.

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 iopofosine 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 inherent in the development of pharmaceutical products, including the following:

- The inherent difficulty in selecting the right drug and drug target and avoiding unwanted side effects, as well as unanticipated problems relating to product development, testing, enrollment, obtaining regulatory approvals, maintaining regulatory compliance, manufacturing, competition and costs and expenses that may exceed current estimates;

[Table of Contents](#)

- 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. In future clinical trials, we or our partners may discover additional side effects and/or a higher frequency of side effects than those observed in previously completed clinical trials.
- Future clinical study results may be inconsistent with testing results obtained to-date. The results of preliminary and mid-stage clinical trials do not necessarily predict clinical or commercial success, and larger later-stage clinical trials may fail to confirm the results observed in the previous clinical trials.
- A clinical trial may show that a product candidate is safe and effective for certain patient populations in a particular indication, but other clinical trials may fail to confirm those results in a subset of that population or in a different patient population, which may limit the potential market for that product candidate.
- 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.

With respect to our own compounds in development, we have established anticipated timelines with respect to the initiation of clinical trials based on existing knowledge of the compounds. However, we cannot provide assurance that we will meet any of these timelines for clinical development. Additionally, the initial results of a completed earlier clinical trial of a product candidate do not necessarily predict final results and the results may not be repeated in later clinical trials.

Because of the uncertainty of whether the accumulated preclinical evidence (PK, pharmacodynamic, safety and/or other factors) or early clinical results will be observed in later clinical trials, we can make no assurances regarding the likely results from our future clinical trials or the impact of those results on our business.

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.

We cannot predict whether regulatory clearance or approval will be obtained for any product that we hope to develop. Of particular significance to us are the requirements relating to research and development and testing. The activities associated with the

[Table of Contents](#)

research, development and commercialization of iopofosine and other future candidates in our pipeline must undergo extensive clinical trials, which can take many years and require substantial expenditures, subject to extensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. The process of obtaining regulatory approvals in the U.S. and other foreign jurisdictions is expensive, and lengthy, if approval is obtained at all.

Before commencing clinical trials in humans, we, or our collaborative partners, will need to submit and receive approval from the FDA of an IND application. Clinical trials are subject to oversight by institutional review boards and the FDA and:

- must be conducted in conformance with the FDA's good clinical practices and other applicable regulations;
- must meet requirements for institutional review board oversight;
- must meet requirements for informed consent;
- are subject to continuing FDA and regulatory oversight;
- may require large numbers of test subjects; and
- may be suspended by us, our collaborators or the FDA at any time if it is believed that the subjects participating in these trials are being exposed to unacceptable health risks or if the FDA finds deficiencies in the IND or the conduct of these trials.

We do not know whether we will be permitted to undertake clinical trials of potential products beyond the trials already concluded and the trials currently in process. It will take us or our collaborative partners several years to complete any such testing, and failure can occur at any stage of testing. Interim results of trials do not necessarily predict final results, and acceptable results in early trials may not be repeated in later trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials.

Before receiving FDA approval or similar approval in the European Union or other jurisdiction to market a product, we must demonstrate with substantial clinical evidence that the product is safe and effective in the patient population and the indication that will be treated. Data obtained from preclinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory approvals. Our clinical trials may fail to produce results satisfactory to the FDA or regulatory authorities in other jurisdictions. The regulatory process also requires preclinical testing, and data obtained from preclinical and clinical activities are susceptible to varying interpretations. In connection with clinical trials of our product candidates, we may face the following risks among others:

- the product candidate may not prove to be effective;
- the product candidate may cause harmful side effects;
- the clinical results may not replicate the results of earlier, smaller trials;
- we or third parties with whom we collaborate, may be significantly impacted by the evolving impacts of the ongoing COVID-19 pandemic;
- we, or the FDA or similar foreign regulatory authorities, may delay, terminate or suspend the trials;
- our results may not be statistically significant;
- patient recruitment and enrollment may be slower than expected;
- patients may drop out of the trials or otherwise not enroll; and
- regulatory and clinical trial requirements, interpretations or guidance may change.

The FDA has substantial discretion in the approval process and may refuse to approve any NDA or sNDA and decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. Varying interpretations of the data obtained

[Table of Contents](#)

from preclinical and clinical testing could delay, limit or prevent regulatory approval of our products for any individual, additional indications.

In order to be commercially viable, we must successfully research, develop, manufacture, introduce, obtain the required regulatory approval described above for, our product candidates, in order to market and distribute our product candidates. 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 addition, delays or rejections may be encountered based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, adverse publicity, as well as other regulatory action against our potential products or us.

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.

If regulatory approval of a product is granted, this approval will be limited to those indications or disease states and conditions for which the product is demonstrated through clinical trials to be safe and efficacious. We cannot assure you that any compound developed by us, alone or with others, will prove to be safe and efficacious in clinical trials and will meet all of the applicable regulatory requirements needed to receive marketing 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.

Outside the US, our ability, or that of our collaborative partners, to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically includes all of the risks and costs associated with FDA approval described above and may also include additional risks and costs, such as the risk that such foreign regulatory authorities, which often have different regulatory and clinical trial requirements, interpretations and guidance from the FDA, may require additional clinical trials or results for approval of a product candidate, any of which could result in delays, significant additional costs or failure to obtain such regulatory approval. There can be no assurance, however, that we or our collaborative partners will not have to provide additional information or analysis, or conduct additional clinical trials, before receiving approval to market product candidates.

The FDA has granted rare pediatric disease designation, RPDD, to iopofosine for treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma; however, we may not be able to realize any value from such designation.

Our iopofosine 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, or a patient population greater than 200,000 in the U.S. when there is no reasonable expectation that the cost of developing and making available the drug in the U.S. will be recovered from sales in the U.S. for that drug or biological product. 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 redeemed to obtain priority review for a subsequent NDA or BLA. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application.

The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval. In addition, the priority review voucher is only awarded to an NCE. Thus, if iopofosine is approved first for an indication that is not a rare pediatric disease, our application may not be eligible to receive the voucher. 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 iopofosine 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.

In addition, we typically rely on third-party clinical investigators to conduct our clinical trials and other third-party organizations to oversee the operations of such trials and to perform data collection and analysis. The clinical investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. Failure of the third-party organizations to meet their obligations, whether due to the impacts of the ongoing COVID-19 pandemic or otherwise, could adversely affect clinical development of our products. As a result, we may face additional delaying factors outside our control if these parties do not perform

their obligations in a timely fashion. For example, any number of those issues could arise with our clinical trials causing a delay. Delays of this sort could occur for the reasons identified above or other reasons. If we have delays in conducting the clinical trials or obtaining regulatory approvals, our product development costs will increase. For example, we may need to make additional payments to third-party investigators and organizations to retain their services or we may need to pay recruitment incentives. If the delays are significant, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to become profitable will be delayed. Moreover, these third-party investigators and organizations may also have relationships with other commercial entities, some of which may compete with us. If these third-party investigators and organizations assist our competitors at our expense, it could harm our competitive position.

