

Prospectus



865,000 Class A Units with each Class A Unit consisting of (i) one (1) Share of Common Stock and (ii) one (1) Common Warrant to purchase one (1) Share of Common Stock

335,000 Class B Units with each Class B Unit consisting of (i) one (1) Pre-Funded Warrant to Purchase one (1) Share of Common Stock and (ii) one (1) Common Warrant to purchase one (1) Share of Common Stock

72,000 Representative Warrants to Purchase 72,000 Shares of Common Stock

1,607,000 Shares of Common Stock Issuable Upon Exercise of (i) 335,000 Pre-Funded Warrants, (ii) 1,200,000 Common Warrants and (iii) 72,000 Representative Warrants

We are offering 865,000 Class A Units (the "Class A Units") with each Class A Unit consisting of (i) one (1) share of our common stock, par value \$0.00001 per share (the "common stock") and (ii) one (1) warrant to purchase one (1) share of common stock (each, a "Common Warrant") at a public offering price of \$5.00 per Class A Unit.

We are also offering to certain purchasers whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, 335,000 Class B Units (the "Class B Units"), with each Class B Unit consisting of (i) one (1) pre-funded warrant (each, a "Pre-Funded Warrant") to purchase one (1) share of common stock, in lieu of shares of common stock and (ii) one (1) Common Warrant. The purchase price of each Class B Unit will be equal to \$4.99999. Each Pre-Funded Warrant is exercisable for one (1) share of our common stock and has an exercise price of \$0.00001 per share, and a perpetual term. This prospectus also relates to the offering of common stock issuable upon exercise of the Pre-Funded Warrants and Common Warrants. We collectively refer to the Class A Units, Class B Units, the shares of common stock, Pre-Funded Warrants, Common Warrants and the shares of common stock underlying the Pre-Funded Warrants and Common Warrants as the "securities."

The Class A Units and Class B Units will not be certificated and the shares of common stock, Pre-Funded Warrants, and Common Warrants are immediately separable and will be issued separately in this offering. Each Common Warrant will be exercisable immediately upon issuance, have a term of five (5) years from the date of issuance and an exercise price equal to \$5.25.

The underwriter has the option to purchase up to 180,000 additional shares of common stock and/or additional Common Warrants to purchase up to an additional 180,000 shares of common stock solely to cover over-allotments, if any, at the public offering price, less the underwriting discounts and commissions. The over-allotment option may be used to purchase shares of common stock and/or Common Warrants, or any combination thereof, as determined by the underwriter. The overallotment option is exercisable for forty-five days from the date of this prospectus.

Our executive officers agreed to purchase an aggregate of 25,000 Class A Units for a total purchase price of approximately \$125,000 at the public offering price and on the same terms as other purchasers in the offering. The underwriter will receive the same underwriting discount and commissions on the securities purchased by such persons in this offering as they will on any other securities sold to the public in this offering.

Our common stock is listed on The Nasdaq Capital Market under the symbol “CLRB”. On June 30, 2025, the last reported sale price of our common stock was \$7.11 per share.

On June 24, 2025, a reverse stock split of our outstanding shares of common stock took effect at a ratio of one-for-thirty (the “Reverse Stock Split”), which was approved by our Board of Directors and majority of stockholders, and consummated pursuant to a Certificate of Amendment filed with the Secretary of State of Delaware on June 23, 2025. There will be no change to the number of authorized shares or the par value per share. Unless the context expressly dictates otherwise, all references to share and per share amounts referred to in this prospectus give effect to the Reverse Stock Split. However, our periodic and current reports that are incorporated by reference, and all other documents that were filed prior to June 24, 2025, do not give effect to the Reverse Stock Split.

Investing in our securities involves a high degree of risk. Before making an investment decision, please read the information under “Risk Factors” beginning on page 17 of this prospectus and under similar headings in any amendment or supplement to this prospectus or in any filing with the Securities and Exchange Commission that is incorporated by reference herein.

	Class A Unit	Class B Unit	Total
Public offering price (1)	\$ 5.00	\$ 4.99999	\$ 5,999,997
Underwriting discounts and commissions (2)	\$ 0.40	\$ 0.40	\$ 480,000
Proceeds to us, before expenses (3)	\$ 4.60	\$ 4.59999	\$ 5,519,997

- (1) The public offering price and underwriting discount corresponds to (i) a public offering price per Class A Unit of \$5.00 (\$4.60 net of the underwriting discount) and (ii) a public offering price per Class B Unit of \$4.99999 (\$4.59999 net of the underwriting discount).
- (2) We have agreed to reimburse the the underwriter for certain expenses and issue the underwriter, or its designees, warrants to purchase up to 6.0% of the number of Class A Units and Class B Units sold in this offering, including shares of common stock sold pursuant to the over-allotment option, if any. See “*Underwriting*” on page 56 for additional information regarding underwriting compensation.
- (3) The above summary of offering proceeds does not give effect to any proceeds from the cash exercise of any Pre-Funded Warrants, Common Warrants, or representative warrants being issued in this offering.

The underwriter expects to deliver the securities to purchasers in the offering on or about July 2 , 2025.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

Ladenburg Thalmann

The date of this prospectus is July 1, 2025.

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The registration statement we filed with the Securities and Exchange Commission, or the SEC, includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus, the related exhibits filed with the SEC, and the documents incorporated by reference herein before making your investment decision. You should rely only on the information provided in this prospectus and the documents incorporated by reference herein or any amendment thereto. In addition, this prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading “Where You Can Find Additional Information.” Information contained in later-dated documents incorporated by reference will automatically supplement, modify or supersede, as applicable, the information contained in this prospectus or in earlier-dated documents incorporated by reference.

We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus, the documents incorporated by reference herein or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The information contained in this prospectus, the documents incorporated by reference herein or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. We are not, and the underwriter is not, making an offer to sell these securities in any state or jurisdiction where the offer or sale is not permitted.

The terms “Collectar Biosciences,” “Collectar,” the “Company,” “our,” “us” and “we,” as used in this prospectus, refer to Collectar Biosciences, Inc., a Delaware corporation, and its subsidiaries unless we state otherwise or the context indicates otherwise.

SUMMARY

This summary highlights information contained elsewhere in this prospectus. Because it is a summary, it may not contain all of the information that is important to you. Accordingly, you are urged to carefully read the entire prospectus, any applicable prospectus supplement and any related free writing prospectus, including the risks of investing in our securities discussed under the heading "Risk Factors" contained in any applicable prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus. You should also carefully read the information incorporated by reference into this prospectus, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part.

Company 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 ether 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. On April 30, 2025, we announced that we will explore a full range of strategic alternatives to advance our platform and radiopharmaceutical drug development pipeline. Strategic alternatives under consideration may include, but are not limited to mergers, acquisitions, partnerships, joint ventures, licensing arrangements or other strategic transactions.

The Company is primarily focused on the development of its radioconjugate PDC programs, also known as phospholipid radioconjugates or PRCs, designed to provide targeted delivery of a radioisotope directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates our PRCs from many traditional on-market treatments and radiotherapeutics. Our three lead programs are: CLR 121125 (CLR 125), an iodine-125 Auger-emitting program, prepared to enter a clinical trial in 2025; CLR 121225 (CLR 225), an actinium-225 based program; and iopofosine I 131 (iopofosine I 131, or simply iopofosine), a beta-emitting iodine-131 based program which has been studied extensively, as described below. On June 4, 2025, the Company announced that the U.S Food and Drug Administration (the "FDA") has granted Breakthrough Therapy Designation for iopofosine I 131, as a radioconjugate monotherapy for the treatment of relapsed/refractory Waldenstrom macroglobulinemia (r/r WM).

- CLR 125, the Auger-emitting PRC, utilizes iodine-125 and has been observed to show tolerability with minimal toxicities in animal models. Additionally, the Company observed CLR 125 to have good activity in multiple solid tumor models, especially in triple negative breast cancer. Auger emitters provide the greatest precision in targeted radiotherapy as the emission can only travel a few nanometers. The Company believes that this means that to cause the necessary breakage of the tumor cell DNA, the isotope must get inside the cell and near the cell nucleus to be effective. The Company believes that CLR 125 achieves this due to the Company's novel phospholipid ether drug conjugate platform. CLR 125 is prepared to be the subject of a Phase 1b dose finding study in the second half of 2025 as described below, subject to our ability to obtain additional financing.
- CLR 225, the alpha-emitting, actinium-225 based PRC has been observed to show activity in multiple solid tumor animal models, including pancreatic, colorectal, and breast cancer. The Company observed CLR 121225 to be well tolerated in these models with the animals showing no adverse events at the highest doses tested. The Company also observed that the compound has excellent biodistribution and uptake by the tumor. Furthermore, in multiple models of pancreatic adenocarcinoma, including highly refractory pancreatic cancer, we have observed the compound's proportional dose response with a single dose providing either tumor stasis at the lowest dose tested or tumor volume reduction at the higher doses. The Company is currently prepared to initiate a Phase 1 imaging and dose escalation safety study in the second half of 2025, subject to our ability to obtain additional financing.

Iopofosine, the beta-emitting PRC, utilizes iodine-131 and was studied in our CLOVER-WaM Phase 2 study of iopofosine in patients with relapsed/refractory (r/r) Waldenstrom's macroglobulinemia (WM) where it was observed to result in statistically significant outcomes on both primary and secondary endpoints, and our Phase 2b studies in r/r multiple myeloma (MM) patients and r/r central nervous system lymphoma (CNSL) are ongoing. The CLOVER-2 Phase 1a study for a variety of pediatric cancers has concluded and a Phase 1b study in pediatric patients with high grade glioma is enrolling. Additionally, a Phase 1 Investigator-initiated study conducted by the University of Wisconsin Madison of iopofosine in combination with external beam radiation in patients with recurrent head and neck cancer has also been completed. As with all clinical trials, adverse events, serious adverse events or fatalities may arise during a clinical trial resulting from medical problems that may not be related to clinical trial treatments. Furthermore, due to recent communications with the FDA regarding a confirmatory study to support accelerated approval and the regulatory submission for iopofosine, the Company is, in addition to determining the availability of funding for such a study, pursuing strategic options for the further development and commercialization of this product candidate. As part of our previous announcement to seek a full range of strategic alternatives, we have initiated a process that includes identifying a strategic partner with the resources to develop iopofosine I 131.

Clinical and Preclinical Pipeline

Preclinical Evaluations of CLR 125

In preclinical, *in vivo* evaluations of CLR 125, utilizing triple-negative breast cancer (TNBC) models, the compound was observed to have tumor uptake at a substantially higher rate than that of healthy tissue. Additionally, no signs of end-organ toxicity were observed, including hematological toxicity.

CLR 125 Proposed Study

The anticipated use of funds generated from this offering is to provide necessary capital for operating expenses and to initiate a Phase 1b clinical study in TNBC with CLR 125, which is chemically and structurally the same as iopofosine, with the only difference being the iodine isotope with which it is radiolabeled. The clinical experience of iopofosine informs the biodistribution of the compound and may instruct the potential potency and side effects of CLR 125, although given the different physical properties of the emissions from CLR 125, the Company believes that side effects could be less.

We expect the study to be a Phase 1b, randomized, open-label, multi-center study comparing the safety and efficacy of CLR 125 in patients with advanced TNBC who are relapsed/refractory (r/r) to at least one prior therapy. Three dose levels will be assessed in parallel, with enrollment of patients in a 1:1:1 manner. We expect that each arm will have a minimum of 15 evaluable patients. CLR 125 will be administered as a fractionated dose on Day 1 and Day 3 for cycle 1 and repeat approximately every 8-week for subsequent cycles. Depending on arm assignments, patients will receive between two and four cycles. An expansion arm may be evaluated of at least 15 patients following evaluation of the three dose levels by the data monitoring committee (DMC).

We anticipate a maximum of 75 patients to be enrolled in the trial. Safety and tolerability of CLR 125 will be assessed by physical examination, Eastern Cooperative Oncology Group (ECOG) performance status, vital signs, laboratory changes over time, ECGs, and adverse events of special interest. Efficacy of CLR 125 will be assessed by CT (or MRI if needed) examinations obtained at six-week intervals following the initial dose of CLR 125.

The study objective is to determine the Phase 2 dosing level with secondary endpoints including safety, tolerability, initial response assessment and distribution.

Preclinical Evaluations of CLR 225

In preclinical, *in vivo* evaluations of CLR 225, utilizing a pancreatic cancer model, the compound was observed to reduce tumor volume and improved survival benefit at four different dosing levels. Observed biodistribution exhibited substantial uptake in the tumor while remaining low in healthy tissue.

