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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended: December 31, 2025

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

For the transition period from to .

Commission File Number 001-36598

CELLECTAR BIOSCIENCES, INC.

(*Exact name of Registrant as specified in its Charter*)

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.00001	CLRB	Nasdaq Capital Market

Securities Registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of June 30, 2025, was $12,846,737.

As of February 24, 2026, there were 4,240,129 shares of the registrant's $0.00001 par value common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the Registrant's 2026 Annual Meeting of Stockholders are incorporated by reference in Part III of this annual report on Form 10-K. The definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this annual report on Form 10-K.

CELLECTAR BIOSCIENCES, INC.
FORM 10-K

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FORWARD-LOOKING STATEMENTS

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

- our current views with respect to our business strategy, business plan and research and development activities;
- the progress of our product development programs, including clinical testing and the timing of commencement and results thereof;
- statements regarding execution of our regulatory strategy;
- 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 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 annual report on Form 10-K.

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

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

PART I

Item 1. Business.

Business Overview

We are a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer. Our core objective is to leverage our proprietary phospholipid 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.

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") granted Breakthrough Therapy Designation for iopofosine I 131, as a radioconjugate monotherapy for the treatment of relapsed/refractory Waldenstrom macroglobulinemia (r/r WM). On October 6, 2025, the Company announced that after a scientific advice procedure, the Scientific Advice Working Party (SAWP) of the European Medicines Agency (EMA) advised that filing for a Conditional Marketing Authorization (CMA) for iopofosine I 131 as a treatment for post - Bruton Tyrosine Kinase inhibitor (BTKi) refractory patients with Waldenstrom macroglobulinemia (WM) could be acceptable for a CMA.

- CLR 125, an Auger-emitting PRC, utilizes iodine-125 as its radiation source 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 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 condition because of the Company's novel phospholipid ether drug conjugate platform. CLR 125 is the subject of a Phase 1b dose finding study as described below.

- CLR 225, an alpha-emitting, actinium-225 based PRC has shown activity in multiple solid tumor animal models including pancreatic, colorectal and breast cancers. CLR 121225 was well tolerated in these models with the animals showing no adverse events at the highest doses tested. The compound demonstrated excellent biodistribution and uptake by tumors. Furthermore, in multiple models of pancreatic adenocarcinoma, including highly refractory pancreatic cancer, we have observed proportional dose response with a single dose of CLR 225 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 subject to our ability to obtain additional financing.

- Iopofosine, a beta-emitting iodine-131 PRC, was studied in our CLOVER WaM Phase 2 study of iopofosine in patients with r/r 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). 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 in follow-up. 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.

- To further develop iopofosine I 131, the Company will likely require either a strategic partner with the necessary resources or sufficient additional funding to initiate and at least partially enroll a confirmatory study, which has been identified as a required predicate to the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the accelerated approval of iopofosine I 131 as a treatment for WM.

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 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 at 11.4 months of follow-up and 76% of patients remaining progression free at a median follow-up of eight months. These outcomes exceed historic 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 sequalae. 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. The Phase 2b study evaluated 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 2026. 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 Break-through Designation for r/r Waldenstrom's macroglobulinemia (WM), 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 PRIME designation and ODD to iopofosine for treatment of r/r MM and 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, and clarified by subsequent written correspondence, the Company believes that it understands a path forward for potential accelerated and full approval of iopofosine I 131 based upon the CLOVER WaM study and the initiation of a comparator controlled Phase 3 confirmatory trial assessing progression free survival as the primary endpoints in WM patients. The submission for accelerated approval utilizing the CLOVER WaM study data can occur at the time of the initiation of Phase 3 randomized controlled confirmatory study and patient enrollment must be ongoing at the time of decision on the accelerated NDA. The confirmatory study will be executed in an earlier line of therapy than was tested in the CLOVER WaM patients. The initiation of this study is dependent on funding.

Clinical and Preclinical Pipeline

CLR 125 Study

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.

The Company initiated a Phase 1b clinical study in TNBC with CLR 125. The study is a randomized, open-label, multi-center study designed to compare 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-weeks for subsequent cycles. Depending on arm assignments, patients will receive between two and four cycles. An expansion arm may consist 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 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 at 11.4 months of follow-up and 76% of patients remaining progression free at a median follow-up of eight months. These outcomes exceed historic 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 sequalae. 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. The Phase 2b study evaluated 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 2026. 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 regiments 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 Break-through Designation for r/r WM and 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 PRIME designation for WM and ODD to iopofosine for treatment of r/r MM and WM, as well as PRIME designation for WM. 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's (EMA) Micro, Small and Medium-sized Enterprise office granted us Small and Medium-Sized Enterprise (SME) status. 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 assistance, endpoints and statistical considerations assistance, and fees for pre- and post-authorization regulatory inspections as well as 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 non-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.

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 Cellectar's CLOVER-1 study and additional patients enrolled in Part B from March through May 2020 and received >60mCi 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 >60mCi 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 was 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 Cellectar 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 Cellectar to select a series of highly potent cytotoxic small molecule payloads for further development.

- In collaboration with other parties, Cellectar 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.

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 not designed 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, epitopes utilized are often present on normal tissue, resulting in on-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.

Technology Overview

Our product candidates are based on a cancer-targeting delivery platform of optimized phospholipid ether (PLE) analogs (phospholipid ether proprietary delivery vehicle) that interact with lipid rafts. Lipid rafts are specialized regions of a cell's membrane phospholipid bilayer that contain high concentrations of cholesterol and sphingolipids and serve to organize cell surface and intracellular signaling molecules. As a result of enrichment and stabilization of lipid rafts in cancer cells, including cancer stem cells, our product candidates provide selective targeting preferentially to cancer cells over normal healthy cells. The cancer-targeting PLE delivery vehicle was deliberately designed to be combined with therapeutic, diagnostic and imaging molecules. For example, the cytotoxic radioisotope, iodine-131, can be attached via a stable covalent bond to the PLE resulting in our lead PDC, iopofosine. Non-radioactive molecules, including many classes of small molecule chemotherapeutic compounds, oligos, peptides and other molecules can also be attached to the delivery vehicle.

In parallel to advancing the clinical development of our lead PDCs in both adult and pediatric orphan indications, we remain focused on exploring the creation of additional PDCs ranging from newly discovered to well-characterized anti-cancer agent payloads. The objective is to develop PDC chemotherapeutics through conjugation of our delivery vehicle and non-targeted anti-cancer agents to improve therapeutic indices and expand potential indications through the targeted delivery of chemotherapeutic payloads. Other than CLR 12120, all are from non-radiotherapeutic treatment modalities, i.e. small-molecule, peptide, or oligonucleotide cancer-targeting chemotherapeutics in pre-clinical research. To date, multiple cancer-targeting product profiles have been generated from a single chemical core structure that is the foundation of our technology platform. We also believe that additional cytotoxic PDCs may be developed possessing enhanced therapeutic indices versus the original, non-targeted cytotoxic payload as a monotherapy.

Malignant tumor targeting, including targeting of cancer stem cells, has been demonstrated *in vivo* in animal models as well as in clinical studies. Mice without intact immune systems and inoculated with Panc-1 (pancreatic carcinoma) cells, were injected with CLR 1502, 24 or 96 hours prior to imaging. *In vivo* optical imaging showed pronounced accumulation of CLR 1502 (a fluorescent-labeled PDC) in tumors versus non-target organs and tissues. Similarly, positron emission tomography (PET) imaging of tumor-bearing animals (colon, glioma, triple negative breast, and pancreatic tumor xenograft models) administered the imaging agent CLR 124 clearly shows selective uptake and retention by both primary tumors and metastases, including cancer stem cells. PET/CT analysis following co-injection of iopofosine (for therapy) and CLR 124 (for imaging) revealed time-dependent tumor responses and disappearance over nine days in a cancer xenograft model. We believe that the capability of our technology to target and be selectively retained by cancer stem cells *in vivo* was demonstrated by treating glioma stem cell-derived orthotopic tumor-bearing mice with another fluorescent-labeled PDC (CLR 1501), and then removing the tumor and isolating cancer stem cells, which continued to display CLR 1501 labeling even after three weeks in cell culture.

The basis for selective tumor targeting of our compounds lies in differences between the plasma membranes of cancer cells as compared to those of most normal cells. Data suggests that lipid rafts serve as portals of entry for PDCs such as iopofosine and our multiple series of drug conjugates. The marked selectivity of our compounds for cancer cells versus non-cancer cells likely results from cancer cells maintenance of an overabundance of lipid rafts and the stabilization of these microdomains within the plasma membrane as compared to normal cells. Following cell entry via lipid rafts, iopofosine is transported into the cytoplasm, where it traffics along the Golgi apparatus and is distributed to various peri-nuclear organelles (including mitochondria and the endoplasmic reticulum). The pivotal role played by lipid rafts is underscored by the fact that disruption of lipid raft architecture significantly eliminates uptake of our PDC delivery vehicle into cancer cells.