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 not be able to initiate or continue clinical studies or trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials as required by the FDA or other regulatory authorities, whether due to the impacts of the ongoing COVID-19 pandemic or otherwise. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our clinical trials may be delayed, or our clinical trials could become too expensive to complete. Significant delays in clinical testing could negatively impact our product development costs and timing. Our estimates regarding timing are based on a number of assumptions, including assumptions based on past experience with our other clinical programs. If we are unable to enroll the patients in these trials at the projected rate, the completion of the clinical program could be delayed and the costs of conducting the program could increase, either of which could harm our business.

Due to the evolving effects of the COVID-19 pandemic, for several of our development programs, we are experiencing a disruption or delay in our ability to enroll and assess patients, maintain patient enrollment, supply study drug, report trial results, or interact with regulators, ethics committees or other important agencies due to limitations in employee resources or otherwise. In addition, some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 may adversely impact our clinical trial operations. In light of the evolving effects of the COVID-19 pandemic, we have taken, and will continue to take, measures to implement remote and virtual approaches to clinical development, including remote patient monitoring where possible, and if the COVID-19 pandemic continues and persists for an extended period of time, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

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. We have been granted ODD in the U.S. for iopofosine 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 iopofosine as a therapeutic for the treatment of multiple myeloma and Waldenstrom's macroglobulinemia.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the US, or a patient population greater than 200,000 in the US where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the US. In the US, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Even though we have received orphan drug designation as described above, we may not be the first to obtain marketing approval for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. 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. In addition, exclusive marketing rights in the US for iopofosine for an orphan-designated indication or any future product candidate may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. 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. 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 product with orphan exclusivity. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. In addition, exclusive marketing rights in the US for ipofosine or any future product candidate may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Further, the seven-year marketing exclusivity, if granted, 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. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of our product candidates.

If a product candidate is intended for the treatment of a serious or life-threatening condition and the product candidate demonstrates the potential to address unmet medical need for this condition, the sponsor may apply for FDA fast track designation. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the review team during product development, and the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

However, fast track designation does not change the standards for approval and does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. As a result, while the FDA has granted fast track designation to ipofosine for WM patients having received two or more prior treatment regimens and/or we may seek and receive fast track designation for our future product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

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 non patented 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;
- the timing of market introduction of the product as well as competitive products;
- the clinical indications for which the product is approved;
- establishing and demonstrating the advantages, safety and efficacy of our technologies;
- relative convenience and ease of administration, and the convenience of prescribing, administering and initiating patients on the product and the length of time the patient is on the product;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of physicians to change their current treatment practices;
- the willingness of hospitals and hospital systems to include our product candidates as treatment options;
- demonstration of efficacy and safety in clinical trials;
- the prevalence and severity of any side effects;
- the ability to offer product candidates for sale at competitive prices;
- the price we charge for our product candidates;
- the strength of marketing and distribution support;
- impacts due to the evolving effects of the COVID-19 pandemic;
- the ability to distinguish safety and efficacy from existing, less expensive generic alternative therapies, if any;
- the potential and perceived value and advantages of the product over alternative treatments;

[Table of Contents](#)

- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- 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. If we are unable to sustain anticipated level of sales growth from our products, if approved, we may need to reduce our operating expenses, access other sources of cash or otherwise modify our business plans, which could have a negative impact on our business, financial condition and results of operations.

Regulatory approval for any approved product is limited by the FDA, the European Commission and other regulators to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and we may incur significant liability if it is determined that we are promoting the “off-label” use of any of our future product candidates if approved.

Any regulatory approval is limited to those specific diseases, indications and patient populations for which a product is deemed to be safe and effective by the FDA, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency and other regulators. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product’s labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications and patient populations that are specifically approved by the FDA or similar regulatory authorities in jurisdictions outside the U.S. These “off-label” uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. We have implemented compliance and monitoring policies and procedures, including a process for internal review of promotional materials, to deter the promotion for off-label uses. We cannot guarantee that these compliance activities will prevent or timely detect off-label promotion by sales representatives or other personnel in their communications with health care professionals, patients and others, particularly if these activities are concealed from the Company. Regulatory authorities in the US generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with the FDA’s or other competent national authority’s regulations or guidelines, we may be subject to warnings from, or enforcement action by, these regulatory authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require a recall or institute fines, which could result in the disgorgement of money, operating restrictions, injunctions or civil or criminal enforcement, and other consequences, any of which could harm our business.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading and non-promotional scientific exchange concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. If the FDA or other regulatory or enforcement authorities determine that our communications regarding our marketed product are not in compliance with the relevant regulatory requirements and that we have improperly promoted off-label uses, or that our communications regarding our investigational products are not in compliance with the relevant regulatory requirements and that we have improperly engaged in pre-approval promotion, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Any product for which we have obtained regulatory approval, or for which we obtain approval in the future, is subject to, or will be subject to, extensive ongoing regulatory requirements by the FDA, EMA and other comparable regulatory authorities, and if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, we may be subject to penalties, we may be unable to generate revenue from the sale of such products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased.

Any product for which we have obtain regulatory approval in the future, along with the manufacturing processes and practices, post-approval clinical research, product labeling, advertising and promotional activities for such product, are subject to continual requirements of, and review by, the FDA, the EMA and other comparable international regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, current good manufacturing practices (cGMP) requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians, import and export requirements and recordkeeping. If we or our suppliers encounter manufacturing, quality or compliance difficulties with respect to any of our product candidates, when and if approved, whether due to the impacts of the ongoing COVID-19 pandemic (including as a result of disruptions of global shipping and the transport of products) or otherwise, we may be unable to obtain or maintain regulatory approval or meet commercial demand for such products, which could adversely affect our business, financial conditions, results of operations and growth prospects.

In addition, the FDA often requires post-marketing testing and surveillance to monitor the effects of products. The FDA, the EMA and other comparable international regulatory agencies may condition approval of our product candidates on the completion of such post-marketing clinical studies. These post-marketing studies may suggest that a product causes undesirable side effects or may present a risk to the patient. Additionally, the FDA may require a REMS to help ensure that the benefits of the drug outweigh its risks. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, requirements that patients enroll in a registry or undergo certain health evaluations or other measures that the FDA deems necessary to ensure the safe use of the drug.

Discovery after approval of previously unknown problems with any of our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on product manufacturing processes;
- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- untitled or warning letters or other adverse publicity;
- withdrawal of products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- refusal to permit the import or export of our products;
- product seizure;
- fines, restitution or disgorgement of profits or revenue;
- refusal to allow us to enter into supply contracts, including government contracts;

[Table of Contents](#)

- injunctions; or
- imposition of civil or criminal penalties.

If such regulatory actions are taken, the value of our company and our operating results will be adversely affected. Additionally, if the FDA, the EMA or any other comparable international regulatory agency withdraws its approval of a product that is or may be approved, we will be unable to generate revenue from the sale of that product in the relevant jurisdiction, our potential for generating positive cash flow will be diminished and the capital necessary to fund our operations will be increased. Accordingly, we continue to expend significant time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, post-marketing studies and quality control.