Clinical Studies in Iopofosine

The CLOVER-1 Phase 2 study of iopofosine, conducted in r/r B-cell malignancies, met the primary efficacy endpoints from the Part A dose-finding portion. The CLOVER-1 Phase 2b study, where iopofosine remains under further evaluation in highly refractory MM and CNSL patients, is closed to enrollment but ongoing with patients in follow-up. Fatalities have occurred in patients post-treatment with iopofosine.

The CLOVER-WaM study was designed as a pivotal registration study evaluating iopofosine in WM patients that were r/r to at least two prior lines of therapy including having failed or had a suboptimal response to a Bruton tyrosine kinase inhibitor (BTKi). The study completed enrollment in the fourth quarter of 2023, and initial top line data from the study was reported in January 2024. CLOVER-WaM was a single-arm study with a target enrollment of 50 patients. Based upon the data from September 2024, the CLOVER-WaM study enrolled a total of 55 patients in the modified Intent to Treat (mITT) population and met its primary endpoint with a major response rate (MRR) of 58.2% (95% confidence interval [44.50%, 75.80%, two-sided p value < 0.0001]) exceeding the FDA agreed-upon statistical hurdle of 20%. The overall response rate (ORR) in evaluable patients was 83.6%, and 98.2% of patients experienced disease control. Responses were durable, with median duration of response not reached with 11.4 months of follow-up and 76% of patients remaining progression free at a median follow-up of eight months. These outcomes exceed real world data, which demonstrate a 4-12% MRR and a duration of response of approximately six months or less despite continuous treatment in a patient population that is less pretreated and not refractory to multiple classes of drugs. Notably, iopofosine I 131 monotherapy achieved a 7.3% complete remission (CR) rate in this highly refractory WM population. Overall, 45 (69.2%) patients had prior exposure to at least 3 drug classes and 19 (29.2%) patients had prior exposure to at least 4 drug classes of anti-cancer therapies. Forty-eight (73.8%) patients had prior exposure to a BTKi of which 37 (77.1%) were deemed to be refractory to BTKis. Forty-three (66.2%) patients were exposed to BTKi and anti-CD20 antibody with 25 (58.1%) being refractory to both BTKi and anti-CD-20 antibodies. Thirty-seven (56.9%) patients had prior exposure to BTKi, anti-CD20 antibody, and chemotherapy and 18 (48.6%) patients were refractory to all three classes of drugs, BTKi, anti-CD20 antibody, and chemotherapy. Iopofosine I 131 was well tolerated and its toxicity profile was consistent with the Company's previously reported safety data. The safety population was 65 patients which was composed of patients that received at least a single dose of iopofosine I 131 but did not receive enough drug to be assessed for efficacy. There were 3 (4.6%) patients that experienced treatment-related adverse events (TRAEs) leading to discontinuation. The rates of greater TRAEs observed in more than 10% of patients included thrombocytopenia (56 [86.2%] patients), neutropenia (52 [80.0%] patients), anemia (42 [64.6%] patients) and decreased white blood cell count (21 [32.3%] patients) among hematologic toxicities and fatigue (22 [33.8%] patients), nausea (19 [29.2%] patients) and diarrhea (13 [20.0%] patients) among non-hematologic toxicities. The rates of Grade 3 or greater TRAEs observed in more than 10% of patients included thrombocytopenia (53 [81.5%] patients), neutropenia (43 [66.2%] patients), anemia (31 [47.7%] patients), decreased white blood cell count (18 [27.7%]), decreased lymphocyte count 8 (12.3%). All patients recovered from cytopenias with no reported aplastic sequelae. Importantly, there were no clinically significant bleeding events, and the rate of febrile neutropenia was 10.8%. There were no treatment-related deaths in the study.

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 and CNSL expansion cohort (Phase 2b). The Phase 2b study will evaluate highly refractory MM patients in triple class, quad- and penta-drug refractory patients, including post-BCMA immunotherapy patients and r/r CNSL 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 2025. 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 1a pediatric study an open-label, sequential-group, dose-escalation study was conducted internationally at seven leading pediatric cancer centers. The study was 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 maximum tolerated dose was determined to be greater than 60mCi/m2 administered as a fractionated dose. CLOVER-2 Phase 1b study is an open-label, international dose-finding study evaluating two different doses and dosing regimens of iopofosine in r/r pediatric patients with high grade gliomas. 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. This study is partially funded (~\$2M) by a National Institutes of Health SBIR grant from the National Cancer Institute.

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 (RPDD) for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. The European Commission granted ODD to iopofosine for treatment of r/r MM and WM, as well as PRIME designation for WM.

Additionally, 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 a 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.

Phase 3 Study in Patients with r/r Waldenstrom's macroglobulinemia

On March 6, 2025 the Company conducted its End-of-Phase-2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA). As a result of the meeting, the Company believes that it understands the path forward for a one trial design for potential accelerated and full approval based upon a randomized Phase 3 trial assessing major response rate and progression free survival, respectively, as the primary endpoints in WM patients previously treated with a BTKi. The FDA and Cellectar agreed to utilize an Investigator Choice comparator approach, where investigators can select between one of two fixed duration treatments currently recommended by the NCCN guidelines. The initiation of this study is dependent on funding.

This meeting followed a November 2024 meeting where the FDA informed the Company that while the data from the CLOVER WaM study was meaningful, the FDA's preferred route to accelerated approval of iopofosine in WM was via a one trial design approach which would be in alignment with the recently issued accelerated approval guidance.

PDC Platform

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 a specific cell surface epitope or antigen as are required by other targeted delivery platforms but rather a unique change in the tumor cell membrane. Our PDC platform takes advantage of a metabolic pathway (beta oxidation) utilized by nearly all tumor cell types in all stages of the tumor cycle. Tumor cells modify the cell membrane to create specific, highly organized microdomains by which to transport lipids and long chain fatty acids into the cytoplasm, 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. The direct intracellular delivery allows our molecules to avoid the specialized, highly acidic cellular compartment known as lysosomes, which allows a PDC to deliver payloads that previously could not be delivered in this targeted manner. Additionally, molecules targeting specific cell surface epitopes face challenges in completely eliminating a tumor because the targeted antigens are limited in the total number presented on the cell surface, limiting total potential uptake and resulting in heterogenous uptake across the tumor, have longer cycling time from internalization to relocation on the cell surface, again diminishing their availability for binding, and are not present on all of the tumor cells because of the heterogenous nature of cancer cells, further increasing the unequal distribution of the drug across the tumor. This means a subpopulation of tumor cells always exists that cannot be addressed by therapies targeting specific surface epitopes. Additionally, the epitope utilized is also present on other normal tissue, resulting in off-target toxicities.

Beyond the benefits provided by the mechanism of entry, the PDC platform features include the capacity to link with almost any molecule, provide a significant increase in targeted oncologic payload delivery, a more uniform delivery, and the ability to target all types of tumor cells. As a result, we believe that we can create 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 without the expense of having to generate significant compound libraries.

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

The Phase 2 CLOVER-1 study was 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 were 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 was 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 was clinical benefit response (CBR), with secondary endpoints of ORR, PFS, time to next treatment (TtNT), median Overall Survival (mOS), 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 six WM patients and an 83.3% major response rate with one patient achieving a complete response (CR), which reached 39 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, iopofosine was well tolerated, 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 MM 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 Collectar'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.

In December 2021, we presented data from 11 MM patients from our 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 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 five 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 treatment emergent adverse events of neuropathy, arrhythmia, cardiovascular event, bleeding, ocular toxicities, renal function, alterations in liver enzymes, or infusion-site reactions or adverse events. We continue to enrich the r/r MM patient cohort with patients that are even more refractory, specifically enrolling patients that are quad-class refractory (triple class plus refractory to any of the recent approved product classes) and have relapsed post-BCMA immunotherapy. We reported in the Blood Cancer Journal in August 2022 that we observed iopofosine had a 50% ORR in patients receiving >60 mCi total administered dose (3/6 patients).

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 >60mCi 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 >60mCi TBD had a 42% and 43% ORR, respectively and a combined rate of 42%. These patients were also heavily pre-treated, having a median of three prior lines of treatment (range, 1 to 9) with the majority of patients being refractory to rituximab and/or ibrutinib. The patients had a median age of 70 with a range of 51 to 86. All patients had bone marrow involvement with an average of 23%. In addition to these findings, subtype assessments were completed in the r/r B-cell NHL patients. We observed a 30% ORR in patients with DLBCL, 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 >60mCi TBD. Therefore, patients are now grouped as receiving <60mCi or >60mCi TBD.

The most frequently reported adverse events in all patients were cytopenias, which followed a predictable course and timeline. The frequency of adverse events did not increase as doses were increased and the profile of cytopenias remained 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 or more prior treatment regimens.

Phase 1 Study in Patients with r/r Multiple Myeloma

In February 2020, final results from a multicenter, Phase 1 dose escalation clinical trial of iopofosine in r/r MM were presented. The trial was designed to evaluate the safety and potential initial efficacy of iopofosine administered in an up to 30-minute I.V. infusion either as a single bolus dose or as a fractionated dose in heavily pretreated MM patients. The study enrolled a total of 26 evaluable patients at three trial sites. For the trial, which used a modified three-plus-three 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 free light chain (FLC) was also observed.

Iopofosine in combination with dexamethasone was under investigation in adult patients with r/r MM. MM is an incurable cancer of the plasma cells and is the second most common form of hematologic cancer. 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 50% or greater decrease in M protein or to 50% or greater decrease in FLC levels (for patients in whom M protein is unmeasurable). Secondary objectives included the evaluation of therapeutic activity by assessing surrogate efficacy markers, which include M protein, 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.

Cohorts five and six received fractionated dosing of 31.25 mCi/m² (~62.5mCi TBD) and 37.5 mCi/m² (~75mCi TBD), each administered on day 1 and day 8. Following the determination that all prior dosing cohorts were tolerated, we initiated a cohort seven utilizing a 40mCi/m² (~95mCi TBD) fractionated dose administered 20mCi/m² (~40mCi TBD) on days 1 and day 8. Cohort seven was the highest pre-planned dose cohort and subjects have completed the evaluation period. 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 two 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 four, approximately 20-minute, IV infusions of iopofosine over 3 months, with doses given 14 days apart in each cycle and a maximum of two cycles. Low dose dexamethasone 40 mg weekly (20mg in patients ≥ 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.

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 2018, the FDA granted ODD and RPDD for iopofosine for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma.

In August 2020, based on data on four dose levels from 15mCi/m² up to 60mCi/m², the iDMC 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 five 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. The part A portion of this Phase 1 study has concluded, and part B has initiated to determine the appropriate dosing regimen in pediatric patients with r/r HGG. In 2022, the NCI awarded Collectar a \$1,900,000 SBIR Phase 2 grant to explore iopofosine in pediatric HGG.

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 six-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 was to assess the safety and potential benefits of iopofosine in combination with EBRT in a cohort of up to 24 patients. This portion of the study has fully enrolled, and data were reported at the ASTRO 2024 conference on March 2, 2024. Complete remission was achieved in 64% of patients, with an ORR of 73% (n=11). Prior to treatment with iopofosine I 131, six patients had multiple recurrences, and one had metastatic disease, both of which are indicative of poor outcomes. Additionally, in the study we observed durability of tumor control with an overall survival of 73% and progression free survival of 36% at 12 months. Eleven patients (92%) experienced a treatment-related adverse event. Treatment-related adverse events of grade 3 or higher occurring in 20% or more patients were thrombocytopenia (75%), lymphopenia (75%), leukopenia (75%), neutropenia (67%), and anemia (42%). Observed adverse events were consistent with the known toxicity profile of iopofosine I 131, with cytopenias being the most common. All patients recovered. We believe that these data support the notion of enhanced patient outcomes when combining the use of iopofosine I 131 in combination with external beam radiation for a treatment of solid tumors.

Additional Pipeline Candidates

We believe our PDC platform has potential to provide targeted delivery of a diverse range of oncologic payloads, as exemplified by our lead product candidates discussed above. Additional pipeline product candidates, listed below, may also result in improvements to the current standard of care (SOC) for the treatment of a broad range of human cancers:

- The company has developed a series of proprietary small molecule phospholipid drug conjugates. These programs employ either novel payload or novel linkers. Many of these molecules have demonstrated efficacy and tolerability in preclinical mouse models. The collaboration with IntoCell Inc. successfully met its agreed upon endpoint. The collaboration provided significant data which has led Collectar to select a series of highly potent cytotoxic small molecule payloads for further development.
- In collaboration with other parties, Collectar has also validated that the PLE is capable of delivering peptide payloads and oligonucleotide (siRNA, mRNA, etc.) payloads to the tumors when delivered systemically. These molecules have also been shown to demonstrate activity and safety in multiple preclinical mouse models. Based upon these collaborations and the data, the company has initiated internal proprietary programs with each of these treatment modalities. We are also evaluating other alpha-emitting isotopes such as astatine-211 and lead-212 in preclinical studies.