Products in Development

Iopofosine

Iopofosine is a radioconjugate, composed of our proprietary PLE, 18-(p-[I-131]iodophenyl) octadacyl phosphocholine, acting as a cancer-targeting delivery and retention vehicle, covalently labeled with iodine-131, a cytotoxic (cell-killing) radioisotope with a half-life of eight days that is already in common use to treat thyroid, pediatric tumors and other cancer types including NHL. Iopofosine binds to the cell surface and is delivered into the cytoplasm of the cancer cell. It is this "intracellular radiation" mechanism of cancer cell killing, coupled with delivery to a wide range of malignant tumor types that we believe provides iopofosine with anti-cancer activity and a unique product profile. Selective uptake and retention have been observed in cancer stem cells compared with normal cells, offering the prospect of longer lasting anti-cancer activity.

CLR 121125

CLR 121125 is our lead Auger-emitting radioconjugate program. The compound utilizes iodine-125 and has demonstrated excellent tolerability with no toxicities in animal models. Additionally, CLR 121125 has been shown to have good activity in multiple solid tumor models and especially in triple negative breast cancer. Auger emitters provide the greatest precision in targeted radiotherapy as the emission can only travel a few nanometers. This means 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. CLR 121125 achieves this due to our novel phospholipid ether drug conjugate platform. CLR 121125 is currently projected to be the subject of a Phase 1b dose finding study in the first half of 2026.

Tumor treatment with radioactive isotopes has been used as a fundamental cancer therapeutic for decades. The goals of targeted cancer therapy - selective delivery of effective doses of isotopes that destroy tumor tissue, sparing of surrounding normal tissue, and non-accumulation in vital organs such as the liver and kidneys - remain goals of new therapies as well. We believe our targeted delivery technology has the potential to achieve these goals. Iopofosine has been shown in animal models and various clinical studies to reliably, and near-universally, accumulate in cancer cells including cancer stem cells. This strategy has allowed us to take a multi-indication approach in the development and potential commercialization of iopofosine. To date, we have focused on rare cancers with significant unmet need including WM, MM, sarcomas, and HGG, among others.

CLR 121225

CLR 121225 is our lead alpha emitting, actinium-225, based radioconjugate program. The compound has demonstrated activity in multiple solid tumor animal models, including pancreatic, colorectal, and breast cancer. CLR 121225 has been shown to be well tolerated in these models with the animals showing no adverse events at the highest doses tested. It was shown 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. We are currently prepared, subject to additional funding, to initiate a Phase 1 imaging and dose escalation safety study.

Market Overview

Our target market is broad and represents the market for the treatment of cancer. The American Cancer Society estimates 1 in 3 people will develop cancer in their lifetime. Approximately 2.11 million new cancer cases will be diagnosed in the U.S. in 2026 and approximately 626,140 cancer deaths in the U.S. The global market for cancer drugs reached $215 billion in annual sales (2026), and with a compound annual growth rate (CAGR) of 11.17% could reach $555 billion by 2035, according to a report dated December 2025 by Coherent Market Insights. This growth will be driven by regulatory approvals, fierce competition, and an aging population (Global Data Research Group 2023), and an increased adoption of cell and gene therapies, antibody-drug conjugates, multispecific antibodies, and radioligand therapies.

Waldenstrom's Macroglobulinemia

WM is a rare and incurable disease defined by specific genotypic subtypes that define patient responses and long-term outcomes. The U.S. annual incidence is 1,500 - 1,900 with prevalence of approximately 26,000 and 110,000 patients globally. WM is a lymphoma, or cancer of the lymphatic system. The disease occurs in a type of white blood cell called a B-lymphocyte or B-cell, which normally matures into a plasma cell that plays an important part in the body's immune system by manufacturing immunoglobulins

(antibodies) to help the body fight infection. In WM, there is a malignant change to the B-cell in the late stages of maturing, and it continues to proliferate into a clone of identical cells, primarily in the bone marrow but also in the lymph nodes and other tissues and organs of the lymphatic system. These clonal cells overproduce an antibody of a specific class called IgM.

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

Several drugs have demonstrated activity either alone or in combinations but only a single class of BTKi's, in the form of two drugs (ibrutinib and zanubrutinib), have received regulatory approval. Treatment is mainly focused on the control of symptoms and the prevention of organ damage. Front-line treatments for WM include rituximab alone or in combination with other agents, including ibrutinib. In the salvage therapy (second line or later) setting, BTKi's, and other combinations are considered (bendamustine, proteosome inhibitors, etc.). Ibrutinib and zanubrutinib are the only drugs to receive regulatory approval (in 2015 and 2020, respectively) as a salvage therapy; in late 2019, ibrutinib was approved for front-line treatment in combination with rituximab. Factors such as long-term cytopenias, age, hyper-viscosity, the need for quick disease control, lymphadenopathy, co-morbidities, and IgM-related end-organ damage are key considerations in the choice of treatment.

Multiple Myeloma

According to the National Cancer Institute SEER database, multiple myeloma (MM) is the second most common hematologic cancer with a U.S. incidence and prevalence of 36,110 and 192,144, respectively. All patients' disease will experience relapse or become refractory to treatment, with a majority experiencing first relapse within 2 years after diagnosis. At any given time, it's estimated that approximately 64% of the living Multiple Myeloma population is in the relapsed or refractory stage.

In 2025, Global Data estimated MM global market to be over $24B and is forecasted to increase to nearly $29B in 2032. The increase in drug sales over this period will be mainly driven by the increasing incidence of MM with the U.S. market remaining the largest potential market. It is believed the largest growth will occur in patients receiving at least three lines of treatment because of the expanding elderly population and increasing rates of survival from newly approved therapies indicated for earlier lines of treatment.

Based on the iopofosine Phase 1 and Phase 2 product profile we observed in fifth-line patients to date, we believe iopofosine may address the unmet medical need in the heavily pre-treated patient population described above.

B-Cell Non-Hodgkin's Lymphoma

B-cell Non-Hodgkin's Lymphoma (BCNHL) represents cancers of the lymphatic system. BCNHL may be indolent or aggressive and circulate in the blood or form tumors in lymph nodes. According to the American Cancer Society, the estimated 2025 US incidence of BCNHL was 68,298cases. Nine types of B-cell lymphomas include CLL, SLL, MCL, MZL, and the most common lymphoma, DLBCL. According to a report dated January 2026 by Global Data Research Group, the global BCNHL market was valued at $8.7 billion for 2026, with a forecasted increase to $9.7 billion in 2032 at a CAGR of 2.7%.

We believe there is a significant unmet medical need in B-cell lymphoma as a result of continued high mortality and poor response rates in second and third- line treatments compounded by the limited durability of responses.

Based on the iopofosine Phase 2 product profile we observed in DLBCL patients to date treated with a single dose, we believe iopofosine may address the unmet medical need in the patient population described above as well.

Neuroblastoma

Neuroblastoma, a neoplasm of the sympathetic nervous system, is the most common extracranial solid tumor of childhood, accounting for approximately 7-10% of childhood cancers and 50% of infant cancers, in the U.S. The NCI states the incidence is about 10.54 cases per 1 million per year in children younger than 15 years and 90% are younger than 5 years at diagnosis. Over 650 new cases are diagnosed each year in North America. Approximately 50% of patients present with metastatic disease requiring systemic treatment. Clinical consequences include abdominal distension, proptosis, bone pain, pancytopenia, fever and paralysis.

Although treatment rates have improved within the clinical paradigm, half of children with neuroblastoma still relapse or fail to respond to upfront therapy. Survival for those with high-risk relapsed or refractory neuroblastoma currently reports as a five-year overall survival rate of 20%.

High Grade Glioma

High Grade Glioma (HGG) is a fast-growing tumor of glial cells in the brain or spinal cord. The WHO classifies these as Grade 3 or 4 based on the growth rate, and these tumors are often incurable. Approximately 10-20% of pediatric tumors are HGG, amounting to a global incidence of approximately 33,000 cases. Available treatment options are limited to surgery, radiation therapy, and aggressive chemotherapeutic combinations. Prognosis continues to improve with development of targeted therapies, but the five-year overall survival rate is still less than 20%.

Sarcomas

Sarcomas represent a heterogeneous disease group. Sarcomas grow in connective tissue, or cells that connect or support other kinds of tissue in the body. These tumors are most common in the bones, muscles, tendons, cartilage, nerves, and blood vessels. Sarcomas represent 15% of all pediatric tumors and 21% of pediatric solid tumors. The American Cancer Society estimates that there will be 2,301 cases diagnosed in 2026. The median age at diagnosis is 16, and the median age of death is 18.