If any of our third-party contractors fail to perform their responsibilities to comply with FDA rules and regulations, the marketing and sales of our products could be delayed and we may be subject to enforcement action, which could decrease our revenues.

Conducting our business requires us to manage relationships with third-party contractors. As a result, our success depends partially on the success of these third parties in performing their responsibilities to comply with FDA rules and regulations. Although we pre-qualify our contractors and we believe that they are fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities.

If any of our partners or contractors fail to perform their obligations in an adequate and timely manner or fail to comply with the FDA's rules and regulations, then the marketing and sales of our products could be delayed. The FDA may also take enforcement actions against us based on compliance issues identified with our contractors. If any of these events occur, we may incur significant liabilities, which could decrease our revenues. For example, sales and medical science liaison or MSL personnel, including contractors, must comply with FDA requirements for the advertisement and promotion of products.

If manufacturers obtain approval for generic versions of our products, once approved, or of products with which we compete, our business may be harmed.

Under the FDCA, the FDA can approve an abbreviated new drug application (ANDA) for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. Generally, in place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s), strength, dosage form and route of administration and that it is bioequivalent to the branded product.

The FDCA requires that an applicant for approval of a generic form of a branded drug certify either that its generic product does not infringe any of the patents listed by the owner of the branded drug in the Orange Book or that those patents are not enforceable. This process is known as a paragraph IV challenge. Upon notice of a paragraph IV challenge, a patent owner has 45 days to bring a patent infringement suit in federal district court against the company seeking ANDA approval of a product covered by one of the owner's patents. If this type of suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application. If the litigation is resolved in favor of the ANDA applicant or the challenged patent expires during the 30-month stay period, the stay is lifted, and the FDA may thereafter approve the application based on the standards for approval of ANDAs. Once an ANDA is approved by the FDA, the generic manufacturer may market and sell the generic form of the branded drug in competition with the branded medicine.

The ANDA process can result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe the owner's patents. If this were to occur with respect to iopofosine or any future products, once approved, with which our products competes, our business would be harmed.

Unforeseen safety issues could emerge with our products, once approved, that could require us to change the prescribing information to add warnings, limit use of the product, and/or result in litigation. Any of these events could have a negative impact on our business.

Discovery of unforeseen safety problems or increased focus on a known problem with respect to our products, once approved, could impact our ability to commercialize our products and could result in restrictions on its permissible uses, including withdrawal of the medicine from the market.

[Table of Contents](#)

If we or others identify additional undesirable side effects caused by our products after approval:

- regulatory authorities may require the addition of labeling statements, specific warnings, contraindications, or field alerts to physicians and pharmacies;
- regulatory authorities may withdraw their approval of the product and require us to take our approved drugs off the market;
- we may be required to change the way the product is administered, conduct additional clinical trials, change the labeling of the product, or implement a Risk Evaluation and Mitigation Strategy, or REMS;
- we may have limitations on how we promote our drugs;
- third-party payers may limit coverage or reimbursement for our products;
- sales of our approved products may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our products, once approved and could substantially increase our operating costs and expenses, which in turn could delay or prevent us from generating significant revenue from sale of any products for which we obtain approval.

If a safety issue emerges post-approval, we may become subject to costly product liability litigation by our customers, their patients or payers. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. If we cannot successfully defend ourselves against claims that our approved products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- the inability to commercialize any products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of studies;
- significant costs to defend the related litigation;
- substantial monetary awards to patients; and
- loss of 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.

[Table of Contents](#)

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.

Efforts to educate the physicians, patients, healthcare payors and others in the medical community on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates are approved, if at all, but do

not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable on a sustained basis.

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 commercial success of any product for which we obtain regulatory approval in the future will depend substantially on the extent to which the costs of our product or product candidates are or will be paid by third-party payors, including government health care programs and private health insurers. There is a significant trend in the health care industry by public and private payers to contain or reduce their costs, including by taking the following steps, among others: decreasing the portion of costs payers will cover, ceasing to provide full payment for certain products depending on outcomes or not covering certain products at all. If payers implement any of the foregoing with respect to our products, it would have an adverse impact on our revenue and results of operations. If coverage is not available, or reimbursement is limited, we, or any of our collaborative partners, may not be able to successfully commercialize our product candidates in some jurisdictions. Even if coverage is provided, the approved reimbursement amount may not be at a rate that covers our costs, including research, development, manufacture, sale and distribution. In the US, no uniform policy of coverage and reimbursement for products exists among third-party payors; therefore, coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific, clinical or other support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

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. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, which was passed in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers, has been subject to judicial, legislative, and regulatory efforts to replace it or to alter its interpretation or implementation. Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been enacted. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. In addition, the Further Consolidated Appropriations Act of 2020 fully repealed the Affordable Care Act’s mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and also eliminated the health insurer tax. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseparable feature of the Affordable Care Act, and because it was repealed as part of the Tax Cuts and Job Act of 2017, the remaining provisions of the Affordable Care Act are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the law. It is unclear how future actions before the Supreme Court, other such litigation, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments, will remain in effect into 2031, unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Sequestration will start again on April 1, 2022. From April 1 to June 30, 2022, payment for Medicare fee-for-service claims will be adjusted downwards by 1%; beginning July 1, 2022, the payment will be adjusted downwards by 2%. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (ATRA), which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and may affect the prices we may set.

In the U.S., there have been several recent Congressional inquiries and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer-sponsored patient assistance programs, and reform government program reimbursement methodologies for drugs. The Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection under the federal Anti-Kickback Statute for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through Pharmacy Benefit Managers (PBMs), unless the price reduction is required by law. The implementation of the rule has been delayed by ongoing litigation and a Congress-passed moratorium on implementation before January 1, 2026. The rule also creates a new safe harbor manufacturer for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between PBMs and manufacturers, the implementation of which have also been delayed until January 1, 2026. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which, among other changes, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacture price, for single source and innovator multiple source drugs, beginning January 1, 2024. The American Rescue Plan Act also temporarily increased premium tax credit assistance for individuals eligible for subsidies under the ACA for 2021 and 2022 and removed the 400% federal poverty level limit that otherwise applies for purposes of eligibility to receive premium tax credits. The Biden administration has begun taking executive actions to address drug pricing and other healthcare policy changes, including reversing certain measures by the Trump administration. For example, on July 9, 2021, President Biden signed an executive order to promote competition in the U.S. economy that included several initiatives addressing prescription drugs. Among other provisions, the executive order directed the Secretary of HHS to issue a report to the White House within 45 days that includes a plan to, among other things, reduce prices for prescription drugs, including prices paid by the federal government for such drugs. In response to the Executive Order, on September 9, 2021, HHS issued a Comprehensive Plan for Addressing High Drug Prices that identified potential legislative policies and administrative tools that Congress and the agency can pursue in order to make drug prices more affordable and equitable, improve and promote competition throughout the prescription drug industry, and foster scientific innovation.