Recent Developments

Breakthrough Designation

On June 4, 2025, we announced that the FDA has granted Breakthrough Therapy Designation for iopofosine I 131, as a radioconjugate monotherapy for the treatment of relapsed/refractory Waldenstrom macroglobulinemia (r/r WM).

Warrant Inducement

On June 5, 2025, we entered into inducement offer letter agreements with certain holders (the “Holders”) of certain of our (i) Common Stock Purchase Warrants to purchase shares of Common Stock, issued on June 5, 2020 (the “2020 Warrants”), (ii) Common Stock Purchase Warrants to purchase shares of Common Stock, issued on October 25, 2022 (the “2022 Warrants”), and (iii) Common Stock Purchase Warrants to purchase shares of Common Stock, issued on July 21, 2024 (the “2024 Warrants” and together with the 2020 Warrants and the 2022 Warrants, the “Existing Warrant(s)”) (the “Warrant Inducement”). Pursuant to the Warrant Inducement, the Holders agreed to exercise the Existing Warrants for cash at a reduced exercise price of \$0.3041 per share (on a pre-Reverse Stock Split basis) in consideration for exercising in full for cash all of the Existing Warrants held by the Holders at the reduced exercise price on or before 9:00 a.m. Eastern Time on June 5, 2025. The Warrant Inducement provided for the immediate exercise of certain outstanding Existing Warrants to purchase an aggregate of 8,281,322 shares of common stock (on a pre-Reverse Stock Split basis).

The shares of common stock underlying the Existing Warrants have either been registered pursuant to the registration statement on Form S-1 filed with the SEC on May 8, 2020, as amended (File No. 333-238132), or registered for resale pursuant to either the registration statement on Form S-1 filed with the SEC on November 23, 2022 (File No. 333-268544) or the registration statement on Form S-1 filed with the SEC on January 29, 2025 (File No. 333-284580).

Reverse Stock Split

At 12:01 a.m. Eastern Time on Tuesday, June 24, 2025 (the “Effective Time”), our Reverse Stock Split became effective.

In connection with the Reverse Stock Split, every 30 shares of our common stock issued and outstanding as of the Effective Time was automatically converted into one share of our common stock. Stockholders who otherwise held a fractional share of common stock will receive a cash payment in lieu of such fractional share. On the Effective Time, our shares of common stock issued and outstanding were reduced from 54,361,197 to approximately 1,812,039 shares of common stock issued and outstanding. Our shares of common stock commenced trading on a split-adjusted basis when the Nasdaq Capital Market opened on June 24, 2025, and will continue to trade under its existing symbol “CLRB.” The new CUSIP number for the common stock following the Reverse Stock Split is 15117F880.

As a result of the Reverse Stock Split, the number of shares of common stock available for issuance under our equity incentive plans were proportionately affected. Additionally, under the terms of our outstanding stock options and warrants, when the Reverse Stock Split became effective, the number of shares of our common stock covered by each of them were divided by the number of shares being combined into one share of our common stock in the Reverse Stock Split and the exercise or conversion price per share was increased to a dollar amount equal to the current exercise or conversion price, multiplied by the number of shares being combined into one share of our common stock in the Reverse Stock Split. This resulted in the same aggregate price being required to be paid upon exercise as was required immediately preceding the Reverse Stock Split. Furthermore, the conversion ratio of our outstanding preferred stock was also adjusted proportionately.

Our periodic and current reports that are incorporated by reference, and all other documents that were filed prior to June 24, 2025, do not give effect to the Reverse Stock Split. The following selected “previously reported” information has been derived from our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 13, 2025, and our unaudited financial statements included in our Quarterly Report on Form 10-Q for the period ended March 31, 2025, filed with the SEC on May 13, 2025. The “post Reverse Split” information below recasts the “previously reported” share and per share information to reflect the June 24, 2025 one-for-thirty Reverse Stock Split, discussed elsewhere in the registration statement.

	Twelve Months Ended December 31, 2024	2023	Three Months Ended March 31, 2025	2024
Weighted-average common shares outstanding, basic - previously reported	36,622,474	12,221,571	46,079,875	29,346,679
Weighted-average common shares outstanding, diluted - previously reported	37,143,769	12,221,571	46,079,875	29,346,679
Weighted-average common shares outstanding, basic - post-Reverse Split	1,220,749	407,386	1,535,996	978,223
Weighted-average common shares outstanding, diluted - post-Reverse Split	1,238,126	407,386	1,535,996	978,223
Net loss per share, basic - previously reported	\$ (1.22)	\$ (3.50)	\$ (0.14)	\$ (0.91)
Net loss per share, diluted - previously reported	\$ (1.40)	\$ (3.50)	\$ (0.14)	\$ (0.91)
Net loss per share, basic - post-Reverse Split	\$ (36.52)	\$ (104.99)	\$ (4.20)	\$ (27.30)
Net loss per share, diluted - post-Reverse Split	\$ (41.89)	\$ (104.99)	\$ (4.20)	\$ (27.30)
	As of Dec 31, 2024	As of Dec 31, 2023	As of Mar 31, 2025	
Common stock - previously reported	\$ 461	\$ 207	\$ 461	
Additional paid-in capital - previously reported	\$ 261,115,905	\$ 182,924,210	\$ 261,678,642	
Common stock issued and outstanding - previously reported	46,079,875	20,744,110	46,079,875	
Common stock - post-Reverse Split	\$ 15	\$ 7	\$ 15	
Additional paid-in capital - post-Reverse Split	\$ 261,116,351	\$ 182,924,410	\$ 261,679,088	
Common stock issued and outstanding - post-Reverse Split	1,535,996	691,470	1,535,996	

Submission of First-in-Humans Phase 1 Clinical Trial Protocol to US Food and Drug Administration for CLR 125 to Treat Triple-Negative Breast Cancer

On June 24, 2025, we submitted a protocol with the U.S. Food and Drug Administration (FDA) for a Phase 1 study of our Auger emitting radiopharmaceutical, CLR 125, for the treatment of relapsed triple-negative breast cancer (TNBC).

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company” and accordingly have elected to take advance of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

Corporate Information

Our principal executive offices are located at 100 Campus Drive, Florham Park, New Jersey 07932 and the telephone number of our principal executive offices is (608) 441-8120. We maintain a website at www.cellectar.com. The information included or referred to on, or accessible through, our website does not constitute part of, and is not incorporated by reference into, this prospectus.

THE OFFERING

Class A Units we are offering	865,000 Class A Units with each Class A Unit consisting of (i) one (1) share of our common stock and (ii) one (1) Common Warrant.
Class B Units we are offering	335,000 Class B Units with each Class B Unit consisting of (i) one (1) Pre-Funded Warrant and (ii) one (1) Common Warrant. In the event that certain purchasers whose purchase of shares of common stock in the Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the closing of this offering, such purchasers will have the opportunity to purchase, if such purchasers so choose, Class B Units, in lieu of the Class A Units that would otherwise result in any such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Each Pre-Funded Warrant is exercisable for one share of our common stock. The exercise price of each Pre-Funded Warrant is \$0.00001 per share. The Pre-Funded Warrants are exercisable immediately and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any Pre-Funded Warrants sold in this offering. To better understand the terms of the Pre-Funded Warrants, you should carefully read the "Description of Securities We Are Offering" section of this prospectus. You should also read the form of Pre-Funded Warrant, which is filed as an exhibit to the registration statement that includes this prospectus.
Public offering price	The public offering price of each Class A Unit is \$5.00. The public offering price of each Class B Unit is \$4.99999.
Common Warrants	Each Class A Unit and Class B Unit purchased in this offering, as the case may be, will include one (1) Common Warrant to purchase one (1) share of common stock at an exercise price of \$5.25 per share, subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations, or similar events affecting our common stock, will be immediately exercisable upon issuance and will expire five (5) years from the date of issuance. The shares of common stock in the Class A Units or the Pre-Funded Warrants in the Class B Units, as applicable, and the accompanying Common Warrants, can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance. This offering also relates to the offering of the shares of common stock issuable upon exercise of the Common Warrants. Each Common Warrant is exercisable for one (1) share of common stock. To better understand the terms of the Common Warrants, you should carefully read the "Description of Securities We Are Offering" section of this prospectus. You should also read the form of Common Warrant, which is filed as an exhibit to the registration statement that includes this prospectus.
Over-allotment option	The underwriter has the option to purchase an aggregate of 180,000 additional shares of common stock and/or additional Common Warrants to purchase up to 180,000 shares of common stock solely to cover over-allotments, if any, at the price to the public less the underwriting discounts and commissions. The over-allotment option may be used to purchase shares of common stock and/or Common Warrants in any combination as determined by the underwriter. The over-allotment option is exercisable for forty-five (45) days from the date of this prospectus.

Common stock outstanding immediately before this offering	1,812,039 shares of common stock.
Common stock outstanding immediately after this offering	2,677,039 shares of common stock, or 2,857,039 shares if the underwriter exercises the over-allotment option in full, and assuming none of the Common Warrants, Pre-Funded Warrants or representative warrants issued in this offering are exercised.
Use of proceeds	We estimate that we will receive net proceeds of approximately \$5.0 million (or \$5.8 million if the underwriter exercises the over-allotment option in full) from the sale of the securities offered by us in this offering (excluding any proceeds from the cash exercise of Common Warrants). We intend to use the net proceeds from this offering for general corporate purposes, including working capital and operating expenses, and to initiate a Phase 1b clinical study of our compound CLR 121125 (CLR 125) in triple-negative breast cancer. See “ <i>Use of Proceeds</i> ” for additional information.
Lock-Up Agreements	We, and each of our officers and directors are subject to certain lock-up restrictions as set forth in more detail in the “ <i>Underwriting</i> ” section.
Nasdaq Symbol	Our common stock is listed on The Nasdaq Capital Market under the symbol “CLRB.” There is no established trading market for the Pre-Funded Warrants or the Common Warrants and we do not expect such markets to develop. In addition, we do not intend to apply for the listing of the Pre-Funded Warrants or Common Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Pre-Funded Warrants and Common Warrants will be limited.
Risk Factors	An investment in our securities involves a high degree of risk. See “ <i>Risk Factors</i> ” beginning on page 17 of this prospectus and the other information included and incorporated by reference in this prospectus for a discussion of the risk factors you should carefully consider before deciding to invest in our securities.

Unless otherwise indicated, all information in this prospectus assumes no exercise of outstanding options or warrants.

Unless otherwise indicated, all information contained in this prospectus assumes no exercise of any Common Warrants or representative warrants issued in this offering.

Unless otherwise indicated, the number of shares of common stock to be outstanding immediately after this offering is based on 1,535,996 shares of common stock outstanding as of March 31, 2025, which is adjusted to 1,812,039 to give effect to 276,043 shares that were issued pursuant to the Warrant Inducement, and which excludes:

- any shares of common stock issuable upon the exercise of the underwriter's over-allotment option;
- any shares of common stock issuable upon the exercise of Pre-Funded Warrants issued in this offering;
- any shares of common stock issuable upon the exercise of Common Warrants issued in this offering;
- any shares of common stock issuable upon the exercise of the representative warrants issued as compensation to the underwriter in this offering;
- an aggregate of 211,816 shares of common stock issuable upon the exercise of outstanding stock options issued to employees, directors and consultants;
- an aggregate of 13,040 shares of common stock issuable upon the conversion of outstanding shares of Series E-2 preferred stock;
- an aggregate of 3,704 shares of common stock issuable upon the conversion of outstanding shares of Series D preferred stock; and
- an aggregate of 522,011 additional shares of common stock reserved for issuance under outstanding warrants having expiration dates between June 2025 and July 2029, and exercise prices ranging from \$58.80 to \$362.250 per share.