We are focused on 3 subsets of sarcomas:

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

Based on information from Datamonitor Healthcare, the global value of the pediatric sarcoma market is expected to be $1.094 billion in 2025. This growth is expected to be driven by the high rate of recurrence in pediatrics, increased incidence in select markets and new targeted therapies coming to the market.

Manufacturing

The Company has built a collaborative outsourcing model for supply of all its drug candidates and the key components. This model allows the Company to source each isotope and finished product through a decentralized and distributed network of contract manufacturers. As it relates to CLR 121225, it was announced in late 2024 that the one of the sources for actinium would be Northstar Medical Radioisotopes. In December 2025, the Company announced a multi-year supply agreement with Ionetix Corporation for two critical alpha-emitting radioisotopes: Actinium-225 (Ac-225) and Astatine-211 (At-21). The finished PRCs are currently supplied by either AtomVie or SpectronRx. Both organizations specialize in radiopharmaceutical production and can supply multiple different finished, ready-to-use radiotherapeutics simultaneously. Like the source of the isotopes, the Company expects to identify additional manufacturers of its PRCs as they advance through the clinic.

Iopofosine drug product is made via a five-step synthetic process. The release specifications for the drug product have been established and validated. Through process improvements, we have been able to achieve longer expiry dating for the compound extending finished product shelf-life to further facilitate ex-U.S. distribution from North America. We have successfully executed large scale production of iopofosine drug substance via a contract manufacturing organization that has been inspected and approved by the FDA and the EMA. We have also observed 60-month stability for iopofosine drug substance in desiccated and refrigerated forms at small scale and are replicating this at large scale.

AtomVie (formerly known as The Centre for Probe Development and Commercialization (CPDC)), a validated Current Good Manufacturing Practices (cGMPs) manufacturing organization specializing in radiopharmaceuticals, is our primary source of iopofosine drug product supply.

Sales and Marketing

According to Fortune Business Insights, the solid tumors market size reached a value of $170.3 billion in 2023, and the market is expected to reach $375.4 billion by 2034, exhibiting a growth rate (CAGR) of 7.45% during 2024-2034. North America represents 44% of the global market with the Asia Pacific region expected to grow most rapidly during this period.

Pancreatic cancer is one of the leading causes of cancer death globally with the treatment market size valued at $2.86 billion in 2023. The market is projected to grow from $3.30 billion in 2024 to $10.69 billion by 2032, exhibiting a CAGR of 15.8%. The U.S. pancreatic cancer treatment market size is projected to grow significantly and will represent nearly 50% of the global market. According to the American Cancer Society, in the United States, pancreatic cancer is expected to affect 67,530 people in 2026, with 52,740 deaths. According to the Pancreatic Cancer Action Network, the 5-year relative survival rate for pancreatic cancer is 13%. Pancreatic cancer affects men and women nearly equally.

Triple-negative breast cancer (TNBC) is an aggressive type of invasive breast cancer. TNBC differs from other types of invasive breast cancer in that it tends to grow and spread faster, has fewer treatment options, and tends to have a worse prognosis. The term triple-negative breast cancer refers to the fact that the cancer cells don't have estrogen or progesterone receptors (ER or PR) and also don't produce any or much of the protein called HER2. According to DelveInsight, TNBC represents 15-20% of all breast cancers and occurs most frequently in women under the age of 40. According to Global Data Research Group the global TNBC treatment market size is estimated at $5.48 billion in 2026 and will thereafter increase at a CAGR of 4.6%, to reach $6.54 billion by the end of 2034. According to the same report, it is estimated that in 2026 there will be approximately 121,915 prevalent cases of TNBC in the US, with 23% of those cases being advanced (Stages III/IV). The 5-year relative survival rate is 77% across all stages of the disease.

The US WM market currently represents approximately $2.1 billion and is a very concentrated market, with 15 states harboring 80% of the WM cases. We are currently exploring options for the WM opportunity outside of the US market, which will seek to establish an arrangement with one or more biotechnology or pharmaceutical companies having strong product development and commercialization expertise and distribution infrastructure in Europe and parts of global markets.

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

Currently, many classes of approved products with various mechanisms of action exist, including immune-modulating agents, proteasome inhibitors, histone deacetylase inhibitors, monoclonal antibodies, corticosteroids, and traditional chemotherapeutics for the treatment of liquid and solid tumors. There also remain a significant number of compounds being researched and developed for the treatment of cancer. We are focused on the product development and commercialization of adult and pediatric orphan-designated indications with unmet clinical need and believe that our core PDC technology provides a uniquely advantageous approach to cancer therapy utilizing the beta-, alpha- and Auger-emitting capabilities of iopofosine, CLR 121225, and CLR 121125, respectively.

Intellectual Property

Our core technology platform is based on research conducted at the University of Michigan in 1994, where phospholipid ether analogs were initially designed, synthesized, radiolabeled, and evaluated. This research was transferred to the University of Wisconsin-Madison between 1998 and the subsequent founding of Cellectar in 2000 to further develop and commercialize the technology. We obtained exclusive rights to the related technology patents owned by University of Michigan in 2003 and continued development of the PDC platform while obtaining ownership of numerous additional patents and patent applications (with various expiry until 2034 without extensions). We have established a broad U.S. and international intellectual property rights portfolio around our proprietary cancer-targeting PLE technology platform including our PDC Programs.

In November 2015, we converted our previously filed provisional patent application for Phospholipid-Ether Analogs as Cancer Targeting Drug Vehicles to non-provisional US and International (PCT) patent applications and were published by the U.S. Patent & Trade Office (USPTO) in May of 2016. These patent applications further protect composition of matter and method of use for PDCs developed with our proprietary phospholipid-ether delivery vehicle conjugated with any existing or future cytotoxic agents, including chemotherapeutics for targeted delivery to cancer cells and cancer stem cells. Additional cytotoxic PDC compounds are covered by pending patent applications directed to the composition of matter and method of use for cancer therapy provide intellectual property protection is possible in the U.S. and up to 157 additional countries. These applications, if granted, offer protection extending through at least 2035 in the U.S. and key international markets.

We have taken a broad approach to creating market exclusivity for iopofosine both within the U.S., and globally, including all major markets. This approach includes numerous patents, patent applications and regulatory filings to provide maximum market exclusivity. Our patent portfolio for iopofosine includes all the typical filings as well as unique methods of use, methods of synthesis, use in combinations, use to treat cancer stem cells, novel formulations, etc. In addition to our patents, we were granted ODD for iopofosine by the FDA for the treatment of MM in December 2014 and for WM in January 2020. Furthermore, we received ODD from the European Union for MM in September 2019, and for WM in January 2021. Our patents have a variety of expected expiration dates with some potentially being extended on a country-by-country basis. In 2018, the FDA granted ODD and a RPDD for iopofosine for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma.

We expect to continue to file patent applications and acquire licenses to other patents covering methods of use, composition of matter, formulation, method of synthesis and other patentable claims related to iopofosine, CLR 121125, CLR 121225, and new PDCs. These patent applications will be filed in key commercial markets worldwide.

In addition to the above noted patents/applications directed to iopofosine, CLR 121125, CLR 121225, and our PDC pipeline portfolio, we own other patents/applications directed to different forms of phospholipid ethers, methods of use and methods of manufacturing of phospholipid ethers.

Separate from any patent protection and following product approval by regulatory authorities, data exclusivity may be available for various compounds for up to 10 years on a country-by-country basis (e.g., up to five years in the U.S. and up to ten years in Europe).

Licenses / Collaborations

In August 2018, we entered into a collaboration with Orano Med for the development of novel PDCs utilizing Orano Med's alpha emitter lead-212 conjugated to our phospholipid ether; the companies evaluated the new PDCs in up to three oncology indications. The collaboration successfully met its endpoints. The *in vivo* animal data demonstrated that the PDC combined with an alpha emitting radioisotope resulted in significant reduction in tumor volumes in all animal models tested. However, because of the limited half-life and associated logistical challenges associated with lead-212, Cellectar elected to advance an alternative alpha-emitting radioisotope.

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

Research and Development

Our primary activity to date has been research and development. Clinical development has been completed primarily through contract research organizations at hospitals and academic centers. We have established a collaboration outsourcing model to leverage third-party expertise, accelerate project timelines, improve productivity and limit costs. Our research and development expenses were approximately $11,499,000 and $26,136,000 for 2025 and 2024, respectively.

Regulation

The production, distribution, and marketing of products employing our technology, and our development activities, are subject to extensive governmental regulation in the U.S. and in other countries. In the U.S., we are subject to the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations of the FDA, as well as to other federal, state, and local statutes and regulations, including the federal, state and local laws and regulations governing the storage, use and disposal of hazardous materials, including radioactive isotopes. These laws, and similar laws outside the U.S., govern the clinical and pre-clinical testing, research and development, manufacture, quality control, safety, effectiveness, approval, labeling, distribution, sale, import, export, storage, record-keeping, reporting, advertising and promotion, sampling, and tracking and tracing of drugs. Product development and approval within this regulatory framework, if successful, will take many years and involve the expenditure of substantial resources. Violations of regulatory requirements at any stage may result in various adverse consequences, including the delay in approving or refusal to approve a product by the FDA or other health authorities. Violations of regulatory requirements also may result in enforcement actions, which include civil money penalties, injunctions, seizure of regulated product, and civil and criminal charges. The following paragraphs provide further information on certain legal and regulatory issues with a particular potential to affect our operations or future marketing of products employing our technology.