We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action. However, we expect these initiatives to increase pressure on drug pricing. Further, certain broader legislation that is not targeted to the health care industry may nonetheless adversely affect our profitability. Any additional healthcare reform measures could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and other federal and state healthcare laws, and the failure to comply with such laws could result in substantial penalties. Our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payers and customers, may expose us to broadly applicable federal, state and foreign fraud and abuse and other healthcare laws and regulations including anti-kickback and false claims laws, data privacy and security laws, and transparency reporting laws. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any product for which we have obtained regulatory approval, or for which we obtain regulatory approval in the future. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws and regulations intended to prevent fraud, misconduct, bribery kickbacks, self-dealing and other abusive or inappropriate practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, including promoting off-label uses of our products, commission compensation, certain customer incentive programs, certain patient support offerings, and other business arrangements generally. Activities subject to

[Table of Contents](#)

these laws also involve the improper use or misrepresentation of information obtained in the course of patient recruitment for clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. See “Part I, Item 1, Business – Regulation – Other U.S. Regulatory Requirements” of this Annual Report on Form 10-K for more information on the healthcare laws and regulations that may affect our ability to operate.

We are also exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the US and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

We are also subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. Efforts to ensure that our business arrangements will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

Failure to meet Nasdaq’s continued listing requirements could result in the delisting of our common stock, negatively impact the price of our common stock and negatively impact our ability to raise additional capital.

On November 1, 2021, we have received a letter from the Listing Qualifications Staff of The Nasdaq Stock Market LLC (“Nasdaq”), notifying us that we no longer meet the requirement that we maintain a minimum bid price of \$1 per share, as set forth in Nasdaq Listing Rule 5550(a)(2).

As of the date of this annual report on Form 10-K, we are not in compliance with Nasdaq listing rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have until May 2, 2022, in which to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must be at least \$1 per share for a minimum of ten consecutive business days during this 180-day period. In the event that we do not regain compliance within this 180-day period, we may be eligible to seek an additional compliance period of 180 calendar days if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and provide written notice to Nasdaq of our intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice to us that our common stock will be subject to delisting.

If our common stock becomes subject to delisting, it would be subject to rules that impose additional sales practice requirements on broker-dealers who sell our securities. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our common stock. This would adversely affect the ability of investors to trade our common stock and would adversely affect the value of our common stock. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our common stock. If we seek to implement a further reverse stock split in order to remain listed on Nasdaq, the announcement or implementation of such a reverse stock split could negatively affect the price of our common stock.

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 payable) 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 Middleton, Wisconsin. The space in New Jersey consists of approximately 4,000 square feet and is rented for approximately \$13,100 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 October 31, 2022.

Item 3. Legal Proceedings.

On October 15, 2021, the Company filed a lawsuit against Dr. Jamey Weichert, a former director and executive officer of the Company (“Dr. Weichert”) and Dr. Anatoly Pinchuk, a former employee and consultant of the Company (“Dr. Pinchuk”) in the U.S. District Court for the Western District of Wisconsin. The Company is alleging, among other claims, that Dr. Weichert and Dr. Pinchuk breached their contractual and fiduciary duties to the Company by diverting intellectual property that rightfully belonged to the Company to a company controlled by Dr. Weichert. Although the disputed intellectual property does not directly affect the clinical studies of iopofosine or other compounds in the Company’s clinical pipeline, the disputed intellectual property may potentially enhance future areas of research, development, and commercialization. The Company is seeking monetary damages, injunctive relief, and reasonable attorneys’ fees and expenses in conjunction with this lawsuit.

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 CLR.B.

On February 25, 2022 there were 245 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

The following table provides information as of December 31, 2021, regarding shares authorized for issuance under our equity compensation plans, including individual compensation arrangements.

Equity compensation plan information

<u>Plan category</u>	<u>Number of shares to be issued upon exercise of outstanding options and rights (#)</u>	<u>Weighted-average exercise price of outstanding options and rights (\$)</u>	<u>Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a) (#))</u>
	<u>(a)</u>	<u>(b)</u>	<u>(c)</u>
Equity compensation plans approved by stockholders	4,136,950	\$ 1.98	3,521,949
Equity compensation plans not approved by stockholders	101,250	\$ 14.01	n/a
Total	4,238,200	\$ 2.27	3,521,949

Item 6. [Reserved]**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, iopofosine, 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 iopofosine from many traditional on-market treatments. Iopofosine 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, testing, and manufacturing product candidates, which primarily include the 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, 2021 and 2020

Research and Development. Research and development expense for the year ended December 31, 2021 was approximately \$17,586,000, compared to approximately \$10,141,000 for the year ended December 31, 2020.

The following table is a comparison summary of research and development costs for the years ended December 31, 2021 and December 31, 2020:

	Year Ended December 31,		Variance
	2021	2020	
Clinical project costs	\$ 10,844,000	\$ 3,794,000	\$ 7,050,000
Manufacturing and related costs	2,520,000	2,322,000	198,000
Pre-clinical project costs	50,000	213,000	(163,000)
General research and development costs	4,172,000	3,812,000	360,000
	<u>\$ 17,586,000</u>	<u>\$ 10,141,000</u>	<u>\$ 7,445,000</u>

The overall increase in research and development expense of approximately \$7,445,000, or 73%, was primarily a result of an increase in clinical project costs primarily related to our WM pivotal study of approximately \$7,050,000 and general research and development cost of approximately \$360,000. Manufacturing and related costs remained relatively consistent.

General and Administrative. General and administrative expense for the year ended December 31, 2021 was approximately \$6,545,000, compared to approximately \$5,150,000 in 2020. The increase of \$1,395,000, or 27%, in general and administrative costs was primarily a result of an increase in professional fees and insurance, personnel costs and stock-based compensation expense.

Other income (expense), net. Interest income, net, for the year ended December 31, 2021 was approximately \$2,000, as compared to approximately \$11,000 for the year ended December 31, 2020. The decrease is a result of decreased returns on investments. Other income for the year ended December 31, 2021 was approximately \$7,000. Other income for the year ended December 31, 2020 was approximately \$185,000 because of 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.

Liquidity and Capital Resources

Year ended December 31, 2021 Compared to Year Ended December 31, 2020

As of December 31, 2021, we had cash, cash equivalents and restricted cash of \$35.7 million, compared to \$57.2 million as of December 31, 2020. This decrease was primarily a result of research and development expense and general and administrative expenses. The cash used in operating activities during the twelve months ended December 31, 2021 was approximately \$22,569,000.

Our cash requirements have historically been for our research and development activities, finance and administrative costs, capital expenditures and overall working capital. We have experienced negative operating cash flows since inception and have funded our operations primarily from sales of common stock and other securities. As of December 31, 2021, we had an accumulated deficit of approximately \$150,898,000.

Liquidity Outlook

We have incurred losses since inception in devoting substantially all of our efforts toward research and development. During the year ended December 31, 2021, we generated a net loss of approximately \$24.1 million, and used approximately \$22.6 million in cash from operations. We expect that we will continue to generate operating losses for the foreseeable future. As of December 31, 2021, our consolidated cash balance was approximately \$35.7 million. We believe our cash balance as of December 31, 2021 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 and our ability to meet the continued listing standards of Nasdaq, there are currently no known trends, demands, commitments, events or uncertainties that are likely to materially affect our liquidity.