Summary Risk Factors

Investing in our securities involves a high degree of risk. You should carefully consider all of the risks discussed in the section entitled “Risk Factors,” 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:

Risks Related to This Offering

- The net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient to progress CLR 125 through a Phase 1b dose finding study data readout and we will require additional funding to do so. If no additional sources of funding materialize, the Company may be required to seek other alternatives which may include, among others, the sale of assets, discontinuance of certain operations, a wind-down of operations and/or filing for bankruptcy protection.
- Management will have broad discretion as to the use of the proceeds from this offering, if any, and may not use the proceeds effectively.
- If we do not maintain a current and effective prospectus relating to the common stock issuable upon exercise of the Common Warrants, public holders will only be able to exercise such Common Warrants on a “cashless basis.”
- If you purchase our common stock, Pre-Funded Warrants and Common Warrants in this offering, you will incur immediate and substantial dilution in the book value of your shares.
- Significant holders or beneficial holders of our common stock may not be permitted to exercise Pre-Funded Warrants or Common Warrants that they hold.
- The Common Warrants are speculative in nature.
- We may be required to repurchase the Common Warrants, which may prevent or deter a third party from acquiring us.
- An investment in the Pre-Funded Warrants, Common Warrants and our common stock has numerous tax consequences.
- Our stock price has experienced, and may continue to experience, price fluctuations.
- Future sales of a significant number of our shares of common stock in the public markets, or the perception that such sales could occur, could depress the market price of our shares of common stock.
- There is no public market for the Common Warrants or Pre-Funded Warrants being offered in this offering.
- Holders of our Common Warrants and Pre-Funded Warrants will have no rights as a common stockholder until they acquire our common stock.
- We have never paid dividends and we do not anticipate paying dividends in the future.
- A significant number of shares of our common stock are issuable pursuant to outstanding stock awards, and we expect to issue additional stock awards and shares of common stock in the future. Exercise of these awards and sales of shares will dilute the interests of existing security holders and may depress the price of our common stock.
- You may experience future dilution as a result of future equity offerings.
- 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.
- If our business plans are not successful, we may not be able to continue operations as a going concern and investors in this offering may lose their entire investment in us.

Risks Related to Capital and Our Operations

- If the Company’s exploration of strategic alternatives is unsuccessful, its financial condition and results of operations may be materially adversely affected.
- We will require additional capital in order to continue our operations and may have difficulty raising additional capital.
- Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Risks Related to Manufacturing and Supply

- We rely on a collaborative outsourced business model, and disruptions with our third-party collaborators may impede our ability to gain FDA approval and delay or impair commercialization of any products.

Risks Related to Research and Development and the FDA

- 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.
- 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.
- 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 because of unexpected side effects or other safety risks that could preclude approval of our product candidates.
- The biopharmaceutical industry is subject to extensive regulatory obligations and policies that are subject to change, including due to judicial challenges.

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 are exposed to product, clinical and preclinical liability risks that could create a substantial financial burden should we be sued.

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.
- 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.

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.
- 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.

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.
- 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.

Risks Related to Internal Controls

- We identified certain misstatements to our previously issued financial statements and have restated the financial statements described below, which has exposed us to additional risks and uncertainties.
- We identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and share price.

Risks Related to Our Equity Securities

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

General Risk Factors

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

RISK FACTORS

An investment in our securities involves a high degree of risk. Prior to making a decision about investing in our securities, prospective investors should consider carefully all of the information included and incorporated by reference or deemed to be incorporated by reference in this prospectus, including the risk factors incorporated by reference herein from our [Annual Report on Form 10-K for the fiscal year ended December 31, 2024](#) and our [Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2025](#), as updated by annual, quarterly and other reports and documents we file with the SEC after the date of this prospectus and that are incorporated by reference herein. Each of these risk factors could have a material adverse effect on our business, results of operations, financial position or cash flows, which may result in the loss of all or part of your investment. For more information, see “Where You Can Find Additional Information” and “Incorporation of Documents by Reference.”

The risks described in these documents are not the only ones we face. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. Further, past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. Please also read carefully the section below entitled “Forward-Looking Statements.”

Risks Related to This Offering

The net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient to progress CLR 125 through a Phase 1b dose finding study data readout and we will require additional funding to do so. If no additional sources of funding materialize, the Company may be required to seek other alternatives which may include, among others, the sale of assets, discontinuance of certain operations, a wind-down of operations and/or filing for bankruptcy protection.

Our intended use of net proceeds from this offering will be for general corporate purposes, including working capital and operating expenses and to initiate a Phase 1b dose finding study for CLR 121125 in triple-negative breast cancer. However, we do not expect that our net use of proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to progress this study through a preliminary data readout. As such, our ability to progress through a preliminary data readout and our current operating plan will continue to depend on our ability to obtain additional funding from the sale of equity and/or debt securities, strategic transaction or other sources of capital.

Our ability to obtain additional funding on acceptable terms or at all is subject to a variety of risks and uncertainties outside of our control. Those risks and uncertainties are further exacerbated since the Company is not expected to have any readouts of its data from the Phase 1b dose finding study of CLR 121125 in close proximity to the time when it may need to seek additional funding.

The Company plans to continue actively pursuing additional funding, however, there can be no assurance that such additional funding will materialize. If no additional sources of funding materialize, the Company may be required to seek other alternatives which may include, among others, the sale of assets, discontinuance of certain operations, a wind-down of operations and/or filing for bankruptcy protection.

Management will have broad discretion as to the use of the proceeds from this offering, if any, and may not use the proceeds effectively.

We currently anticipate that any net proceeds from this offering will be used for general corporate purposes, including working capital and operating expenses, and to initiate a Phase 1b clinical study of our compound CLR 125 in triple-negative breast cancer. However, we have not determined the specific allocation of the net proceeds from this offering, if any, among these potential uses. Our management will have broad discretion as to the application of the net proceeds from this offering, if any, and could use them for purposes other than those contemplated at the time of the offering. Our management may use the net proceeds for corporate purposes that may not improve our financial condition or market value.

If we do not maintain a current and effective prospectus relating to the common stock issuable upon exercise of the Common Warrants, public holders will only be able to exercise such Common Warrants on a “cashless basis.”

If we do not maintain a current and effective prospectus relating to the shares of common stock issuable upon exercise of the Common Warrants at the time that holders wish to exercise such respective warrants, they will only be able to exercise them on a “cashless basis,” and under no circumstances would we be required to make any cash payments or net cash settle such warrants to the holders. As a result, the number of shares of common stock that holders will receive upon exercise of the Common Warrants will be fewer than it would have been had such holders exercised their Common Warrants for cash. We will use our best efforts to maintain a current and effective prospectus relating to the shares of common stock issuable upon exercise of such Common Warrants until the expiration of such Common Warrants or until all Common Warrants have been exercised in full. However, we cannot assure you that we will be able to do so. If we are unable to do so, the potential “upside” of the holder’s investment in our Company may be reduced.

If you purchase our common stock, Pre-Funded Warrants and Common Warrants in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The public offering price in this offering is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock and Common Warrants in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock and Common Warrants in this offering will incur immediate dilution of \$0.03 per share.

As a result of the dilution to investors purchasing securities in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will incur as a result of purchasing securities in this offering, see “Dilution.”

Significant holders or beneficial holders of our common stock may not be permitted to exercise Pre-Funded Warrants or Common Warrants that they hold.

The Pre-Funded Warrants and Common Warrants being offered hereby will prohibit a holder from exercising its Pre-Funded Warrants or Common Warrants if doing so would result in such holder (together with such holder’s affiliates and any other persons acting as a group together with such holder or any of such holder’s affiliates) beneficially owning more than 4.99% of our common stock outstanding immediately after giving effect to the exercise, provided that, at the election of a holder and notice to us, such beneficial ownership limitation as to such holder shall be 9.99% of our common stock outstanding immediately after giving effect to the exercise. As a result, if you hold a significant amount of our securities, you may not be able to exercise your Pre-Funded Warrants or Common Warrants for shares of our common stock, in whole or in part, at a time when it would be financially beneficial for you to do so.

The Common Warrants are speculative in nature.

The Common Warrants offered hereby do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price. Specifically, commencing on the date of issuance, holders of the Common Warrants may acquire the common stock issuable upon exercise of such Common Warrants at an exercise price of \$5.25 per share of common stock. Moreover, following this offering, the market value of the Common Warrants will be uncertain and there can be no assurance that the market value of the Common Warrants will equal or exceed the exercise price of the Common Warrants, and consequently, whether it will ever be profitable for holders of the Common Warrants to exercise the Common Warrants.

An investment in the Pre-Funded Warrants, Common Warrants and our common stock has numerous tax consequences.

There are numerous tax consequences to investors as a result of their investment in the Company. We encourage investors to seek advice from competent tax advisors as to the consequences of an investment in our Pre-Funded Warrants, Common Warrants and common stock. See “Material U.S. Federal Income Tax Considerations.”

Our stock price has experienced, and may continue to experience, price fluctuations.

Our stock price has been and continues to be highly volatile. 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 meet the continued listing standards of the Nasdaq Capital Market (“Nasdaq”) exchange.

Future sales of a significant number of our shares of common stock in the public markets, or the perception that such sales could occur, could depress the market price of our shares of common stock.

Sales of a substantial number of our shares of common stock in the public markets, or the perception that such sales could occur, including from the exercise of outstanding warrants or sales of common stock issuable thereunder, could depress the market price of our shares of common stock and impair our ability to raise capital through the sale of additional equity securities. A substantial number of shares of common stock are being offered by this prospectus. We cannot predict the number of these shares that might be sold nor the effect that future sales of our shares of common stock, including shares issuable upon the exercise of outstanding warrants, would have on the market price of our shares of common stock.

There is no public market for the Common Warrants or Pre-Funded Warrants being offered in this offering.

There is no established public trading market for the Common Warrants or Pre-Funded Warrants being offered in this offering, and we do not expect such markets to develop. In addition, we do not intend to apply to list the Common Warrants or Pre-Funded Warrants on any securities exchange or nationally recognized trading system, including The Nasdaq Stock Market. Without an active market, the liquidity of the Common Warrants and Pre-Funded Warrants will be limited.

Holders of our Common Warrants and Pre-Funded Warrants will have no rights as a common stockholder until they acquire our common stock.

Until holders of our Common Warrants and Pre-Funded Warrants acquire shares of our common stock upon exercise of the Common Warrants and Pre-Funded Warrants, the holders will have no rights with respect to shares of our common stock issuable upon exercise of the Common Warrants and Pre-Funded Warrants. Upon exercise of the Common Warrants and Pre-Funded Warrants, holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

We have never paid dividends and we do not anticipate paying dividends in the future.

We have never paid dividends on our capital stock and do not anticipate paying any dividends for the foreseeable future. We anticipate that the Company will retain its earnings, if any, for future growth. Investors seeking cash dividends should not invest in the Company's common stock for that purpose.

A significant number of shares of our common stock are issuable pursuant to outstanding stock awards, and we expect to issue additional stock awards and shares of common stock in the future. Exercise of these awards and sales of shares will dilute the interests of existing security holders and may depress the price of our common stock.

As of June 24, 2025, there were approximately 1,812,039 shares of common stock outstanding, as well as outstanding awards to purchase approximately 211,816 shares of common stock under various incentive stock plans of the Company. Additionally, as of June 24, 2025, there were approximately 98,909 shares of common stock available for future issuance under various incentive plans. We may issue additional common stock, warrants and other convertible securities from time to time to finance our operations. We may also issue additional shares to fund potential acquisitions or in connection with additional stock options or other equity awards granted to our employees, officers, directors and consultants under our various incentive plans. The issuance of additional shares of common stock, warrants or other convertible securities and the perception that such issuances may occur or exercise of outstanding warrants or options may have a dilutive impact on other stockholders and could have a material negative effect on the market price of our common stock.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share paid by any investor in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by any investor in this offering, and investors purchasing shares or other securities in the future could have rights superior to you. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by any investor in this offering.

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.

We must continue to satisfy Nasdaq continued listing requirements, including, among other things, certain corporate governance requirements, minimum stockholders' equity of \$2.5 million, and a minimum closing bid price requirement of \$1.00 per share. If a company fails for 30 consecutive business days to meet the \$1.00 minimum closing bid price requirement, Nasdaq will send a deficiency notice to the company, advising that it has been afforded a "compliance period" of 180 calendar days to regain compliance with the applicable requirements.

On January 30, 2025, we received a deficiency letter from Nasdaq notifying us that, for the last 30 consecutive business days, the closing bid price for our common stock was below the minimum \$1.00 per share required for continued listing on Nasdaq pursuant to the minimum closing bid price requirement. The Nasdaq deficiency letter had no immediate effect on the listing of our common stock. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been given 180 calendar days, or until July 29, 2025, to regain compliance with the minimum closing bid price requirement by causing our stock to close above \$1.00 for a minimum of 10 consecutive trading days. If we do not regain compliance with the minimum closing bid price requirement by July 29, 2025, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intent to cure the deficiency during the second compliance period.