U.S. Research, Development, and Product Approval Process

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

The research, development, and approval process in the U.S. and elsewhere is intensive and rigorous and generally takes many years to complete. The typical process required by the FDA before a therapeutic drug may be marketed in the U.S. includes:

- pre-clinical laboratory and animal tests, and formulation studies, performed under the FDA's Good Laboratory Practices (GLP) regulations;
- submission to the FDA of an IND, which must become effective before human clinical studies may commence;
- approval by an independent institutional review board (IRB) for each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical studies performed under the FDA's Good Clinical Practices (GCP) regulations, to evaluate the drug's safety and effectiveness for its intended uses;
- submission of a marketing application to the FDA for one or more proposed indications;
- review by an FDA advisory committee, if requested by the FDA;
- Satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities in which the drug is manufactured, processed, packed, or held complies with current Good Manufacturing Practices (cGMP), requirements and standards designed to that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCP and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and potentially post-market requirement, or PMR, and commitment, or PMC, studies.

Pre-Clinical Testing

During pre-clinical testing, studies are performed with respect to the chemical and physical properties of candidate formulations. Preclinical studies include laboratory evaluation as well as in vitro and animal studies to assess product chemistry, formulation, and toxicity, and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. These studies are subject to applicable GLP requirements. Biological testing is typically done in animal models to demonstrate the activity of the compound against the targeted disease or condition and to assess the apparent effects of the new product candidate on various organ systems, as well as its relative therapeutic effectiveness and safety. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, including but not limited to animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

Submission of IND

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

Clinical Studies

Clinical study programs in humans generally follow a three-phase process. Typically, Phase 1 studies are conducted in small numbers of healthy volunteers or, on occasion, in patients afflicted with the target disease. Phase 1 studies are conducted to determine the metabolic and pharmacological action of the product candidate in humans and the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. During Phase 1, sufficient information about the drug's safety and tolerability, pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. In Phase 2, controlled clinical studies are generally conducted in larger groups of patients having the target disease or condition to determine the common short-term side effects and risks associated with the drug, and to obtain preliminary data on the safety and effectiveness of the product candidate and optimal dosing. This phase also helps further determine the safety profile of the product candidate. In Phase 3, large-scale clinical studies are generally conducted in patients having the target disease or condition to provide sufficient data of effectiveness and safety of the product candidate that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling, as required by U.S. regulatory agencies.

In the case of products for certain serious or life-threatening diseases, the initial human testing may be done in patients with the disease rather than in healthy volunteers. Because these patients are already afflicted with the target disease or condition, it is possible that such studies will also provide results traditionally obtained in Phase 2 studies. These studies are often referred to as "Phase 1/2" studies. However, even if patients participate in initial human testing and a Phase 1/2 study is carried out, the sponsor is still responsible for obtaining all the data usually obtained in both Phase 1 and Phase 2 studies.

U.S. law requires that studies conducted to support approval for product marketing be "adequate and well controlled." In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as an active reference control, however, if testing in a patient population that does not have an approved treatment and where it would be unethical to only provide a placebo, single-arm, open label studies may be acceptable in coordination with the FDA. Studies must also be conducted in compliance with good clinical practice requirements, and informed consent must be obtained from all study subjects. The clinical study process for a new compound can take ten years or more to complete.

At any time during this 30-day period, or thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. The FDA may prevent clinical studies from beginning or may place clinical studies on hold at any point in this process if, among other reasons, it concludes that study subjects are being exposed to an unacceptable health risk. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin or resume. Studies may also be prevented from beginning or may be terminated by institutional review boards, which must review and approve all research involving human subjects. Side effects or adverse events that are reported during clinical studies can delay, impede, or prevent marketing authorization. Similarly, adverse events that are reported after marketing authorization can result in additional limitations being placed on a product's use and, potentially, the termination of ongoing clinical trials and withdrawal of the product from the market.

Submission of NDA

Following the completion of clinical studies, the data are analyzed to determine whether the studies support an application for product approval. In the U.S., if the product is regulated as a drug, an NDA must be submitted and approved before commercial marketing may begin. The NDA must include, among other things, a substantial amount of data and other information concerning the safety and effectiveness of the compound from preclinical, laboratory, animal, toxicology and human clinical testing, as well as data and information on manufacturing, product quality and stability, and proposed product labeling.

Each domestic and foreign manufacturing establishment, including any contract manufacturers we may decide to use, must be listed in the NDA and must be registered with the FDA. The application generally will not be approved until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process and determines that the facility complies with cGMP requirements. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease or condition to be treated by the drug, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing an NDA and supplements thereto, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant. For fiscal year 2024, the application fee for an application requiring clinical data alone is $4,048,695, although we may qualify for a waiver of these FDA filing fees since we are a small business entity. In addition, the sponsor of an approved NDA is also subject to annual program fees. Application and program fees are typically increased annually.

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

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

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

Even if the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that warning statements be included in the product labeling, require that additional studies, including Phase 4 studies, be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further

testing requirements and submission to the FDA of a supplemental NDA (sNDA), which may require FDA review and approval. prior to implementation. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Expedited Approval Pathways

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

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

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

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

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

Accelerated Approval Pathway

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

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

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

Post NDA Regulation

Significant and pervasive continuing legal and regulatory requirements also apply after FDA approval to market under an NDA. These include, among other things, requirements related to adverse events and other reporting, product advertising and promotion, and ongoing adherence to cGMP requirements, as well as the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product labeling, or manufacturing process. The FDA also enforces the requirements of the Prescription Drug Marketing Act and its implementing regulations which, among other things, impose various requirements in connection with the distribution of product samples to physicians. The FDA also enforces the Drug Supply Chain Security Act, or DSCSA, which regulates the distribution and tracing of prescription drugs and prescription drug samples at the federal level, sets minimum standards for the regulation of drug distributors by the states, and imposes requirements to track and trace drug products, ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before implementation. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory

requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program.

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

The regulatory framework applicable to the production, distribution, marketing and/or sale of our product pipeline may change significantly from the current descriptions provided herein in the time that it may take for any of our products to reach a point at which an NDA is approved.

Overall research, development, and approval times depend on a number of factors, including the period of review at the FDA, the number of questions posed by the FDA during review, how long it takes to respond to the FDA's questions, the severity or life-threatening nature of the disease in question, the availability of alternative treatments, the availability of clinical investigators and eligible patients, the rate of enrollment of patients in clinical studies, and the risks and benefits demonstrated in the clinical studies.

Orphan Drug Designation and Exclusivity

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

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

Pediatric Studies and Exclusivity

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

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

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

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

Abbreviated New Drug Applications for Generic Drugs

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

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

505(b)(2) New Drug Applications

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

Hatch-Waxman Patent Certification and the 30-month Stay

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

When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved

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

Patent Term Extension

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

Exclusivity Under the Hatch-Waxman Amendments

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

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

Other U.S. Regulatory Requirements

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

- the federal Anti-Kickback Statute, which is a criminal law that prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (the Affordable Care Act) to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other, including, for example, consulting/speaking arrangements, discount and rebate offers, grants, charitable contributions, and patient support offerings, among others. A conviction for violation of the federal Anti-Kickback Statute can result in criminal fines and/or imprisonment and requires mandatory exclusion from participation in federal health care programs. Exclusion may also be imposed if the government determines that an entity has committed acts that are prohibited by the federal Anti-Kickback Statute. Although there are a number of statutory exceptions and regulatory safe harbors to the federal Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical and biological products, including certain discounts, or engaging such individuals as speakers or consultants, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor;

- the federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act (FCA), which prohibits, among other things, (i) knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent; (ii) knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim; (iii) knowingly making, using or causing to made or used a false record or statement material to an obligation to pay money to the government; or (iv) knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Private individuals, commonly known as "whistleblowers," can bring FCA *qui tam* actions, on behalf of the government and may share in amounts paid by the entity to the government in recovery or settlement. Pharmaceutical companies have been investigated and/or subject to government enforcement actions asserting liability under the FCA in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Moreover, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false or fraudulent claim or statement for violations. Such per-claim penalties are currently set at $13,508 to $27,018 per false claim or statement for penalties assessed after January 30, 2023, with respect to violations occurring after November 2, 2015. Criminal penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program, including any third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements or representations, or making false

statements relating to healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, including protected health information (PHI). HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, implemented as the Open Payments Program, which requires certain manufacturers of drugs, devices, biologics and medical supplies, among others, to report annually to the CMS, information related to payments and other transfers of value made by that entity to U.S. licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, certified nurse midwives, and U.S. teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

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

Our research and development, manufacturing, and administration of our drugs involve the controlled use of hazardous materials, including chemicals and radioactive materials, such as radioactive isotopes. Therefore, we are subject to federal, state and local laws and regulations governing the storage, use and disposal of these materials and some waste products and are required to maintain both a manufacturer's license and a radioactive materials license with State of Wisconsin agencies.