Critical Accounting Policies and Estimates

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

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

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

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, 2021 or 2020.

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.

[Table of Contents](#)

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.

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 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

INDEX TO FINANCIAL STATEMENTS FOR CELLECTAR BIOSCIENCES, INC.

	<u>Page</u>
Report of Independent Registered Public Accounting Firm (Baker Tilly US, LLP, Philadelphia, Pennsylvania, PCAOB ID No. 23)	59
Consolidated Balance Sheets as of December 31, 2021 and 2020	60
Consolidated Statements of Operations for the Years Ended December 31, 2021 and 2020	61
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2021 and 2020	62
Consolidated Statements of Cash Flows for the Years Ended December 31, 2021 and 2020	63
Notes to Consolidated Financial Statements	64

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Collectar Biosciences, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Collectar Biosciences, Inc. and Subsidiary (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, 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, 2021 and 2020, and the results of their operations and their cash flows for the years then ended, 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 Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgements. We determined that there are no critical audit matters.

/s/ Baker Tilly US, LLP

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

Philadelphia, Pennsylvania
March 21, 2022

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

	December 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 35,703,975	\$ 57,165,377
Prepaid expenses and other current assets	867,485	774,432
Total current assets	36,571,460	57,939,809
Fixed assets, net	344,491	355,982
Right-of-use asset, net	204,644	282,365
Long-term assets	75,000	75,000
Other assets	6,214	6,214
TOTAL ASSETS	\$ 37,201,809	\$ 58,659,370
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 3,854,914	\$ 3,443,197
Lease liability	135,449	119,904
Total current liabilities	3,990,363	3,563,101
Lease liability, net of current portion	166,292	301,740
TOTAL LIABILITIES	4,156,655	3,864,841
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized; Series C preferred stock: 0 and 215 shares issued and outstanding as of December 31, 2021 and 2020, respectively	—	1,148,204
Series D preferred stock: 111 and 1,519 shares issued and outstanding as of December 31, 2021 and 2020, respectively	1,382,023	18,887,645
Common stock, \$0.00001 par value; 160,000,000 and 80,000,000 shares authorized; 61,101,263 and 45,442,729 shares issued and outstanding as of December 31, 2021 and 2020, respectively	611	454
Additional paid-in capital	182,560,309	161,533,653
Accumulated deficit	(150,897,789)	(126,775,427)
Total stockholders' equity	33,045,154	54,794,529
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 37,201,809	\$ 58,659,370

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

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	<u>Year Ended December 31,</u>	
	<u>2021</u>	<u>2020</u>
COSTS AND EXPENSES:		
Research and development	\$ 17,586,469	\$ 10,140,681
General and administrative	6,544,811	5,149,668
Total costs and expenses	<u>24,131,280</u>	<u>15,290,349</u>
LOSS FROM OPERATIONS	<u>(24,131,280)</u>	<u>(15,290,349)</u>
OTHER INCOME:		
Other income	6,634	—
Gain on extinguishment of debt	—	185,280
Interest income, net	2,284	10,897
Total other income, net	<u>8,918</u>	<u>196,177</u>
NET LOSS	<u>\$ (24,122,362)</u>	<u>\$ (15,094,172)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>\$ (0.43)</u>	<u>\$ (0.76)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	<u>55,515,727</u>	<u>19,812,659</u>

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

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

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Par Amount			
BALANCE AT DECEMBER 31, 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
Conversion of preferred into common shares	(1,623)	(18,653,826)	14,611,569	146	18,653,680	—	—
Conversion of warrants into common shares	—	—	1,005,320	10	1,213,914	—	1,213,924
Issuance of common stock, net of issuance costs	—	—	41,692	1	34,872	—	34,873
Stock-based compensation	—	—	—	—	1,124,190	—	1,124,190
Retired shares	—	—	(47)	—	—	—	—
Net loss	—	—	—	—	—	(24,122,362)	(24,122,362)
BALANCE AT DECEMBER 31, 2021	111	\$ 1,382,023	61,101,263	\$ 611	\$ 182,560,309	\$(150,897,789)	\$ 33,045,154

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,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (24,122,362)	\$ (15,094,172)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	149,915	141,453
Stock-based compensation	1,124,190	467,541
Gain on extinguishment of debt	—	(185,280)
Loss on disposal of asset	2,937	—
Noncash lease expense	77,721	66,476
Changes in:		
Prepaid expenses and other current assets	(93,053)	(3,480)
Accounts payable and accrued liabilities	411,717	780,604
Lease liability	(119,903)	(105,885)
Cash used in operating activities	<u>(22,568,838)</u>	<u>(13,932,743)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	<u>(141,361)</u>	<u>(62,353)</u>
Cash used in investing activities	<u>(141,361)</u>	<u>(62,353)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from long-term obligations	—	184,000
Proceeds from issuance of common stock, net of underwriting issuance costs	34,873	59,719,256
Proceeds from exercise of warrants	1,213,924	642,495
Cash provided by financing activities	<u>1,248,797</u>	<u>60,545,751</u>
INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	<u>(21,461,402)</u>	<u>46,550,655</u>
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF PERIOD	<u>57,165,377</u>	<u>10,614,722</u>
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF PERIOD	<u>\$ 35,703,975</u>	<u>\$ 57,165,377</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest expense	\$ —	\$ 1,584
Gain on extinguishment of debt	\$ —	\$ 185,280
Conversion of preferred stock to common stock	\$ 18,653,826	\$ —

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, our, we) 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 and deliver 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 \$150,898,000 as of December 31, 2021. During the year ended December 31, 2021, the Company generated a net loss of approximately \$24,122,000 and the Company expects that it will continue to generate operating losses for the foreseeable future. However, the Company believes that its cash balance as of December 31, 2021 is adequate to fund its 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 notes to the consolidated financial statements.

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and 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 and share-based compensation. 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, 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, and at a minimum annually, evaluates long-lived assets for potential impairment. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. Such analyses necessarily involve judgement. The Company did not experience any events or changes in circumstances that indicate the carrying amount of the assets may not be recoverable as of December 31, 2021. There were no fixed asset impairment charges recorded during the years ended December 31, 2021 or 2020.

Right-of-Use Asset and Lease Liability — The Company accounts for all material leases in accordance with FASB Accounting Standards Codification (ASC) Topic 842, *Leases*. Right-of-use (ROU) assets are amortized over their estimated useful life, which represents the full term of the lease. See Note 11.

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 2021 and 2020 ranged from twelve months to three years.

Research and Development — Research and development costs are expensed as incurred. The Company recognizes revenue and cost reimbursements from government grants when it is probable that the Company will comply with the conditions attached to the grant arrangement and the grant proceeds will be received. Government grants are recognized in the Consolidated Statements of Operations on a systematic basis over the periods in which the Company recognizes the related costs for which the government grant is intended to compensate. Specifically, when government grants are related to reimbursements for cost of revenues or operating expenses, the government grants are recognized as a reduction of the related expense in the Consolidated Statements of Operations.