On June 24, 2025, we effected the 1-for-30 Reverse Stock Split to regain compliance with the bid price requirement prior to the July 29, 2025 compliance deadline. There is no assurance we will regain and maintain compliance with Nasdaq continued listing requirements.

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 our business plans are not successful, we may not be able to continue operations as a going concern and investors in this offering may lose their entire investment in us.

We have historically incurred substantial losses to fund our business operations including our research and development activities. We will, in all likelihood, sustain operating expenses without corresponding revenues for the foreseeable future. This may result in our incurring net operating losses that will increase continuously until we are able to obtain regulatory approval for, and commercialize, our product candidates, the occurrence of which cannot be assured. If we cannot continue as a going concern, investors in this offering may lose their entire investment in us.

Risks Related to Capital and Our Operations

If the Company's exploration of strategic alternatives is unsuccessful, its financial condition and results of operations may be materially adversely affected.

As previously announced, the Company has engaged a financial advisor to assist it in evaluating potential strategic alternatives to enhance stockholder value. Strategic alternatives under consideration may include, but are not limited to mergers, acquisitions, business combinations, partnerships, joint ventures, licensing arrangements or other strategic transactions. The Company and its financial advisor have engaged in preliminary discussions with potential counterparties but there is no assurance that the potential strategic alternatives will lead to a definitive agreement. If the Company is unable to consummate a strategic transaction, or if there is any significant delay in closing such a transaction, the Company's financial condition and results of operations may be materially adversely affected. In addition, the Company may be required to seek other alternatives which may include, among others, the sale of the Company or its assets, discontinuance of certain operations, a wind-down of operations and/or filing for bankruptcy protection.

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 March 31, 2025, our consolidated cash balance was approximately \$13.9 million. We believe our cash balance as of March 31, 2025, excluding the proceeds from this offering, is adequate to fund our basic budgeted operations into the fourth quarter of 2025.

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 other source of capital. The Company plans to continue actively pursuing financing alternatives, however, there can be no assurance that it will obtain the necessary funding, raising substantial doubt about the Company's ability to continue as a going concern within one year of the date these financial statements are issued. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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, 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.

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 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 AtomVie and SpectronRx as sources to supply drug product for our ongoing research and clinical studies.

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. 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. 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 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 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 nearly 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;
- 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, clinical trial patient enrollment in, 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 research, development and commercialization of CLR 121225, CLR 121125, 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 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 from preclinical and clinical testing could delay, limit or prevent regulatory approval of our products for any individual, additional indications.

To be commercially viable, we must successfully research, develop, manufacture, introduce, and 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.

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.

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 iopofosine 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.

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.

Iopofosine 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.

Furthermore, due to recent communications with the FDA regarding a confirmatory study to support accelerated approval and the regulatory submission for iopofosine, the Company is, in addition to determining the availability of funding for such a study, pursuing strategic options for the further development and commercialization of this product candidate.

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.

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.

Additionally, 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.

Furthermore, 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 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. 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.

We may be required to suspend or discontinue clinical studies because of 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.

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that are subject to change, including due to judicial challenges.

On June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) “must exercise their independent judgment” and “may not defer to an agency interpretation of the law simply because a statute is ambiguous.” The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation judicial scrutiny. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict.

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, and 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 ODD as described above, we may not be the first to obtain marketing approval for the orphan-designated indication because of 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 iopofosine 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.

In addition, Congress is considering updates to the orphan drug provisions of the FDCA in response to a recent decision by the U.S. Court of Appeals for the Eleventh Circuit. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, results of operations, financial condition and prospects.

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 several 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;
- 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;
- 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 levels 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 may be diminished, and the capital necessary to fund our operations may 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, 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;
- 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 fulfil 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 compete, 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.

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.

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.

As a result of 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 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 U.S., 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 Affordable Care Act 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 included 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 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 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 any healthcare reform measures of the Trump 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, as a result of 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 with a subsequent reduction to 1% implemented from April 1, 2022 until June 30, 2022. To offset the temporary suspension during the COVID-19 pandemic, in 2030, reductions in Medicare payments will be 2.25% for the first half of the year, and 3% in the second half of the year. 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. See Part I, Item 1, Business-Regulation-Reimbursement and Pricing Controls in our Annual Report on Form 10-K for the year ended December 31, 2024 for more information on recent healthcare reform measures that may affect our ability to operate.

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 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 our 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

We identified certain misstatements to our previously issued financial statements and have restated the financial statements described below, which has exposed us to additional risks and uncertainties.

We have restated our previously issued audited financial statements as of and for the years ended December 31, 2022 and 2023 and our interim financial statements as of and for the quarterly periods ended March 31, 2024, March 31, 2023 through September 30, 2023 and March 31, 2022 through September 30, 2022.

As a result of the misstatements discussed and the Restatement, we have become subject to a number of additional risks and uncertainties and unanticipated costs for accounting, legal and other fees and expenses, including risks of lawsuits relating to securities offered by us in public and private offerings as well as claims by purchasers of our shares of common stock in the public market. Any actions, lawsuit or other legal proceedings related to the misstatements or the Restatement could result in liabilities, reputational harm and defense and other costs, regardless of the outcome of the lawsuit or proceeding.

We cannot ensure that litigation or other claims by stockholders will not be brought in the future arising out of the Restatement. We may also be subject to further examinations, investigations, proceedings and orders by regulatory authorities as a result of the Restatement. Any such further actions could be expensive and damaging to our business, results of operations and financial condition.

We identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and share price.

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. There are identified material weaknesses that are described further in Item 9A. of our Annual Report on Form 10-K for the year ended December 31, 2024. These material weaknesses resulted in our historical financial statements requiring restatement, as is noted above, and delayed our required filings with the SEC, a situation that could recur in the event that we do not effectively remediate the existing material weaknesses and/or experience additional material weaknesses.

Risks Related to Our Equity Securities

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 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.

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.

General Risk Factors

Conflicts, military actions, terrorist attacks, natural disasters, public health crises, including the occurrence of a contagious disease or illness, 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 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.

FORWARD-LOOKING STATEMENTS

This prospectus, together with any accompanying prospectus supplement, includes and incorporates by reference forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. Examples of our forward-looking statements include:

- our current views with respect to our business strategy, business plan and research and development activities;
- the progress of our product development programs, including clinical testing and the timing of commencement and results thereof;
- our projected operating results, including research and development expenses;
- our ability to identify a strategic partner with the resources to develop iopofosine I 131 (also known as iopofosine or CLR 131) or otherwise continue the development or pursue other strategic options in connection with iopofosine;
- our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise;
- our ability to initiate a Phase 1b dose finding study for CLR 121125 and obtain the necessary additional funding for such study;
- our ability to initiate a Phase 1 imaging and dose escalation safety study for CLR 121225 and obtain the necessary additional funding for such study;
- our ability to continue development plans for our clinical and preclinical assets;
- our ability to continue development plans for our Phospholipid Drug Conjugates (PDC)[™];
- our ability to advance our technologies into product candidates;
- 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/Waldenstrom macroglobulinemia, and the expected benefits of orphan drug status;
- any disruptions to our suppliers;
- 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, cyber-attacks and general instability;
- the future impacts of legislative and regulatory developments in the United States 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 prospectus.

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

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately \$5.0 million (or \$5.8 million if the underwriter exercises the over-allotment option in full) from the sale of the securities offered by us in this offering excluding any proceeds from the cash exercise of Common Warrants. If a holder of Common Warrants elects to exercise the Common Warrants issued in this offering in cash, we may receive additional proceeds from the exercise of the Common Warrants. We cannot predict when or if the Common Warrants will be exercised. It is possible that the Common Warrants may expire and may never be exercised.

We intend to use the net proceeds from this offering for general corporate purposes, including working capital and operating expenses, and to initiate a Phase 1b clinical study of our compound CLR 121125 (CLR 125) in triple-negative breast cancer. Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot currently allocate specific percentages of the net proceeds that we may use for the purposes specified above, and we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the progress, cost and results of our preclinical and clinical development programs, and whether we are able to enter into future licensing or collaboration arrangements. We may find it necessary or advisable to use the net proceeds for other purposes, and our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from this offering.

DIVIDEND POLICY

We have never declared nor paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends in respect of our common stock in the foreseeable future.

CAPITALIZATION

The following table sets forth cash and capitalization as of March 31, 2025:

- on an actual basis;
- on pro forma as adjusted basis after adjusting for the Reverse Stock Split and the Warrant Inducement;
- on a pro forma as further adjusted basis to give effect to (i) the issuance and sale of shares of Class A Units in this offering at the public offering price of \$5.00 per Class A Unit (but excluding shares of common stock to be issued and any proceeds received upon cash exercise of the Common Warrants) and (ii) the issuance and sale of shares of Class B Units in this offering at the public offering price of \$4.99999 per Class B Unit (but excluding shares of common stock to be issued and any proceeds received upon cash exercise of the Common Warrants or exercise of Pre-Funded Warrants), assuming no exercise of the representative warrants.

The pro forma information set forth in the table below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

(unaudited)	Actual as of March 31, 2025	Pro Forma as Adjusted as of March 31, 2025	Pro Forma as Further Adjusted as of March 31, 2025
Cash and cash equivalents	\$ 13,905,173	\$ 16,155,173	\$ 21,155,173
Stockholders' equity:			
Series E-2 preferred stock	\$ 520,778	\$ 520,778	\$ 520,778
Common stock, \$0.00001 par value; 170,000,000 shares authorized; 46,079,875 shares issued and outstanding actual, 1,812,039 shares issued and outstanding pro forma, 2,677,039 shares issued and outstanding pro forma as adjusted	\$ 461	18	\$ 27
Additional paid-in capital	\$ 261,678,642	\$ 263,929,088	\$ 268,929,079
Accumulated deficit	\$ (253,946,492)	(253,946,492)	\$ (253,946,492)
Total stockholders' equity	\$ 8,253,389	\$ 10,503,392	\$ 15,503,392
Total capitalization	\$ 22,158,562	\$ 26,658,565	\$ 36,658,565

Unless otherwise indicated, the number of shares of common stock to be outstanding immediately after this offering is based on 1,535,996 shares of common stock outstanding as of March 31, 2025, which is adjusted to 1,812,039 to give effect to 276,043 shares that were issued pursuant to the Warrant Inducement, and which excludes:

- any shares of common stock issuable upon the exercise of the underwriter's over-allotment option;
- any shares of common stock issuable upon the exercise of Pre-Funded Warrants issued in this offering;
- any shares of common stock issuable upon the exercise of Common Warrants issued in this offering;
- any shares of common stock issuable upon the exercise of the representative warrants issued as compensation to the underwriter in this offering;
- an aggregate of 211,816 shares of common stock issuable upon the exercise of outstanding stock options issued to employees, directors and consultants;
- an aggregate of 13,040 shares of common stock issuable upon the conversion of outstanding shares of Series E-2 preferred stock;
- an aggregate of 3,704 shares of common stock issuable upon the conversion of outstanding shares of Series D preferred stock; and
- an aggregate of 522,011 additional shares of common stock reserved for issuance under outstanding warrants having expiration dates between June 2025 and July 2029, and exercise prices ranging from \$58.80 to \$362.250 per share.

DILUTION

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the public offering price per Class A Unit and the net tangible book value per share of our common stock upon consummation of this offering. Dilution results from the fact that the public offering price is substantially in excess of the book value per share attributable to the existing stockholders for the presently outstanding stock.

The historical net tangible book value of our common stock, as adjusted for the Reverse Stock Split, as of March 31, 2025 was approximately \$7.7 million, or approximately \$5.03 per share of common stock. Historical net tangible book value (deficit) per share is determined by dividing the number of outstanding shares of common stock into its total tangible assets (total assets less intangible assets) less total liabilities and preferred shares, if any.

Subsequent to March 31, 2025, among other things, we entered into the Warrant Inducement where we issued an aggregate of 8,281,322 shares of common stock (on a pre-Reverse Stock Split basis).