Moreover, we are now, and may become subject to, additional federal, state, and local laws, regulations, and policies relating to safe working conditions, laboratory practices, the experimental use of animals, and/or the use, storage, handling, transportation, and disposal of human tissue, waste, and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

Approval and Regulation of Medical Products in the EU

Changes to EU's General Pharmaceutical Law

The EU's pharmaceutical legislation is currently changing. In December 2025, the EU legislators reached an agreement on the proposed new rules. This provisional agreement needs to be endorsed by both the Council of the EU and the European Parliament, before being formally adopted and entering into force upon publication in the EU's Official Journal. The final text is not yet available, but key changes will include:

- one year reduction in base-line regulatory market protection;

- re-coup option of lost regulatory market product with strict conditions;

- launch and supply obligations with non-compliance resulting in loss of regulatory data protection and market protection at Member State level;
- expansion of the Bolar exemption to health technology assessments, pricing, and reimbursement submissions;
- reduction in the "standard" orphan market exclusivity period;
- transferable data exclusivity voucher for priority antimicrobials;
- shortened EMA review timelines and other procedural reforms.

The new legislation is expected to enter into application in 24 months. Other proposed EU acts, such as the Critical Medicines Act and the Biotech Act, may bring additional changes.

Approval

In addition to regulations in the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the U.S. Whether or not we obtain FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the EMA, before we may commence clinical trials or market products in those countries or areas. In the EU, our product candidates also may be subject to extensive regulatory requirements. As in the U.S., medicinal products can be marketed only if a marketing authorization from the competent regulatory agency/ies has been obtained (and some Member States also require that a price has been agreed). Similar to the U.S., the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

The EU/European Economic Area (EEA) applies harmonized regulatory rules for medicinal products, including the approval process and requirements governing the conduct of clinical trials. However, certain aspects, in particular pricing and reimbursement, may vary greatly between the Member States and countries and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Non-clinical Studies

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmacotoxicological) studies must be conducted in compliance with the principles of GLP as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development (OECD) requirements.

Clinical Trials

The Clinical Trials Regulation (EU) No 536/2014 (CTR) simplifies and streamlines the authorization, conduct and transparency of clinical trials in the EU. Under the coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one EU Member State submits a single application for approval through the Clinical Trials Information System (CTIS), a clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU Member States and the public.

The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the CTIS; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the appointed reporting EU Member State, whose assessment report is submitted for review by the sponsor and all other competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted, or concerned EU Member States. Part II is assessed separately by each concerned EU Member State. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure are governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the CTR.

A sponsor must obtain prior approval from the competent national authority of the EU Member State(s) in which the clinical trial is to be conducted. If the clinical trial is conducted in different EU Member States, the competent authorities in each of these EU Member States must provide their approval for the conduct of the clinical trial. Furthermore, the sponsor may only start a clinical trial at a specific clinical site after the applicable ethics committee has issued a favorable opinion.

Parties conducting certain clinical trials must provide clinical trial information and a summary of results in accordance with applicable EU transparency requirements.

Marketing Authorization

Marketing authorization applications (MAAs) can be filed through the centralized procedure or the national procedures through the decentralized procedure or the mutual recognition procedure.

The centralized procedure provides for the grant of a single marketing authorization (MA) following a decision by the European Commission, based on a favorable opinion by the EMA, that is valid in all EU Member States, as well as Iceland, Liechtenstein, and Norway, which are part of the EEA. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines), and products with a new active substance indicated for the treatment of specified diseases, including HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases, and other immune dysfunctions and viral diseases. The centralized procedure is optional for products that represent a significant therapeutic, scientific, or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the sponsor in response to questions asked by the Committee for Medicinal Products for Human Use (CHMP). Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding stop-clocks.

The national procedures allow for two other possible routes to authorize medicinal products in several EU countries, which are available for medicinal products that fall outside the scope of the centralized procedure:

- *Decentralized procedure*. Using the decentralized procedure, a sponsor may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. The sponsor may choose a Member State as the reference Member State to lead the scientific evaluation of the application.

- *Mutual recognition procedure*. In the mutual recognition procedure, a medicine is first authorized in one EU Member State (which acts as the reference Member State), in accordance with the national procedures of that country. Following this, further marketing authorizations can be progressively sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization produced by the reference Member State.

Under the above-described procedures, before granting the marketing authorization, the EMA (in the centralized procedure) or the competent authorities of the Member States of the EEA (in the national, decentralized and mutual recognition procedures) make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy.

MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Conditional Approval

In certain circumstances, Regulation (EC) No 726/2004 enables sponsors to obtain a conditional marketing authorization (CMA), subject to meeting specific obligations within defined timelines. Such obligations could include ongoing or now studies or collecting additional data to confirm the medicine's benefit-risk balance remains positive. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the product candidate is intended for the treatment, prevention, or medical diagnosis of seriously debilitating or life-threatening diseases; (2) the product candidate is intended to meet unmet medical needs of patients; (3) the benefit of the immediate availability on the market of the medicinal product concerned

outweighs the risk inherent in the fact that additional data are still required; (4) the risk-benefit balance of the product candidate is positive, and (5) it is likely that the sponsor will be in a position to provide the required comprehensive clinical trial data. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Pediatric Studies

Prior to obtaining a marketing authorization in the EU, sponsors have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan (PIP), covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form, or route of administration for a medicine that is already authorized. The EMA's Pediatric Committee (PDCO) may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate because (a) the product is likely to be ineffective or unsafe in part or all of the pediatric population; (b) the disease or condition occurs only in the adult population; or (c) the product does not represent a significant therapeutic benefit over existing treatments for the pediatric population. Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

PRIME Designation

The EMA's PRIority MEdicines (PRIME) scheme aims to facilitate the development of product candidates in indications, often rare, for which few or no therapies currently exist and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises (SMEs) may qualify for early entry into the PRIME scheme. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated agency contact and rapporteur from the CHMP or Committee for Advanced Therapies (CAT) are appointed early in the PRIME scheme, facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance to the sponsor on the overall development and regulatory strategies.

Periods of Authorization and Renewals

A MA is valid for five years in principle and the MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing Member State. Once renewed, the MA is valid for an unlimited period, unless the European Commission or the competent authorities decide, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (three years after the marketing authorization is granted (or, where previously marketed, is no longer actually present on the market for three consecutive years) may cease to be valid (the so-called sunset clause).

Regulatory Requirements after Marketing Authorization

As in the U.S., both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU Member States both before and after grant of the manufacturing and marketing authorizations. The holder of an EU MA for a medicinal product must, for example, comply with EU pharmacovigilance legislation and its related regulations and guidelines which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. The manufacturing process for medicinal products in the EU is also highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various

requirements set out in the applicable EU laws, including compliance with EU cGMP standards when manufacturing medicinal products and API.

In the EU, advertising of medicinal products is strictly regulated at EU level under Directive 2001/83/EC, which prohibits direct-to-consumer advertising for prescription drugs, while permitting advertising for over-the-counter (OTC) medicines, subject to specific conditions. In addition, the advertising and promotion of authorized products are governed by EU Member States' national laws, including rules on the promotion of medicinal products, interactions with clinicians, misleading and comparative advertising, and unfair commercial practices. Promotional materials and advertising relating to medicinal products must comply with the product's Summary of Product Characteristics (SmPC) as approved by the competent authorities. Promotion that is inconsistent with, or goes beyond, the approved SmPC is considered to constitute unlawful promotion (referred to as off-label promotion) and is prohibited in the EU.

Regulatory Exclusivity

In the EU, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic sponsors from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic sponsor from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

The above-described regulatory exclusivity rules will change with the newly adopted revised EU pharmaceutical legislation, introducing amongst other a one year base-line reduction of market exclusivity which can be "recouped" under certain circumstances.

Orphan Drug Designation and Exclusivity

The criteria for designating an orphan medicinal product in the EU are similar in principle to those in the U.S. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition, (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment, and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. The term 'significant benefit' is defined in Regulation (EC) 847/2000 to mean a clinically relevant advantage or a major contribution to patient care.

Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to 10 years of market exclusivity for the approved therapeutic indication. During this ten-year market exclusivity period, the EMA or the competent authorities of the Member States of the EEA cannot accept an application for a marketing authorization for a similar medicinal product for the same indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The sponsor will receive a fee reduction for the MAA if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

In the EU, to maintain an ODD, a sponsor must demonstrate that it still satisfies the orphan designation criteria at the time of the marketing authorization. This includes a requirement for the sponsor to demonstrate 'significant benefit' compared with any treatments that are authorized at the time of the re-evaluation of the orphan criteria. Comparators may include products that are authorized after the sponsor has submitted its marketing authorization, but before the sponsor's orphan designation criteria have be re-assessed.

The ten-year market exclusivity in the EU may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if: (1) the second sponsor can establish that its product, although similar, is safer, more effective, or otherwise clinically superior; (2) the sponsor consents to a second orphan medicinal product application; or (3) the sponsor cannot supply enough orphan medicinal product.

The above-described ODD rules will change with the newly adopted revised EU pharmaceutical legislation, introducing amongst other a one year base-line reduction of market exclusivity to nine years (but 11 years for a new breakthrough orphan category). Other changes also include only additional one year of market exclusivity for new orphan indication, which can be granted maximum twice.

Reimbursement and Pricing of Prescription Pharmaceuticals

In the EU, similar political, economic, and regulatory developments to those in the U.S. may affect our ability to profitably commercialize our product candidates, if approved. In many countries, including those of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of MA for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials that compare the cost-effectiveness of our products to other available therapies.

The EU provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained.

Reference pricing used by various EU Member States, and parallel trade (i.e., arbitrage between low-priced and high-priced Member States) can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any product candidates, if approved in those countries.

Foreign Regulatory Requirements

We, and any future collaborative partners, may be subject to widely varying foreign regulations that may be quite different from those of the FDA governing clinical studies, manufacture, product registration and approval, and pharmaceutical sales. Whether or not FDA approval has been obtained, we or any future collaboration partners must obtain a separate approval for a product by the comparable regulatory authorities of foreign countries prior to the commencement of product marketing in these countries. In certain countries, regulatory authorities also establish pricing and reimbursement criteria. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current U.S. law, there are restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

Reimbursement and Pricing Controls

In many of the markets where we, or any future collaborative partners would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls by law and to drug reimbursement programs with varying price control mechanisms. Public and private health care payors control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payors limit reimbursement and coverage to the uses of a drug that are either approved by the

FDA or that are supported by other appropriate evidence (for example, published medical literature) and appear in a recognized drug compendium.

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

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

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

Federal law requires that for a company to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs as well as to be purchased by certain federal agencies and grantees, it also must participate in the Department of Veterans Affairs (VA) Federal Supply Schedule (FSS) pricing program. To participate, we will be required to enter into an FSS contract and other agreements with the VA for our products, which may qualify as "covered drugs." Under these agreements, we would need to make our products available to the "Big Four" federal agencies—the VA, the Department of Defense (DoD), the Public Health Service (including the Indian Health Service), and the Coast Guard—at pricing that is capped pursuant to a statutory federal ceiling price, or FCP, formula set forth in Section 603 of the Veterans Health Care Act of 1992 (VHCA). The FCP is based on a weighted average non-federal average manufacturer price (Non-FAMP), which manufacturers are required to report on a quarterly and annual basis to the VA. Pursuant to the VHCA, the knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to a penalty for each item of false information and could result in other potential liability as well, including liability under the False Claims Act.

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

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

Significant uncertainty exists as to the pricing and reimbursement of products approved by the FDA and other government authorities. There have been several recent US Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. For example, included in the Consolidated Appropriations Act of 2021 were several drug price reporting and transparency measures, such as a new requirement for certain Medicare plans to develop tools to display Medicare Part D prescription drug benefit information in real time and for group and health insurance issuers to report information on pharmacy benefit and drug costs to the Secretaries of the Departments of Health and Human Services, Labor and the Treasury. Additionally, on March 11, 2021, Congress enacted the American Rescue Plan Act of 2021, which included among its provisions a sunset of the Affordable Care Act's cap on pharmaceutical manufacturers' rebate liability under the MDRP. Under the Affordable Care Act, manufacturers' rebate liability was capped at 100% of the average manufacturer price for a covered outpatient drug. Effective January 1, 2024, manufacturers' MDRP rebate liability will no longer be capped, potentially resulting in a manufacturer paying more in MDRP rebates than it receives on the sale of certain covered outpatient drugs. On February 2, 2022, the Biden Administration signaled its continued commitment to the Cancer Moonshot initiative, which was initially launched in 2016. In its announcement, the administration noted that its new goals under the initiative include addressing inequities in order to ensure broader access to cutting-edge cancer therapeutics and investing in a robust pipeline for new treatments. Additionally, in August 2022, President Biden signed into law the Inflation Reduction Act of 2022, which implements substantial changes to the Medicare program, including drug pricing reforms and creation of new Medicare inflation rebates. Namely, the IRA imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that, beginning in 2025, will cap beneficiary annual out-of-pocket spending at $2,000, while imposing new discount obligations for pharmaceutical manufacturers; and beginning in 2026, establishes a "maximum fair price" for a fixed number of high expenditure pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with CMS. On October 14, 2022, President Biden issued an Executive Order on Lowering Prescription Drug Costs for Americans, which instructed the Secretary of the Department of Health and Human Services to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs. Most recently, on February 14, 2023, the Department of Health and Human Services issued a report in response to the October 14, 2022 Executive Order, which, among other things, selects three potential drug affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the report addresses: (1) a model that would allow Part D Sponsors to establish a "high-value drug list" setting the maximum co-payment amount for certain common generic drugs at $2; (2) a Medicaid-focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi-state outcomes-based agreements or certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments.

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

Employees and Human Capital

As of December 31, 2025, we had eleven employees, all of whom were full-time. Of these eleven employees, seven employees were engaged in research and development. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

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

Legal Proceedings

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

Corporate Information

Our common stock is listed on the Nasdaq Capital Market under the symbol CLRB. Our principal executive offices are located at 100 Campus Drive, Florham Park, New Jersey 07932, and our telephone number is (608) 441-8120. Our corporate website address is www.cellectar.com. Information contained on or accessible through our website is not a part of this annual report.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common stock held by non-affiliates exceeds $250 million as of the end of that year's second fiscal quarter, or (ii) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our common stock held by non-affiliates exceeds $700 million as of the end of that year's second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Available Information

We file with, or furnish to, the SEC reports including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports pursuant to Section 13(a) or 15(d) of the Exchange Act. These reports are available free of charge on our corporate website (www.cellectar.com) as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Copies of any materials we file with the SEC can be obtained at www.sec.gov. The information provided on our website (or any other website referred to in this report) is not part of this report and is not incorporated by reference as part of this Annual Report on Form 10-K.

Item 1A. Risk Factors.

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

Summary of Risk Factors

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

- We will require additional capital in order to continue our operations and may have difficulty raising additional capital.
- Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.
- 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 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.
- Failure to meet the EU's CMA conditions, in particular the unmet needs condition, means we will have to obtain a marketing authorization through the normal approval process; this requires more robust data at the time of initial application submission.
- 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.
- 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.
- 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 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.
- 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.
- 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.
- We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their current or former employers.
- Acceptance of our products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- Failure to maintain effective internal controls could adversely affect our ability to meet our reporting requirements.
- Failure to meet Nasdaq's continued listing requirements could result in the delisting of our common stock, negatively impact the price of our common stock and negatively impact our ability to raise additional capital.
- Our common stock price 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.

Risks Related to Capital and Our Operations

We will require additional capital in order to continue our operations and may have difficulty raising additional capital.

We expect that we will continue to generate operating losses for the foreseeable future. As of December 31, 2025, our consolidated cash balance was approximately $13.2 million. We believe our cash balance as of December 31, 2025, is adequate to fund our basic budgeted operations into the third quarter of 2026.

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 marketing approval from the FDA, the European Commission (based on recommendation from the EMA), or other regulatory authorities 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 marketing approval from the FDA, European Commission (based on recommendation from the EMA), or other regulatory authorities 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 EU Member States (coordinated by the EMA), and other comparable foreign regulatory authorities 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, the European Commission (based on recommendation from the EMA) or other comparable foreign regulatory authorities 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 or European Commission (based on recommendation from the EMA) 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, the European Commission (based on recommendation from the EMA) 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, Development and Regulatory Approval of Our Product Candidates

All of our product candidates are in clinical development or in preclinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

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 iopofosine, CLR 121225, CLR 121125, 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 EU 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, the EMA, 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, the EMA, 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.

The SAWP has advised that filing for a CMA for iopofosine I 131 as a treatment for post - BTKi refractory patients with WM could be acceptable. However, there can be no guarantee that the EMA will grant CMA in the EU for iopofosine for WM patients having received two or more prior treatment regimens. Even if we are granted a CMA in the EU, we will be required to undergo annual renewal assessments to determine whether the risk-benefit balance remains positive. During or in between such assessments, it may be determined that we do not meet the conditions, which would mean that the CMA is revoked, or that there is a need for additional or modified conditions and/or specific obligations.