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 to not 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 consolidated financial statements as of December 31, 2021 and 2020.

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 consolidated financial statements consist of cash equivalents, prepaid expenses and other assets, accounts payable and long-term obligations. The carrying amount of cash equivalents, prepaid expenses and accounts payable approximate their fair value due to their short-term nature. See Note 11 regarding long-term obligations.

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, 2021 and 2020 is on deposit in interest-bearing accounts with well-established financial institutions. At times, such amounts may exceed the Federal Deposit Insurance Corporation (FDIC) insurance limits. As of December 31, 2021, uninsured cash balances totaled approximately \$35,200,000.

Recently Adopted Accounting Pronouncements — For the fiscal year beginning January 1, 2021, management adopted ASU 2020-06 using the modified retrospective method. ASU 2020-06 simplifies entities' accounting for convertible instruments by eliminating the cash conversion and beneficial conversion feature (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.

New Accounting Pronouncements – Issued but Not Yet Adopted — In December 2021, the FASB issued ASU No. 2021-10, Government Assistance (Topic 832), which aims to provide increased transparency by requiring business entities to disclose information about certain type of government assistance they receive in the notes to the financial statements. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

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.

[Table of Contents](#)

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.

4. FIXED ASSETS

Fixed assets consisted of the following as of December 31:

	<u>2021</u>	<u>2020</u>
Office and laboratory equipment	\$ 575,370	\$ 445,758
Computer software	4,000	4,000
Leasehold improvements	<u>309,897</u>	<u>309,897</u>
Total fixed assets	889,267	759,655
Less— accumulated depreciation and amortization	<u>(544,776)</u>	<u>(403,673)</u>
Fixed assets, net	<u>\$ 344,491</u>	<u>\$ 355,982</u>

For the years ended December 31, 2021 and 2020, the Company recorded approximately \$150,000 and \$141,000 of depreciation and amortization expense, respectively.

5. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities approximately consist of the following:

	<u>2021</u>	<u>2020</u>
Incentive compensation	\$ 504,000	\$ 850,000
Accounts payable	1,415,000	1,429,000
Clinical project costs	1,881,000	787,000
Professional fees	54,000	221,000
Other	<u>1,000</u>	<u>156,000</u>
	<u>\$ 3,855,000</u>	<u>\$ 3,443,000</u>

6. STOCKHOLDERS' EQUITY

Authorized Share Increase

At a special meeting 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.

Equity Distribution Agreement

On August 11, 2020, the Company entered into an equity distribution agreement (the Sales Agreement) with Oppenheimer & Co. Inc. (the Sales Agent). Pursuant to the Sales Agreement, the Company may offer and sell from time-to-time through the Sales Agent, up to \$14.5 million of shares of the Company's common stock, par value \$0.00001 per share (the ATM Shares). The Sales Agent will receive from the Company a commission of 3.0% of the gross proceeds from the sales of the ATM Shares pursuant to the terms of the Sales Agreement. The offering of the ATM Shares pursuant to the Sales Agreement will terminate upon the earliest of (i) the sale of all ATM Shares subject to the Sales Agreement, and (ii) the termination of the Sales Agreement by the Company or the Sales Agent. Net proceeds from the sale of the ATM Shares will be used for general corporate purposes, including working capital.

The ATM Shares issued under the Sales Agreement are offered pursuant to a registration statement on Form S-3, which was declared effective by the U.S. Securities and Exchange Commission (SEC) on August 20, 2020.

[Table of Contents](#)

In June 2021, the Company issued and sold an aggregate of 41,692 ATM Shares pursuant to the Sales Agreement and received gross proceeds of approximately \$69,000 and net proceeds of \$35,000 after deducting commissions to the Sales Agent and other offering expenses.

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, the Company issued and sold 1,518,518 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 would 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. At a special meeting of stockholders held on February 25, 2021, 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. During the twelve months ended December 31, 2021, the total Series D convertible preferred stock converted into 14,074,069 Common Stock at a rate of 1 to 10,000 shares.

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 issued in the public offering was offered by the Company pursuant to a registration statement on Form S-3, which was declared effective by the SEC on August 20, 2020.

The common stock issuable upon conversion of the Series D preferred stock in the private placement was offered by the Company pursuant to a registration statement on Form S-3, which was declared effective by the SEC on February 1, 2021.

In accordance with the concept of ASC 820 regarding the December 2020 public offering, the Company allocated the 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 23, 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 but is an internal proportionate calculation allocating gross proceeds of approximately \$24.5 million to common stock and \$20.5 million to preferred stock.

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. During the year ended December 31, 2020, all 2,789,700 pre-funded warrants and 482,375 Series H warrants were exercised. During the year ended December 31, 2021, 1,005,320 Series H warrants were 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 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.

[Table of Contents](#)

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 Securities Act of 1933 (the Act) and an additional registration statement filed on June 2, 2020 pursuant to Rule 462(b) under the Act.

Common Stock Warrants

The following table summarizes information with regard to outstanding warrants to purchase common stock as of December 31, 2021:

Offering	Number of Shares Issuable Upon Exercise of Outstanding Warrants	Exercise Price	Expiration Date
June 2020 Series H Warrants	7,207,969	\$ 1.2075	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
Total	15,633,825		

7. STOCK-BASED COMPENSATION

Accounting for Stock-Based Compensation

2021 Stock Incentive Plan

The 2021 Stock Incentive Plan (the “2021 Plan”) was adopted on June 23, 2021, authorizing an aggregate of 6,000,000 shares of common stock 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. The Compensation Committee determines exercise prices, vesting periods and any performance requirements on the date of grant, subject to the provisions of the 2021 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 three years. Options granted pursuant to the 2021 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. All outstanding awards under the 2015 Stock Incentive Plan (the “2015 Plan”) remained in effect according to the terms of the 2015 Plan and the respective agreements relating to such awards. In addition, any shares that are currently available under the 2015 Plan and any shares underlying awards under the 2015 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 2021 Plan. As of December 31, 2021, there are an aggregate of 3,521,949 shares available for future grants under the 2021 Plan.

During the twelve-months ended December 31, 2021 and 2020, stock options granted were 3,537,500 and 653,750, respectively. 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,	
	2021	2020
Employee and director stock option grants:		
Research and development	\$ 117,805	\$ 72,579
General and administrative	1,006,385	394,962
Total stock-based compensation	\$ 1,124,190	\$ 467,541

On March 4, 2021, we granted 2,810,000 contingent non-statutory stock option awards at an exercise price of \$1.74 per share to our employees. Each of these grants was contingent on approval of the 2021 Plan that was voted on and approved by the stockholders

[Table of Contents](#)

at the Annual Meeting of Stockholders held on June 23, 2021. In accordance with the timing of the stockholder approval, the Company recognized the compensation expense of the contingent non-statutory stock option awards issued in March 2021 beginning in June 2021 and continuing through the vesting period.

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. The Company accounts for forfeitures as they occur.