On a pro forma as adjusted basis after giving effect to the Warrant Inducement and the Reverse Stock Split, our pro forma net tangible book value would have been \$10.0 million, or approximately \$5.51 per share of common stock

Investors purchasing securities in this offering will incur immediate and substantial dilution. After giving effect to the sale of securities offered in this offering at the public offering price of \$5.00 per Class A Unit and assuming full exercise of the Pre-Funded Warrants (but excluding any shares of common stock to be issued and any proceeds to be received upon cash exercise of the Common Warrants, if any), and after deducting the underwriting commission and estimated offering costs payable by us, our pro forma as further adjusted net tangible book value as of March 31, 2025 would have been approximately \$15.0 million, or approximately \$4.97 per share of common stock. This represents an immediate decrease in net tangible book value of \$0.53 per share to existing stockholders, and an immediate dilution in the as adjusted net tangible book value of \$0.03 per share to investors in this offering.

The following table illustrates this per share dilution:

Public offering price per Class A Unit		\$	5.00
Pro forma as adjusted net tangible book value per share as of March 31, 2025	\$	5.51	
Decrease in pro forma as adjusted net tangible book value per share attributable to this offering		0.53	
Pro forma as further adjusted net tangible book value as of March 31, 2025 (giving effect to this offering)			4.97
Dilution per share to investors		\$	0.03

The discussion and table above assumes (i) full exercise of all Pre-Funded Warrants, (ii) no exercise of Common Warrants sold in this offering, and (iii) no exercise of the representative warrants.

To the extent that stock options are exercised or new stock options are issued under our equity incentive plans, there will be further dilution to investors purchasing securities in this offering. In addition, we will need to raise additional capital because of market conditions and strategic considerations. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

DESCRIPTION OF SECURITIES WE ARE OFFERING

The following summary of certain terms and provisions of the securities that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the underlying securities, the forms of which are filed as exhibits to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the forms of securities for a complete description of the terms and conditions.

Units

Class A Units - We are offering 865,000 Class A Units with each Class A Unit consisting of (i) one (1) share of our common stock and (ii) one (1) Common Warrant to purchase one (1) share of our common stock.

Class B Units - We are also offering 335,000 Class B Units with each Class B Unit consisting of: (i) one (1) Pre-Funded Warrant and (ii) one (1) Common Warrant to purchase one (1) share of our common stock.

The Common Warrants included in the Class A Units and Class B Units are identical.

The shares of common stock in the Class A Units or the Pre-Funded Warrants in the Class B Units, as applicable, and the accompanying Common Warrants, can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance.

Common Stock

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

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

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

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

Description of Common Warrants

Form. Pursuant to a warrant agency agreement between us and Equiniti Trust Company, LLC, as warrant agent, the Common Warrants will be issued in book-entry form and shall initially be represented only by one or more global Common Warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Exercisability. The Common Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as described below). A holder (together with its affiliates) may not exercise any portion of the Common Warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Common Warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Common Warrants. Holders of the Common Warrants may also elect prior to the issuance of the Common Warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock. No fractional shares of common stock will be issued in connection with the exercise of a Common Warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the nearest whole share.

Duration and Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the Common Warrants is \$5.25 per share. The Common Warrants will be immediately exercisable upon issuance and may be exercised until the five (5) year anniversary from the date of issuance. The exercise price of the Common Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and upon any distributions of assets, including cash, stock or other property to our stockholders.

Cashless Exercise. If, at any time after the issuance of the Common Warrants, such holder exercises its Common Warrants and a registration statement registering the issuance of the shares of common stock underlying the Common Warrants under the Securities Act is not then effective or available (or a prospectus is not available for the resale of shares of common stock underlying the Common Warrants), then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of common stock determined according to a formula set forth in the Common Warrants. Notwithstanding anything to the contrary, in the event we do not have or maintain an effective registration statement, there are no circumstances that would require us to make any cash payments or net cash settle the Common Warrants to the holders.

Transferability. Subject to applicable laws, the Common Warrants may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the Common Warrant to us together with the appropriate instruments of transfer.

Exchange Listing. We do not plan on applying to list the Common Warrants on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system. Without an active trading market, the liquidity of the Common Warrants will be limited.

Fundamental Transactions. In the event of a fundamental transaction, as described in the Common Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the outstanding common stock and greater than 50% of the voting power represented by our outstanding securities with voting rights, on an as converted basis, the holders of the Common Warrants will be entitled to receive upon exercise of the Common Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised Common Warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the Common Warrants. Additionally, as more fully described in the Common Warrant, in the event of certain fundamental transactions, the holders of the Common Warrants may be entitled to receive consideration in an amount equal to the Black Scholes value of the Common Warrants.

Rights as a Stockholder. Except by virtue of such holder's ownership of shares of our common stock, the holder of a Common Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Common Warrant.

Description of Pre-Funded Warrants

Form. Pursuant to a warrant agency agreement between us and Equiniti Trust Company, LLC, as warrant agent, the Pre-Funded Warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Exercisability. The Pre-Funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as described below). A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Pre-Funded Warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. Purchasers of Pre-Funded Warrants in this offering may also elect prior to the issuance of the Pre-Funded Warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock. No fractional shares of common stock will be issued in connection with the exercise of a Pre-Funded Warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the nearest whole share.

Duration and Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the Pre-Funded Warrants is \$0.00001 per share of common stock. The Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until the Pre-Funded Warrants are exercised in full. The exercise price of the Pre-Funded Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and upon any distributions of assets, including cash, stock or other property to our stockholders.

Cashless Exercise. If, at any time after the holder's purchase of Pre-Funded Warrants, such holder exercises its Pre-Funded Warrants, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of common stock determined according to a formula set forth in the Pre-Funded Warrants.

Transferability. Subject to applicable laws, the Pre-Funded Warrants may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the Pre-Funded Warrant to us together with the appropriate instruments of transfer.

Exchange Listing. We do not plan on applying to list the Pre-Funded Warrants on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system. Without an active trading market, the liquidity of the Pre-Funded Warrants will be limited.

Fundamental Transactions. In the event of a fundamental transaction, as described in the Pre-Funded Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the outstanding common stock and greater than 50% of the voting power represented by our outstanding securities with voting rights, on an as converted basis, the holders of the Pre-Funded Warrants will be entitled to receive upon exercise of the Pre-Funded Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Pre-Funded Warrants immediately prior to such fundamental transaction.

Rights as a Stockholder. Except by virtue of such holder's ownership of shares of our common stock, the holder of a Pre-Funded Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Pre-Funded Warrant.

Description of Representative Warrants

Form. The representative warrants will be issued in certificated form by the Company.

Exercisability. The representative warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as described below). A holder (together with its affiliates) may not exercise any portion of the representative warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's representative warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the representative warrants. Holders of the representative warrants may also elect prior to the issuance of the representative warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock. No fractional shares of common stock will be issued in connection with the exercise of a representative warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the nearest whole share.

Duration and Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the representative warrants is \$7.75. The representative warrants will be immediately exercisable upon issuance and may be exercised until the five (5) year anniversary from the commencement of sales of this offering. The exercise price of the representative warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and upon any distributions of assets, including stock or other property to our stockholders.

Cashless Exercise. If, at any time after the issuance of the representative warrants, such holder exercises its representative warrants and a registration statement registering the issuance of the shares of common stock underlying the representative warrants under the Securities Act is not then effective or available (or a prospectus is not available for the resale of shares of common stock underlying the representative warrants), then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of common stock determined according to a formula set forth in the representative warrants. Notwithstanding anything to the contrary, in the event we do not have or maintain an effective registration statement, there are no circumstances that would require us to make any cash payments or net cash settle the representative warrants to the holders.

Transferability. The representative warrants will be subject to FINRA Rule 5110(e)(1) in that, except as otherwise permitted by FINRA rules, for a period of 180 days from the commencement of sales of this offering, the representative warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person except as permitted by FINRA Rule 5110(e)(2). In addition, subject to applicable laws, the representative warrants may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the representative warrant to us together with the appropriate instruments of transfer after the initial 180 day period from the commencement of sales of the offering.

Exchange Listing. We do not plan on applying to list the representative warrants on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system. Without an active trading market, the liquidity of the representative warrants will be limited.

Fundamental Transactions. In the event of a fundamental transaction, as described in the representative warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the outstanding common stock and greater than 50% of the voting power represented by our outstanding securities with voting rights, on an as converted basis, the holders of the representative warrants will be entitled to receive upon exercise of the representative warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the representative warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the representative warrants. Additionally, as more fully described in the representative warrant, in the event of certain fundamental transactions, the holders of the representative warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the representative warrants on the date of consummation of such transaction.

Rights as a Stockholder. Except by virtue of such holder's ownership of shares of our common stock, the holder of a representative warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the representative warrant.

Anti-Takeover Effect of Certain Certificate of Incorporation and By-Law Provisions

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

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

Amendments to By-Laws. Our By-Laws are subject to alternation or repeal, and new by-laws may be made, by a majority of the voting power of all then outstanding shares of capital stock entitled to vote generally in the election of directors, voting together a single class. Additionally, our By-Laws provide the Board of Directors with the power to make, adopt, alter, amend and repeal, from time to time, our By-Laws, provided, however, that the stockholders entitled to vote with respect to amendments to our By-Laws may alter, amend or repeal By-Laws made by the Board of Directors.

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

Notice Periods for Stockholder Meetings. Our By-Laws provide that for business to be brought by a stockholder before an annual meeting of stockholders, the stockholder must give written notice to the corporation not later than the close of business on the 90th day, or earlier than the 120th day prior to the one year anniversary of the date of the annual meeting of stockholders of the previous year; provided, however, that in the event that the annual meeting of stockholders is called for a date that is not within 30 days prior to, or more than 60 days after, such anniversary date, notice by the stockholder must be received not later than 120 days prior to such annual meeting and not later than the close of business on the 90th day prior to such annual meeting and the 10th day following the day on which the corporation's notice of the date of the meeting is first given or made to the stockholders or disclosed to the general public. Our By-Laws also provide that the Board of Directors or the chair of such meeting may postpone, reschedule or cancel any annual meeting of stockholders previously scheduled by the Board of Directors and in no event shall the adjournment, recess, postponement, judicial stay or rescheduling of an annual meeting commence a new time period, or extend any time period, for the giving of notice.

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

Nominations. Our By-Laws provide that nominations for election of directors may be made only by (i) the Board of Directors or a committee appointed by the Board of Directors; or (ii) a stockholder entitled to vote on director election, if the stockholder provides notice to the Secretary of the Company presented not less than 90 days nor more than 120 days prior to the anniversary of the last annual meeting (subject to the limited exceptions set forth in the bylaws). These provisions may deter takeovers by requiring that any stockholder wishing to conduct a proxy contest have its position solidified well in advance of the meeting at which directors are to be elected and by providing the incumbent Board of Directors with sufficient notice to allow them to put an election strategy in place. Our bylaws also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and specifies requirements as to the form and content of a stockholder's notice.

Choice of Forum. Our bylaws provides that the Court of Chancery of the state of Delaware shall be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our restated certificate, or our amended and restated bylaws; or
- any action asserting a claim against us that is governed by the internal affairs doctrine.

The provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our bylaws provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our Certificate of Incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Our bylaws further provides that the federal district courts of the United States of America shall be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

No Cumulative Voting. Delaware General Corporation Law provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our Certificate of Incorporation and bylaws do not provide for cumulative voting.

Concentration of Ownership

Our executive officers, directors and holders of five percent or more of our outstanding common stock, together with their respective affiliates, beneficially own or control a significant portion of the outstanding shares of the Company. Accordingly, these stockholders will have substantial influence over the outcome of a corporate action of the Company requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the Company's assets or any other significant corporate transaction. These stockholders may also exert influence in delaying or preventing a change in control of the Company, even if such change in control would benefit the other stockholders of the Company.

Listing

Our common stock is currently traded on the Nasdaq Capital Market under the symbol "CLRB."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC.

UNDERWRITING

We are offering the securities described in this prospectus through the underwriter named below. We have entered into an underwriting agreement dated July 1, 2025 with Ladenburg Thalmann & Co. Inc., as the underwriter in this offering. Subject to the terms and conditions of the underwriting agreement, the underwriter have agreed to purchase the number of our securities set forth opposite its name below.

Underwriter	Number of Class A Units	Number of Class B Units
Ladenburg Thalmann & Co. Inc.	865,000	335,000

A copy of the form of the underwriting agreement has been filed as an exhibit to the registration statement of which this prospectus is part.

We have been advised by the underwriter that it proposes to offer the Class A Units and Class B Units directly to the public at the public offering prices set forth on the cover page of this prospectus. Any securities sold by the underwriter to securities dealers will be sold at the public offering price less a selling concession not in excess of \$0.23952 per share of common stock, \$0.23952 per Pre-Funded Warrant and \$0.00048 per Common Warrant.

The underwriting agreement provides that the underwriter's obligation to purchase the securities we are offering is subject to conditions contained in the underwriting agreement.