Even if we do ultimately receive FDA approval or approval in the European Union 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.

We may seek Breakthrough Therapy designation by the FDA for one or more of our product candidates, which we may not receive. Such designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

On June 4, 2025, the Company announced that the FDA granted Breakthrough Therapy Designation for iopofosine I 131, as a radioconjugate monotherapy for the treatment of relapsed/refractory Waldenstrom macroglobulinemia. In addition, we may seek Breakthrough Therapy designation for one or more of our product candidates, which, if granted, offers the potential for a rolling review of an NDA if a number of conditions are met, which would allow data to be submitted and reviewed as they become available rather than waiting for the full data package to become available to be submitted. Rolling review is often faster than the FDA's standard review process. The FDA has broad discretion whether or not to grant Breakthrough Therapy designations, and even if we believe a particular product candidate is eligible for such a designation, we cannot be certain that the FDA would decide to grant it. Even if we obtain such designations for one or more of our product candidates, we may not experience a faster development process, review or approval compared to non-expedited FDA review procedures. In addition, the FDA may withdraw Breakthrough Therapy designations if it believes that such designations are no longer supported. Although product candidates receiving Breakthrough Therapy designation are generally eligible for the FDA's priority review procedures, receiving such designations does not guarantee that the NDA for such product candidates will receive priority review.

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, 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 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.

In addition, federal agency activities, priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles and legislative developments. For example, the current presidential administration's commitment to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS, FDA, and CMS. Efforts by the current administration to limit federal agency budgets or personnel may result in reductions to agency budgets, employees, and operations. The administration and agencies have also made abrupt announcements about new or changed regulatory policies, such as policies related to the use of artificial intelligence to review product applications. And, the recent federal government shutdown may prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, and may significantly impact the ability of the FDA to timely review and process our regulatory submissions. These developments which may lead to greater uncertainty regarding FDA

policies, slower response times and longer review periods, potentially affecting our ability to progress development of our product candidate or obtain regulatory approval for our product candidate.

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 also not be able to maintain our ODD in the EU. In the EU, to maintain an ODD, a sponsor must demonstrate that it still satisfies the orphan designation criteria at the time of the marketing authorization. This includes a requirement for the sponsor to demonstrate 'significant benefit' compared with any treatments that are authorized at the time of the re-evaluation of the orphan criteria. Comparators may include products that are authorized after the sponsor has submitted its marketing authorization, but before the sponsor's orphan designation criteria have be re-assessed.

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, administrating 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 (based on recommendation from the EMA), and comparable foreign authorities, 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 EMA and other regulators. In addition to the FDA, EMA and other regulators' 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, the European Commission (based on recommendation from the 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 European Commission (based on a recommendation from 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 European Commission (based on a recommendation from the EMA) and other comparable international regulatory authorities 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 European Commission (based on a recommendation from 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 the healthcare reform measures of the Biden administration will impact the Affordable Care Act.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and, 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 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 this Annual Report on Form 10-K for more information on the healthcare laws and regulations that may affect our ability to operate.

We are also exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the US and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized

activities to us. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

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

Regulatory legislative reform measures may have a material adverse effect on our business.

The EU's pharmaceutical legislation is currently changing. In December 2025, the EU legislators reached an agreement on the proposed new rules. This provisional agreement needs to be endorsed by both the Council of the EU and the European Parliament, before being formally adopted and entering into force upon publication in the EU's Official Journal. The final text is not yet available, but key changes will include:

- one year reduction in base-line regulatory market protection;
- re-coup option of lost regulatory market product with strict conditions;
- launch and supply obligations with non-compliance resulting in loss of regulatory data protection and market protection at Member State level;
- expansion of the Bolar exemption to health technology assessments, pricing, and reimbursement submissions;
- reduction in the "standard" orphan market exclusivity period;
- transferable data exclusivity voucher for priority antimicrobials;
- shortened EMA review timelines and other procedural reforms.

The new legislation is expected to enter into application in 24 months. Other proposed EU acts, such as the Critical Medicines Act and the Biotech Act, may bring additional changes.

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 (Restatement).

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. below. 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

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 were 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.

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. On July 9, 2025, we received a letter from Nasdaq confirming that we regained compliance with the minimum bid price requirement in Nasdaq Listing Rule 5550(a)(2), as it was determined that for the last 10 consecutive business

days, from June 24, 2025 to July 8, 2025, the closing bid price of our common stock was at $1.00 per share or greater. There is no assurance we will 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.

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 maintain our listing on the Nasdaq exchange.

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

In the past, we have issued common stock, convertible securities (such as convertible preferred stock and notes payable) and warrants 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.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

We have implemented processes designed to identify, review and manage risks from potential cybersecurity-related data breaches, unauthorized intrusions of our information technology systems, and other information security losses on or through our information technology systems that could result in adverse effects on the confidentiality, integrity, and availability of our systems and electronic information. These processes are managed and monitored by our third-party information technology service providers, as supervised by our Chief Financial Officer (CFO). Our CFO has experience in overseeing our cybersecurity and information technology programs. We rely heavily on information technology consultants for advice and expertise on monitoring evolving industry standards and to monitor our compliance with applicable policies. Our processes include mechanisms, controls, technologies, and systems designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable information technology environment. With the assistance of our third-party vendors, we conduct regular information technology risk evaluations and security audits. Our information technology team conducts diligence on key technology vendors, contractors and suppliers. We also provide ongoing education communications on cyber and information security, among other topics, and monitor phishing campaigns or other misrepresented system access requests to identify any employees that might need additional training.

The Board of Directors, with the assistance of the Audit Committee, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. As part of its oversight responsibilities, the Audit Committee receives periodic updates on cybersecurity and information technology matters and related risk exposures from our CFO.

As of the date of this report, we have not identified any cybersecurity threats or intrusions that have materially affected our strategy, results of operations or financial condition. We and our third-party service providers have, however, been the target of cybersecurity threats and we expect these threats to continue. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, "Risk Factors," in this annual report on Form 10-K.

Item 2. Properties.

We lease administrative office space in Florham Park, New Jersey and Middleton, Wisconsin. On December 30, 2022, we entered into an Amended Agreement of Lease (the "Amended Lease"), with Campus 100 LLC for the Florham Park space. The space in New Jersey consists of approximately 4,000 square feet and is rented for approximately $12,100 per month under an agreement that expires on April 30, 2029, subject to one additional five-year extension. The space in Wisconsin consists of approximately 300 square feet and is rented for approximately $3,400 per month under an ongoing agreement.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

MARKET FOR COMMON EQUITY

Market Information

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

On February 24, 2026 there were 10 holders of record of our common stock. This number does not include stockholders for whom shares were held in a "nominee" or "street" name.

We have not declared or paid any cash dividends on our common stock and do not anticipate declaring or paying any cash dividends in the foreseeable future. We currently expect to retain future earnings, if any, for the continued development of our business.

Our transfer agent and registrar is Equiniti Trust Company LLC, 6201 15th Avenue, Brooklyn, NY 11219.

Item 6. [Reserved]

Not applicable.

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

Overview

We are a late-stage clinical biopharmaceutical company focused on the discovery and development 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") granted Breakthrough Therapy Designation for iopofosine I 131, as a radioconjugate monotherapy for the treatment of relapsed/refractory Waldenstrom macroglobulinemia (r/r WM). On October 6, 2025, the Company announced that after a scientific advice procedure, the Scientific Advice Working Party (SAWP) of the European Medicines Agency (EMA) advised that filing for a Conditional Marketing Authorization (CMA) for iopofosine I 131 as a treatment for post - Bruton Tyrosine Kinase inhibitor (BTKi) refractory patients with Waldenstrom macroglobulinemia (WM) could be acceptable. However, there can be no guarantee that the EMA will grant a CMA, in particular that we continue to meet the unmet needs condition. Even if we are granted a CMA in the EU, we will be required to undergo annual renewal assessments to determine whether the risk-benefit balance remains positive. During or in between such assessments, it may be determined that we do not meet the conditions, which would mean that the CMA is revoked, or that there is a need for additional or modified conditions and/or specific obligations.

- CLR 125, an 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 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 condition because of the Company's novel phospholipid ether drug conjugate platform. CLR 125 is the subject of a Phase 1b dose finding study as described below.

- CLR 225, an alpha-emitting, actinium-225 based PRC has shown activity in multiple solid tumor animal models, including pancreatic, colorectal, and breast cancer. CLR 121225 was well tolerated in these models with the animals showing no adverse events at the highest doses tested. The compound demonstrated excellent biodistribution and uptake by the tumor. Furthermore, in multiple models of pancreatic adenocarcinoma, including highly refractory pancreatic cancer, we have observed proportional dose response with a single dose of CLR 225 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 subject to our ability to obtain additional financing.