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,	
	2021	2020
Volatility	102.19-104.73 %	96-106 %
Risk-free interest rate	0.81-1.04 %	0.42-1.67 %
Expected life (years)	6	6
Dividend	0 %	0 %
Weighted-average exercise price	\$ 1.66	\$ 1.84
Weighted-average grant-date fair value	\$ 0.94	\$ 1.42

Exercise prices for all grants made during the twelve months ended December 31, 2021 and 2020 were equal to the market value of the Company's common stock on the date of grant. There were 3,537,500 stock options granted during the twelve months ended December 31, 2021.

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 as of December 31, 2019	610,714	\$ 6.78		
Granted	653,750	\$ 1.84		
Forfeited	(80,000)	\$ 2.46		
Outstanding as of December 31, 2020	1,184,464	\$ 4.34	8.57	\$ 316,688
Granted	3,537,500	\$ 1.66		
Expired	(41,097)	\$ 15.48		
Forfeited	(442,667)	\$ 1.71		
Outstanding as of December 31, 2021	<u>4,238,200</u>	\$ 2.27	8.79	\$ —
Exercisable as of December 31, 2021	798,238	\$ 4.82	7.24	\$ —
Unvested as of December 31, 2021	<u>3,439,962</u>	\$ 1.68	9.15	\$ —

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, 2021 and 2020 was \$0.94 and \$1.42, respectively. The total fair value of shares vested during the years ended December 31, 2021 and 2020 was \$537,453 and \$389,398, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2021 was \$1.39 and \$0.98, 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 options forfeited during the years ended December 31, 2021 and 2020 was \$1.02 and \$1.90, respectively. The number of options vested during the years ended December 31, 2021 and December 31, 2020 was 381,010 and 209,354, respectively. The number of options unvested at January 1, 2021 and January 1, 2020 was 726,139 and 361,743, respectively. The weighted average grant date fair value of options unvested at January 1, 2021 and January 1, 2020 was \$1.44 and \$1.82, respectively.

As of December 31, 2021, there was approximately \$2,536,428 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, the Company expects to recognize approximately \$1,359,075, \$1,001,776, and \$175,577 during 2022, 2023 and 2024, respectively. The Company's expense estimates are based upon the expectation that all unvested options will vest in the future.

8. INCOME TAXES

	<u>2021</u>	<u>2020</u>
Tax provision (benefit)		
Current		
Federal	\$ —	\$ —
State	—	—
Total current	<u>—</u>	<u>—</u>
Deferred		
Federal	(7,102,248)	(3,481,764)
State	(1,071,157)	(1,416,877)
Total deferred	<u>(8,173,405)</u>	<u>(4,898,641)</u>
Change in valuation allowance	8,173,405	4,898,641
Total	<u>\$ —</u>	<u>\$ —</u>

Deferred tax assets consisted of the following as of December 31:

	<u>2021</u>	<u>2020</u>
Deferred tax assets		
Federal net operating loss	\$ 32,696,266	\$ 30,179,562
Federal research and development tax credit carryforwards	9,599,756	7,063,702
State net operating losses and tax credit carryforwards	5,305,170	4,393,526
Capitalized research and development expenses	12,089,171	9,911,446
Stock-based compensation expense	2,627,881	2,459,336
Depreciable assets	—	—
Other	231,586	419,597
Total deferred tax assets	<u>62,549,830</u>	<u>54,427,169</u>
Deferred tax liabilities		
Depreciable assets	(59,961)	(110,705)
Total deferred tax liabilities	<u>(59,961)</u>	<u>(110,705)</u>
Net deferred tax assets	62,489,869	54,316,463
Less- valuation allowance	(62,489,869)	(5,416,463)
Total deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

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

	<u>Year ended December 31,</u>	
	<u>2021</u>	<u>2020</u>
Income tax benefit using U.S. federal statutory rate	(21.00)%	(21.00)%
State income taxes	(3.51)%	(7.42)%
Permanent nondeductible items	0.01 %	0.00 %
Federal tax credits	(10.51)%	(6.13)%
Change in valuation allowance	33.88 %	34.81 %
Other	1.13 %	(10.26)%
Total	<u>0.00 %</u>	<u>0.00 %</u>

As of December 31, 2021, the Company had federal net operating loss (NOL) carryforwards of approximately \$155,697,000. Federal NOLs generated as of December 31, 2017 will expire in 2021 through 2037, while NOLs generated during

[Table of Contents](#)

2018 and later will be carried forward indefinitely until utilized. As of December 31, 2021, the Company had state NOL carryforwards of approximately \$66,743,000. State NOL carryforwards will expire in 2028 through 2040.

As of December 31, 2021, the Company had federal research and development (R&D) and orphan drug credit carryforwards of approximately \$9,600,000 which will expire in 2022 through 2041. As of December 31, 2021, the Company also had state credit carryforwards of approximately \$883,000 which will expire in 2024 through 2035.

As of December 31, 2021, the Company had federal NOLs and R&D credit carryforwards of \$1,300,575 and \$42,355, respectively, that expired in 2021.

The NOL and R&D credit carryforwards may be, or may become subject to, an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, as well as similar state tax provisions. This could limit the amount of NOLs that the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to an ownership change. Subsequent ownership changes may further affect the limitation in future years. If and when the Company utilizes the NOL carryforwards in a future period, it will perform an analysis to determine the effect, if any, of these loss limitation rules on the NOL carryforward balances.

The Company has evaluated the available evidence supporting the realization of its deferred tax assets, including the amount and timing of future taxable income, and has determined that it is more likely than not that its net deferred tax assets will not be realized. Due to uncertainties surrounding the realization of the deferred tax assets, the Company maintains a full valuation allowance against all of its net deferred tax assets. When the Company determines that it will be able to realize some portion or all of its deferred tax assets, an adjustment to its valuation allowance on its deferred tax assets would have the effect of increasing net income in the period such determination is made.

The Company did not have unrecognized tax benefits or accrued interest and penalties at any time during the years ended December 31, 2021 or 2020 and does not anticipate having unrecognized tax benefits over the next twelve months. The Company is subject to audit by the Internal Revenue Service and state taxing authorities for tax periods commencing 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, warrants, preferred shares convertible into common stock, and pre-funded warrants. Since there is a net loss attributable to common stockholders for the years ended December 31, 2021 and 2020, 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,	
	2021	2020
Warrants	15,633,825	17,456,266
Stock options	4,238,200	1,184,464
Preferred shares convertible to common	1,111,111	15,722,680
Total potentially dilutive shares	<u>20,983,136</u>	<u>34,363,410</u>

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 the consolidated balance sheet which is being amortized 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 lease liability are approximately \$205,000 and (\$302,000), respectively, as of December 31, 2021 and rental expense for the twelve months ended December 31, 2021 was approximately \$113,000. The Company has not entered into any leases with related parties.

Discount Rate

The Company has determined the interest rate implicit in the lease considering factors 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, 2021:

Years ending December 31,	
2022	\$ 158,000
2023	161,000
2024	14,000
Total undiscounted lease payments	333,000
Less: Imputed interest	(31,000)
Present value of lease liabilities	<u>\$ 302,000</u>

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 used 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 and recognized as a gain on extinguishment of debt in the fourth quarter of 2020.