No action has been taken by us or the underwriter that would permit a public offering of the securities in any jurisdiction outside the United States where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offering hereby be distributed or published in any jurisdiction except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the securities in any jurisdiction where that would not be permitted or legal.

The underwriter has advised us that it does not intend to confirm sales to any account over which they exercise discretionary authority.

Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriter by us.

	Per Class A Unit	Per Class B Unit	Total Without Over- Allotment	Total With Full Over- Allotment
Public offering price (1)	\$ 5.00	\$ 4.99999	\$ 5,999,997	\$ 6,899,997
Underwriting discounts and commissions (2)(3)	\$ 0.40	\$ 0.40	\$ 480,000	\$ 552,000
Proceeds to us, before expenses	\$ 4.60	\$ 4.59999	\$ 5,519,997	\$ 6,347,997

(1) The public offering price and underwriting discount corresponds, in respect of the securities of (i) a public offering price per Class A Unit of \$5.00 (\$4.60 net of the underwriting discount) and (ii) a public offering price per Class B Unit of \$4.99999 (\$4.59999 net of the underwriting discount).

(2) We have also agreed to reimburse the accountable expenses of the underwriter, including a pre-closing expense allowance of up to a maximum of \$50,000 and an additional closing expense allowance up to a maximum of \$110,000. We paid an advance expense deposit of \$25,000 to the underwriter for its anticipated accountable expenses. Any expense deposits will be returned to us to the extent the underwriter's accountable expenses are not actually incurred in accordance with FINRA Rule 5110(g)(4)(A).

(3) We have granted a forty-five day over-allotment option to the underwriter to purchase up to an aggregate of 180,000 additional shares of common stock and/or additional Common Warrants to purchase up to 180,000 additional shares of common stock at the public offering prices per security set forth above less the underwriting discounts and commissions solely to cover over-allotments, if any.

We estimate the total expenses payable by us for this offering, assuming no exercise of the over-allotment option, to be approximately \$1,000,000, which amount includes (i) the underwriting discount of approximately \$480,000, (ii) reimbursement of the accountable expenses of the underwriter in an amount not to exceed \$160,000 and (iii) other estimated company expenses of approximately \$360,000, which includes legal, accounting, printing costs and various fees associated with the registration and listing of our securities.

The securities we are offering are being offered by the underwriter subject to certain conditions specified in the underwriting agreement.

Our executive officers agreed to purchase an aggregate of 25,000 Class A Units for a total purchase price of approximately \$125,000 at the public offering price and on the same terms as other purchasers in the offering. The underwriter will receive the same underwriting discount and commissions on the securities purchased by such persons in this offering as they will on any other securities sold to the public in this offering.

Over-allotment Option

We have granted to the underwriter an option exercisable not later than forty-five days after the date of this prospectus to purchase up to an aggregate of an additional 180,000 shares of common stock and/or additional Common Warrants to purchase up to an additional 180,000 shares of common stock, or any combination thereof, as determined by the underwriter, at the public offering price per security set forth on the cover page hereto less the underwriting discounts and commissions. The underwriter may exercise the option solely to cover over-allotments, if any, made in connection with this offering. If any additional shares of common stock and/or Common Warrants are sold, the underwriter will offer such securities on the same terms as those on which the other securities are being offered.

Representative Warrants

We have agreed to issue certain common stock purchase warrants ("representative warrants") to the underwriter, or its designees, upon the closing of this offering, which entitle it to purchase up to 72,000 shares of common stock, or 82,800 shares of common stock assuming the exercise of the over-allotment option in full. The representative warrants will have an exercise price equal to \$7.75 per share of common stock, will be exercisable immediately upon issuance, at any time and from time to time, in whole or in part, during the five-year period commencing from the commencement of sales of this offering. The representative warrants and the shares of common stock underlying the representative warrants are being registered on the registration statement of which this prospectus is a part. See the form of representative warrant for a more complete description of the terms of such representative warrants which has been filed as an exhibit to the registration statement of which this prospectus is part.

Listing

Our shares of common stock are listed on The Nasdaq Capital Market under the symbol "CLRB."

There is no established public trading market for the Common Warrants or Pre-Funded Warrants, and we do not expect such markets to develop. In addition, we do not intend to apply for a listing of the Common Warrants or Pre-Funded Warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Common Warrants and Pre-Funded Warrants will be limited.

Lock-up Agreements

Each of our officers, directors and each of their respective affiliates and associated partners, and certain affiliated stockholders have agreed with the underwriter to be subject to a lock-up period of sixty (60) days following the closing of this offering, subject to certain exceptions. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the (i) issuance and sale of our equity securities from the date of this prospectus for a period of sixty (60) days following the closing of this offering and (ii) entry into certain “variable rate transactions” from the date of this prospectus for a period of one hundred and eighty (180) days following the closing of this offering, in each case subject to certain exceptions. The underwriter may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

Right of First Refusal

Pursuant to our investment banking agreement with the underwriter, from the twelve (12) months following the date of such closing and expiration of the term, should we propose to effect an additional financing, we have agreed to offer the underwriter the opportunity to participate as sole bookrunner, exclusive placement agent or exclusive sales agent or financial advisor in respect of such financing.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC.

Determination of Offering Price

Our common stock is currently traded on The Nasdaq Capital Market under the symbol “CLRB.” On June 30, 2025, the closing price of our common stock was \$7.11 per share. We do not intend to apply for listing of the Common Warrants or Pre-Funded Warrants on any securities exchange or other trading system.

The public offering price of the securities offered by this prospectus was determined by negotiation between us and the underwriter. Among the factors that we considered in determining the public offering price:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The public offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the securities sold in this offering. That price is subject to change as a result of market conditions and other factors, and we cannot assure you that the shares of common stock underlying the Class A Units, Pre-Funded Warrants (contained in the Class B Units) and Common Warrants sold in this offering can be resold at or above the public offering price.

Stabilization, Short Positions and Penalty Bids

The underwriter may engage in syndicate covering transactions stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock:

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.

- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions, and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriters also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transactions, once commenced will not be discontinued without notice.

Other Relationships

Ladenburg Thalmann & Co. Inc. acted as the exclusive placement agent in connection with the Warrant Inducement and from time to time, it or its affiliates may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which it will receive customary fees and commissions.

Indemnification

We have agreed to indemnify the underwriter against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the underwriter may be required to make for these liabilities.

Electronic Distribution

A prospectus in electronic format may be made available on the website maintained by the underwriter, if any, and the underwriters may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on such website is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the underwriter, and should not be relied upon by investors.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a general discussion of the material U.S. federal income considerations applicable to the ownership and disposition of shares of our common stock, Common Warrants and Pre-Funded Warrants acquired in this offering. This discussion is for general information only and is not tax advice. Accordingly, all prospective holders of our common stock, Common Warrants and Pre-Funded Warrants should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock, Common Warrants and Pre-Funded Warrants. This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended (the “Code”), existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences described in this prospectus. We assume in this discussion that each holder holds shares of our common stock, Common Warrants and Pre-Funded Warrants as capital assets within the meaning of Section 1221 of the Code (generally property held for investment).

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular holder in light of that holder’s individual circumstances, does not address the alternative minimum or Medicare contribution taxes, and does not address any aspects of U.S. state, local or non-U.S. taxes or any U.S. federal taxes other than income tax. This discussion also does not consider any specific facts or circumstances that may apply to a holder and does not address aspects of U.S. federal income taxation that may be applicable to holders that are subject to special tax rules, including without limitation:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- real estate investment trusts;
- pension plans, individual retirement accounts and other tax deferred accounts;
- persons that mark their securities to market;
- controlled foreign corporations;
- passive foreign investment companies;
- “dual resident” corporations;
- persons that receive our common stock, Common Warrants or Pre-Funded Warrants as compensation for the performance of services;
- owners that hold our common stock, Common Warrants or Pre-Funded Warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- owners that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below);
- persons that have a functional currency other than the U.S. dollar; and
- certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships or other pass-through entities for U.S. federal income tax purposes, or persons who hold our common stock, Common Warrants or Pre-Funded Warrants through partnerships or other pass-through entities for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock, Common Warrants or Pre-Funded Warrants should consult his, her or its own tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock, Common Warrants or Pre-Funded Warrants through a partnership or other pass-through entity, as applicable.

As used in this prospectus, the term “U.S. holder” means a beneficial owner of common stock, Common Warrants or Pre-Funded Warrants that is for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation (or other entity properly classified as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state within the United States, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if (i) a U.S. court is able to exercise primary supervision over the trust’s administration and one or more “United States persons” (as defined in the Code) have the authority to control all substantial decisions of the trust, or (ii) in the case of a trust that was treated as a domestic trust under the laws in effect before 1997, a valid election is in place under applicable U.S. Treasury regulations to treat such trust as a domestic trust.

The term “non-U.S. holder” means any beneficial owner of common stock, Common Warrants or Pre-Funded Warrants that is not a U.S. holder and is not a partnership or other entity properly classified as a partnership for U.S. federal income tax purposes. For the purposes of this prospectus, U.S. holders and non-U.S. holders are referred to collectively as “holders.”

There can be no assurance that the Internal Revenue Service (the “IRS”) will not challenge one or more of the tax consequences described herein. We have not obtained, nor do we intend to obtain, a ruling from the IRS with respect to the U.S. federal income tax consequences of the purchase, ownership or disposition of our common stock, Common Warrants or Pre-Funded Warrants.

Allocation of Purchase Price of the Class A Units and Class B Units

Each Class A Unit should be treated for U.S. federal income tax purposes as an “investment unit” consisting of one share of our common stock and one Common Warrant. Each Class B Unit should be treated for U.S. federal income tax purposes as an investment unit consisting of one Pre-Funded Warrant and one Common Warrant. The purchase price for each investment unit will be allocated between these components in proportion to their relative fair market values at the time the investment unit is purchased by the holder. This allocation will establish a holder’s initial tax basis for U.S. federal income tax purposes in his, her or its share of common stock (or, in lieu of common stock, Pre-Funded Warrant) and Common Warrant included in each investment unit. We will not be providing holders with such allocation, and it is possible that different holders will reach different determinations regarding such allocation. A holder’s allocation of purchase price between each share of common stock (or, in lieu of common stock, each Pre-Funded Warrant) and the accompanying Common Warrant is not binding on the IRS or the courts, and no assurance can be given that the IRS or the courts will agree with a holder’s allocation.

Accordingly, each prospective holder should consult his, her or its own tax advisor with respect to the allocation, and the risks associated with such allocation, of the holder’s purchase price for the investment unit between our shares of common stock (or, in lieu of common stock, Pre-Funded Warrants) and Common Warrants.

Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, a Pre-Funded Warrant should be treated as a share of our common stock for U.S. federal income tax purposes and a holder of Pre-Funded Warrants should generally be taxed in the same manner as a holder of common stock, as described below. Accordingly, no gain or loss should be recognized upon the exercise of a Pre-Funded Warrant and, upon exercise, the holding period of a Pre-Funded Warrant should carry over to the share of common stock received. Similarly, the tax basis of the Pre-Funded Warrant should carry over to the share of common stock received upon exercise, increased by the exercise price of \$0.00001 per share. Each holder should consult his, her or its own tax advisor regarding the risks associated with the acquisition of Pre-Funded Warrants pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above will be respected for U.S. federal income tax purposes.

Tax Consequences to U.S. Holders

Exercise or Expiration of Common Warrants

Subject to the discussion below with respect to the cashless exercise of a Common Warrant, a U.S. holder will not recognize income, gain or loss on the exercise of a Common Warrant. A U.S. holder's tax basis in the common stock received upon the exercise of a Common Warrant will equal the sum of (i) the initial tax basis of the Common Warrant exercised (as determined pursuant to the rules discussed above under "Allocation of Purchase Price of the Class A Units and Class B Units") and (ii) the exercise price of the Common Warrant. The U.S. holder's holding period for the common stock received upon exercise of a Common Warrant will begin on the day after such exercise (or possibly on the date of exercise) and will not include the period during which the U.S. holder held the Common Warrant.

The tax consequences of a cashless exercise of a Common Warrant are not clear under current U.S. tax law. A cashless exercise may be tax-free, either because the exercise is not a realization event or because the exercise is treated as a recapitalization for U.S. federal income tax purposes. In either case, a U.S. holder's basis in the common stock received in connection with the cashless exercise would equal the U.S. holder's basis in the Common Warrants surrendered in connection with the cashless exercise. If the cashless exercise was not a realization event, it is unclear whether a U.S. holder's holding period for the common stock would be treated as commencing on the date of exercise or on the day following the date of exercise. If the cashless exercise were treated as a recapitalization, the holding period of the common stock would include the holding period of the Common Warrants surrendered in connection with the cashless exercise.