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, 2021, 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, 2021. 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.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

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 2022 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.collectar.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 2022 Annual Meeting of Stockholders under the caption “Compensation of Executive Officers and Directors ¾ Executive Compensation.”

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

The information required by this item with respect to the security ownership of certain beneficial owners and the security ownership of management is incorporated herein by reference to our definitive proxy statement for our 2022 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 2022 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 2022 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 2022 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		Exhibit No.
		Form	Filing Date	
2.1	Agreement and Plan of Merger by and among Novelos Therapeutics, Inc., Cell Acquisition Corp. and Collectar, Inc. dated April 8, 2011	8-K	April 11, 2011	2.1
3.1	Second Amended and Restated Certificate of Incorporation	8-K	April 11, 2011	3.1
3.2	Certificate of Ownership and Merger of Collectar Biosciences, Inc. with and into Novelos Therapeutics, Inc.	8-K	February 13, 2014	3.1
3.3	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	June 13, 2014	3.1
3.4	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	June 19, 2015	3.2
3.5	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	March 4, 2016	3.1
3.6	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	June 1, 2017	3.2
3.7	Certificate of Amendment of 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 D Preferred Stock certificate	8-K	December 28, 2020	4.1
4.3	Description of Securities Registered under Section 12(b) of the Securities Exchange Act of 1934	10-K	March 2, 2021	4.4
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 Restricted Common Stock Agreement**	10-Q	August 14, 2017	10.1
10.5	Form of Series D Common Stock Purchase Warrant	8-K	October 11, 2017	4.1
10.6	Registration Rights Agreement, dated as of October 10, 2017, by and among Collectar Biosciences, Inc. and the Purchasers	8-K	October 11, 2017	10.2
10.7	Form of Non-Statutory Stock Option**	S-8	November 9, 2017	10.2
10.8	Stock Option Agreement with James V. Caruso**	S-8	November 9, 2017	10.4
10.9	Stock Option Agreement with Jarrod Longcor**	S-8	November 9, 2017	10.5
10.10	Series E Common Stock Purchase Warrant	S-1/A	July 18, 2018	4.5
10.11	Form of Warrant Agency Agreement	S-1/A	July 18, 2018	4.7

[Table of Contents](#)

10.12	Agreement of Lease between the Company and KBS II 100-200 Campus Drive, LLC	S-1/A	July 18, 2018	10.35
10.13	Form of Non-Statutory Stock Option (Definitive/Contingent – Employees)**	10-Q	November 13, 2018	10.3
10.14	Form of Non-Statutory Stock Option (Definitive/Contingent – Directors)**	10-Q	November 13, 2018	10.4
10.15	Amended and Restated Employment Agreement between the Company and James Caruso, dated April 15, 2019**	8-K	April 19, 2019	10.1
10.16	Amended and Restated Employment Agreement between the Company and Jarrod Longcor, dated April 15, 2019**	8-K	April 19, 2019	10.2
10.17	Form of Series F Common Stock Purchase Warrant	8-K	May 20, 2019	4.1
10.18	Form of Series G Common Stock Purchase Warrant	8-K	May 20, 2019	4.2
10.19	Securities Purchase Agreement, dated as of May 16, 2019, by and among Collectar Biosciences, Inc. and the Purchasers	8-K	May 20, 2019	10.1
10.20	Private Placement Securities Purchase Agreement, dated as of May 16, 2019, by and among Collectar Biosciences, Inc. and the Purchasers	8-K	May 20, 2019	10.2
10.21	Registration Rights Agreement, dated as of May 16, 2019, by and among Collectar Biosciences, Inc. and the Purchasers	8-K	May 20, 2019	10.3
10.22	Collectar Biosciences, Inc. Amended and Restated 2015 Stock Incentive Plan**	8-K	June 14, 2019	10.1
10.23	Amendment to Amended and Restated Employment Agreement between the Company and Jarrod Longcor dated November 10, 2019**	10-Q	November 12, 2019	10.2
10.24	Form of Underwriting Agreement	S-1/A	May 20, 2020	1.1
10.25	Form of Series H Warrant	S-1/A	May 20, 2020	4.3
10.26	Form of Warrant Agency Agreement	8-K	June 5, 2020	4.3
10.27	Equity Distribution Agreement between Collectar Biosciences, Inc. and Oppenheimer & Co. Inc., dated August 11, 2020	8-K	August 11, 2020	10.1
10.28	Form of Securities Purchase Agreement	8-K	December 28, 2020	10.1
10.29	Form of Registration Rights Agreement	8-K	December 28, 2020	10.2
10.30	Employment Agreement between the Company and Chad Kolean dated February 23, 2022	8-K	February 25, 2022	10.1
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			
104*	Cover Page Interactive Data File			

* Filed herewith.

** Management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary

None.

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 21, 2022

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 Chad J. Kolean, 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 21, 2022

By: /s/ Chad J. Kolean
Chad J. Kolean
Title: Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
March 21, 2022

By: /s/ Frederick W. Driscoll
Frederick W. Driscoll
Title: Director
March 21, 2022

By: /s/ Asher Alban Chanan-Khan
Asher Alban Chanan-Khan
Title: Director
March 21, 2022

By: /s/ Stefan D. Loren
Stefan D. Loren
Title: Director
March 21, 2022

By: /s/ John L. Neis
John L. Neis
Title: Director
March 21, 2022

By: /s/ Douglas J. Swirsky
Douglas J. Swirsky
Title: Director
March 21, 2022

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

Set forth below is a list of the subsidiaries of Cellectar Biosciences, Inc. as of December 31, 2021:

Subsidiary Name	Jurisdiction of Organization
Cellectar, Inc.	Wisconsin

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File Nos. 333-208638, 333-214198, 333-214310, 333-221468, 333-225675, 333-231888, and 333-238132), Form S-1 MEF (File Nos. 333-226374 and 333-238892), Form S-3 (File Nos. 333-208189, 333-244362, and 333-252309), and Form S-8 (File Nos. 333-164398, 333-195255, 333-221469, and 333-233460) of Collectar Biosciences, Inc. of our report dated March 21, 2022, relating to the consolidated financial statements which appears in this annual report on Form 10-K for the year ended December 31, 2021.

/s/ BAKER TILLY US, LLP

Philadelphia, Pennsylvania
March 21, 2022

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

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

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

Date: March 21, 2022

/s/ James V. Caruso

James V. Caruso

President and Chief Executive Officer

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

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

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

Date: March 21, 2022

/s/ Chad J. Kolean

Chad J. Kolean
Chief Financial Officer

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

In connection with the Annual Report on Form 10-K of Collectar Biosciences, Inc. (the "Company") for the year ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James V. Caruso, Chief Executive Officer of the Company, and I, Chad J. Kolean, Chief Financial Officer of the Company, certify, to the best of our knowledge and belief, pursuant to 18 U.S.C. § 1350, adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ James V. Caruso

James V. Caruso
President and Chief Executive Officer

/s/ Chad J. Kolean

Chad J. Kolean
Chief Financial Officer

Dated: March 21, 2022

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