It is possible that a cashless exercise could be treated in part as a taxable exchange in which gain or loss would be recognized. In such event, a U.S. holder could be deemed to have surrendered Common Warrants having an aggregate fair market value equal to the exercise price for the total number of Common Warrants to be exercised. The U.S. holder would recognize capital gain or loss in an amount equal to the difference between the amount deemed realized (*i.e.*, the exercise price for the Common Warrants exercised) and the U.S. holder's tax basis in the Common Warrants deemed surrendered to pay the exercise price. In this case, a U.S. holder's tax basis in the common stock received would equal the sum of the U.S. holder's initial investment in the exercised Common Warrants and the exercise price for such Common Warrants. It is unclear whether a U.S. holder's holding period for the common stock would commence on the date of exercise of the Common Warrants or the day following the date of exercise of the Common Warrants.

Due to the absence of authority on the U.S. federal income tax treatment of a cashless exercise, there can be no assurance which, if any, of the alternative approaches described above would be adopted by the IRS or a court of law. Accordingly, U.S. holders should consult their own tax advisors regarding the tax consequences of a cashless exercise.

If a Common Warrant is allowed to lapse unexercised, a U.S. holder generally will recognize a capital loss equal to such holder's tax basis in the Common Warrant. The deductibility of capital losses is subject to significant limitations.

Distributions on Our Common Stock

As discussed above under “Dividend Policy,” we do not currently expect to make distributions on our common stock. In the event that we do make distributions on our common stock to a U.S. holder, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the U.S. holder’s investment, up to such U.S. holder’s tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “—Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants.” Dividends paid by us generally will be eligible for the reduced rates of tax for qualified dividend income allowed to individual U.S. holders and for the dividends received deduction allowed to corporate U.S. holders, in each case assuming that certain holding period and other requirements are satisfied.

Constructive Distributions on Our Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock that will be issued on the exercise of our warrants (whether Pre-Funded Warrants or Common Warrants), or an adjustment to the exercise price of such warrants, may be treated as a constructive distribution to a U.S. holder of the warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. holder’s proportionate interest in our “earnings and profits” or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to holders of our common stock). Adjustments to the exercise price of a warrant made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holder of the warrant should generally not result in a constructive distribution. Any constructive distributions generally would be subject to the tax treatment described above under “—Distributions on Our Common Stock.”

Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants

Upon the sale, exchange, or other taxable disposition of our common stock or warrants (whether Pre-Funded Warrants or Common Warrants), a U.S. holder will recognize gain or loss equal to the difference between the amount realized upon the disposition and the U.S. holder’s tax basis in the common stock or warrants sold or exchanged. Any gain or loss generally will be capital gain or loss, and will be long-term capital gain or loss if the U.S. holder’s holding period for the common stock or Common Warrants exceeded one year at the time of the disposition. Certain U.S. holders (including individuals) are currently eligible for preferential rates of U.S. federal income taxation in respect of long-term capital gains. The deductibility of capital losses is subject to significant limitations.

Information Reporting and Backup Withholding

In general, information reporting requirements may apply to distributions (whether actual or constructive) paid to a U.S. holder on our common stock or warrants, and to the proceeds of the sale, exchange or other disposition of our common stock and warrants, unless the U.S. holder is an exempt recipient. Backup withholding will apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn). Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against a U.S. holder’s U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Tax Consequences to Non-U.S. Holders

Exercise or Expiration of Common Warrants

In general, a non-U.S. holder will not be required to recognize income, gain or loss upon the exercise of a Common Warrant by payment of the exercise price. To the extent that a cashless exercise results in a taxable exchange, the consequences would be similar to those described below under “—Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants.”

The expiration of a Common Warrant will be treated as if the non-U.S. holder sold or exchanged the Common Warrant and recognized a capital loss equal to the non-U.S. holder's basis in the Common Warrant. A non-U.S. holder will not be able to utilize a loss recognized upon expiration of a Common Warrant against the non-U.S. holder's U.S. federal income tax liability, however, unless the loss (i) is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a "permanent establishment" or "fixed base" in the United States) or (ii) is treated as a U.S. source loss and the non-U.S. holder is present in the United States 183 days or more in the taxable year of disposition and certain other conditions are met.

Distributions on Our Common Stock

As discussed above under "Dividend Policy," we do not currently expect to make distributions on our common stock. In the event that we do make distributions to holders of our common stock or if we are treated as making a constructive distribution to holders of our Common Warrants or Pre-Funded Warrants, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such non-U.S. holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "—Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants."

Distributions (including constructive distributions) made to a non-U.S. holder that are treated as dividends generally will be subject to withholding of U.S. federal income tax at a rate of 30% of the gross amount or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence, unless such dividends are effectively connected with a trade or business conducted by a non-U.S. holder within the U.S. (as discussed below). A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form), as applicable, and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may be able to obtain a refund or credit of any excess amounts withheld by timely filing the required information with the IRS.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a "permanent establishment" or a "fixed base" maintained by the non-U.S. holder within the United States, generally are exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. U.S. effectively connected income, net of specified deductions and credits, is generally taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Constructive Distributions on Our Warrants

As described above under "—Tax Consequences to U.S. Holders—Constructive Distributions on Our Warrants," an adjustment to the Common Warrants or Pre-Funded Warrants could result in a constructive distribution to a non-U.S. holder, which would be treated as described under "—Distributions on Our Common Stock" above. Any resulting withholding tax attributable to deemed dividends would be collected from other amounts payable or distributable to the non-U.S. holder. Non-U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to the Common Warrants and Pre-Funded Warrants.

In addition, regulations governing "dividend equivalents" under Section 871(m) of the Code may apply to the Pre-Funded Warrants. Under those regulations, an implicit or explicit payment made to the holder of Pre-Funded Warrants that references a distribution on our common stock would generally be taxable to a non-U.S. holder in the manner described under "—Distributions on our Common Stock" below. Such dividend equivalent amount would be taxable and subject to withholding whether or not there is actual payment of cash or other property, and we may satisfy any withholding obligations by withholding from other amounts due to the non-U.S. holder. Non-U.S. holders are encouraged to consult their own tax advisors regarding the application of Section 871(m) of the Code to the Pre-Funded Warrants.

Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants

In general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other taxable disposition of shares of our common stock, Common Warrants or Pre-Funded Warrants unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a "permanent establishment" or a "fixed base" maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on such gain at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Tax Consequences to Non-U.S. Holders—Distributions on Our Common Stock" also may apply to such gain;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the taxable disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the taxable disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any; or
- we are, or have been, at any time during the five-year period preceding such taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the 5-year period ending on the date of the taxable disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then a purchaser may withhold 15% of the proceeds payable to a non-U.S. holder from a sale of our common stock, Common Warrants or Pre-Funded Warrants, and the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions paid on our common stock (and constructive distributions on our Common Warrants and Pre-Funded Warrants) to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock, Common Warrants or Pre-Funded Warrants. Dividends paid to non-U.S. holders subject to the U.S. withholding tax, as described above in "Tax Consequences to Non-U.S. Holders—Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock, Common Warrants and Pre-Funded Warrants by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS.

Foreign Accounts

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a 30% withholding tax on dividends (including constructive dividends) on, and gross proceeds from the sale or other disposition of, our common stock and Warrants if paid to a non-U.S. entity unless (i) if the non-U.S. entity is a "foreign financial institution," the non-U.S. entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the non-U.S. entity is not a "foreign financial institution," the non-U.S. entity identifies certain of its U.S. investors, if any, or (iii) the non-U.S. entity is otherwise exempt under FATCA.

While withholding under FATCA may apply to payments of gross proceeds from a sale or other disposition of our common stock, Common Warrants or Pre-Funded Warrants, under proposed U.S. Treasury Regulations withholding on payments of gross proceeds is not required. Although such regulations are not final, applicable withholding agents may rely on the proposed regulations until final regulations are issued.

An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Under certain circumstances, a holder may be eligible for refunds or credits of the tax. Non-U.S. holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock, Common Warrants or Pre-Funded Warrants.

The preceding discussion of material U.S. federal income tax considerations is for informational purposes only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, Common Warrants or Pre-Funded Warrants, including the consequences of any proposed changes in applicable laws.

LEGAL MATTERS

Sidley Austin LLP, New York, New York, will pass upon the validity of the securities offered by this prospectus. The underwriter is being represented by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The financial statements of Collectar Biosciences, Inc. as of December 31, 2024 and 2023, and for each of the two years in the period ended December 31, 2024, incorporated by reference in this prospectus, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report. Such financial statements are incorporated by reference in reliance upon the report of such firm given their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. We have filed with the SEC a registration statement under the Securities Act with respect to the securities being offered under this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities being offered under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. You may obtain copies of the registration statement and its exhibits via the SEC's website at <http://www.sec.gov>.

You can also read our Securities and Exchange Commission filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov. You may also request a copy of these filings, at no cost, by writing us at 100 Campus Drive, Florham Park, New Jersey 07932 or telephoning us at (608) 441-8120.

We are subject to the informational and reporting requirements of the Securities Exchange Act of 1934, as amended, and have filed and will file annual, quarterly and current reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We maintain a website at <https://www.collectar.com>. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to “incorporate by reference” information into this prospectus. This means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is considered to be a part of this prospectus, except for any information that is superseded by other information that is included in this prospectus. The information we incorporate by reference is an important part of this prospectus and information that we subsequently file with the SEC will automatically update and supersede information in this prospectus and in our other filings with the SEC.

We incorporate by reference the documents listed below, which we have already filed with the SEC, and any filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (1) on or after the date of filing of the registration statement of which this prospectus forms a part and (2) on or after the date of this prospectus until the earlier of the date on which all of the securities registered hereunder have been sold or the registration statement of which this prospectus is a part has been withdrawn (in each case, other than information that is deemed, under SEC rules, not to have been filed):

- [our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on March 13, 2025;](#)
- [our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2025, filed with the SEC on May 13, 2025;](#)
- the portions of our [Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 28, 2025](#), that are incorporated by reference in our [Annual Report on Form 10-K for the fiscal year ended December 31, 2024](#);
- our Current Reports on Form 8-K, filed with the SEC on [January 31, 2025](#), [March 17, 2025](#), [May 1, 2025](#), [June 5, 2025](#) (excluding Item 7.01 and the related exhibit 99.1), [June 13, 2025](#), [June 18, 2025](#), [June 25, 2025](#) and [June 26, 2025](#) and
- the description of our common stock and warrants to purchase common stock included in our registration statement on [Form 8-A filed on August 14, 2014](#), as the same may be updated by [Exhibit 4.3 to Amendment No. 1 to our Annual Report on Form 10-K filed on April 1, 2024](#), including all other amendments and reports filed for the purpose of updating such description.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including those made after the date of the initial filing of the registration statement of which this prospectus is a part and those made after the effectiveness of such registration statement, until the termination of the offering of the common stock made by this prospectus, and such filings will become a part of this prospectus from the respective dates that such documents are filed with the SEC. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information herein or in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

You may request and obtain a copy of any of the filings incorporated herein by reference, at no cost, by writing or telephoning us at the following address or phone number:

Collectar Biosciences, Inc.
100 Campus Drive
Florham Park, New Jersey 07932
Attention: Chief Financial Officer
(608) 441-8120



865,000 Class A Units with each Class A Unit consisting of (i) one (1) Share of Common Stock and (ii) one (1) Common Warrant to purchase one (1) Share of Common Stock

335,000 Class B Units with each Class B Unit consisting of (i) one (1) Pre-Funded Warrant to Purchase one (1) Share of Common Stock and (ii) one (1) Common Warrant to purchase one (1) Share of Common Stock

72,000 Representative Warrants to Purchase 72,000 Shares of Common Stock

1,607,000 Shares of Common Stock Issuable Upon Exercise of (i) 335,000 Pre-Funded Warrants, (ii) 1,200,000 Common Warrants and (iii) 72,000 Representative Warrants

PROSPECTUS

Ladenburg Thalmann

July 1, 2025

We have not authorized any dealer, salesperson or other person to give any information or represent anything not contained in this prospectus. You must not rely on any unauthorized information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus does not offer to sell any securities in any jurisdiction where it is unlawful. Neither the delivery of this prospectus, nor any sale made hereunder, shall create any implication that the information in this prospectus is correct after the date hereof.