- Iopofosine, a beta-emitting PRC, utilizes iodine-131 and was studied in our CLOVER WaM Phase 2 study of iopofosine in patients with r/r 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. The Company plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the accelerated approval of iopofosine I 131 as a treatment for WM once the confirmatory trial is underway, which is subject to sufficient funding. 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.

Results of Operations

Research and development. Research and development expenses consist of costs incurred in identifying, developing and testing, and manufacturing product candidates, which primarily include salaries and related expenses for personnel, cost of manufacturing materials and contract manufacturing fees paid to contract manufacturers and contract research organizations, and fees paid to medical institutions for clinical studies. We analyze our research and development expenses based on four categories as follows: clinical project costs, preclinical project costs, manufacturing and related costs, and general research and development costs that are not allocated to the functional project costs, including personnel costs, facility costs, and related overhead costs.

General and administrative. General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, and administrative functions. Other costs include insurance, costs for public company activities, investor relations, directors' fees, and professional fees for legal and accounting services.

Other income (expense), net. Other income (expense), net, consists primarily of the impacts related to issuing and revaluing equity securities, and interest income.

Twelve Months Ended December 31, 2025 and 2024

Research and Development. Research and development expenses for the year ended December 31, 2025, were approximately $11,499,000, compared to approximately $26,136,000 for the year ended December 31, 2024.

The following table provides a summary of research and development costs by category for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Variance
Clinical project costs	$ 3,586,000	$ 10,462,000	$ (6,876,000)
Manufacturing and related costs	4,220,000	10,582,000	(6,362,000)
Pre-clinical project costs	823,000	228,000	595,000
General research and development costs	2,870,000	4,864,000	(1,994,000)
	$ 11,499,000	$ 26,136,000	$ (14,637,000)

The overall decrease in research and development expenses of approximately $14,637,000, or 56%, was primarily a result of a reduction in clinical project costs of approximately $6,876,000 and a decrease in manufacturing and related costs of approximately $6,362,000, driven by the conclusion of patient enrollment and declining patient follow-up for our WM clinical study, partially offset by increased activity in our pre-clinical development project costs.

General and administrative. General and administrative expenses for the year ended December 31, 2025, were approximately $11,481,000, compared to approximately $25,641,000 in 2024. The decrease of $14,160,000, or 55% in general and administrative costs was primarily driven by de-emphasizing pre-commercialization efforts and related personnel cost reductions.

Other income (expense), net. Other income (expense), net, for the year ended December 31, 2025, was approximately $1,189,000 of income, as compared to approximately $7,262,000 of income for the year ended December 31, 2024. A significant portion of this non-cash impact comes from changes in the valuation of the Company's outstanding warrants. Warrant valuation consists of several aspects, but the most significant driver is the price of the Company's common stock at the end of each reporting period. Interest income decreased to approximately $435,000 in 2025, compared to approximately $1,211,000 in 2024, as a result of lower invested balances and reductions in the related interest rates.

Liquidity and Capital Resources

Year ended December 31, 2025, Compared to Year Ended December 31, 2024

As of December 31, 2025, we had cash and cash equivalents of $13.2 million, compared to $23.3 million as of December 31, 2024, a decrease of $10.1 million. Net cash proceeds from the issuance of common stock and warrants during 2025 were approximately $13 million. The cash used in operating activities during the twelve months ended December 31, 2025, was approximately $23.1 million.

Investing activities consist exclusively of fixed asset purchases, which declined in 2025 as compared to 2024 as a result of our completing the establishment of redundancy in each aspect of our product manufacturing supply chain.

Our cash requirements have historically been for our research and development activities, finance and administrative costs, capital expenditures and overall working capital. We have experienced negative operating cash flows since inception and have funded our operations primarily from sales of equity-based securities. As of December 31, 2025, we had an accumulated deficit of approximately $269 million.

Liquidity Outlook

We have incurred losses since inception in devoting substantially all of our efforts toward research and development. During the year ended December 31, 2025, we generated a net loss of approximately $21.8 million and used approximately $23.1 million in cash for operations. We expect that we will continue to generate operating losses for the foreseeable future. As of December 31, 2025, our consolidated cash balance was approximately $13.2 million. As of the date the accompanying consolidated financial statements were issued (the "issuance date"), the Company's available liquidity to fund the Company's operations over the next twelve months beyond the issuance date was limited to approximately $9.7 million of unrestricted cash and cash equivalents. Absent further action taken by management to increase its liquidity, the Company may be unable to fund its operations under normal course beyond the third quarter of 2026. To improve the Company's liquidity, management plans to secure additional outside capital via the sale of equity and/or debt securities or execute a strategic transaction. Management also plans to preserve liquidity, as needed, by implementing cost saving measures. While management believes their plans will be successful, no assurance can be provided such plans will be effectively implemented over the next twelve months beyond the issuance date. In the event management's plans are not effectively implemented, the Company will 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.

These uncertainties raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on the basis that the Company will continue to operate as a going concern, which contemplates it will be able to realize assets and settle liabilities and commitments in the normal course of business for the foreseeable future. Accordingly, the accompanying consolidated financial statements do not include any adjustments that may result from the outcome of these uncertainties.

Critical Accounting Policies and Estimates

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

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

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

Fair value measurements. We account for certain financial assets at fair value, defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., exit price) in the principal, most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. As such, fair value is a market-based measurement that is determined based on assumptions that a market participant would use in pricing an asset or liability. We recorded the preferred stock and warrants separately based on their estimated fair values. Subsequent to issuance, to the extent that such securities are liability classified, they are marked to market, with the change in value reflected in the statement of operations at each reporting date. If management made different assumptions or judgments, material differences in measurements of fair value could occur.

Warrants. We account for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of our control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. If these instruments are initially classified as either liabilities or equity and a subsequent assessment determines that the classification has changed, we reflect that change in the financial statements.

Preferred Stock. We account for preferred stock based upon their specific terms and the authoritative guidance in ASC 480 and ASC 815, including whether they are freestanding instruments, whether any redemption or conversion aspects exist and how they are required to be settled (particularly if there is a cash settlement aspect), whether they contain characteristics that are predominantly debt-like or equity-like, whether they have embedded derivatives, and if they have redemption features. Based upon analysis of these criteria, the preferred stock will be classified as either debt, temporary (or "mezzanine") equity, or permanent equity. The resultant classification is then evaluated quarterly to determine whether any change to the classification is required.

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

Not applicable.

Item 8. Financial Statements.

FINANCIAL STATEMENTS

INDEX TO FINANCIAL STATEMENTS FOR CELLECTAR BIOSCIENCES, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Cellectar Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cellectar Biosciences, Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, statements of convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred significant losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matters

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

Initial Accounting for the July 2025 Underwritten Public Offering — Refer to "Note 2. Summary of Significant Accounting Policies" and "Note 6. Stockholders' Equity" to the financial statements

Critical Audit Matter Description

As more fully described in Note 6 to the financial statements, on July 2, 2025, the Company completed an underwritten public offering for gross proceeds of approximately $6.9 million, prior to deducting underwriting commissions and offering expenses. The offering was composed of shares of the Company's common stock, pre-funded common stock purchase warrants (Pre-funded Warrants), and common warrants to purchase shares of the Company's common stock (Common Warrants). The Company determined that the Common Warrants and Pre-Funded Warrants met all of the criteria for equity classification and recorded them as a component of additional paid-in capital upon the closing of the transaction in July 2025.

We identified the assessment of the initial accounting for the Common Warrants and Pre-funded Warrants as a critical audit matter because of the complexity in applying the accounting framework and the significant judgments made by management in the determination of the classification of the warrants. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of management's classification.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the classification of the Common Warrants and Pre-funded Warrants included the following, among others:

- We read the agreements associated with the Common Warrants and Pre-funded Warrants and tested the accuracy and completeness of the significant terms identified by management for the purpose of determining the appropriate accounting treatment and classification of the warrants.

- With the assistance of professionals in our firm having expertise in the accounting treatment for financial instruments, we evaluated the Company's conclusions regarding the accounting treatment applied to the Common Warrants and Pre-funded Warrants.

Initial Accounting for the October 2025 Warrant Inducement — Refer to "Note 2. Summary of Significant Accounting Policies" and "Note 6. Stockholders' Equity" to the financial statements

Critical Audit Matter Description

As more fully described in Note 6 to the financial statements, on October 7, 2025, the Company entered into warrant exercise inducement offer letters with certain holders of certain existing warrants, pursuant to which the holders agreed to exercise for cash their existing warrants in exchange for the Company's agreement to issue two new warrants for each warrant exercised (October 2025 Inducement Warrants). The gross proceeds to the company from the warrant exercises and new warrant issuances was approximately $5.8 million, prior to deducting placement agent fees and offering expenses. The Company determined that the October 2025 Inducement Warrants met all of the criteria for equity classification and recorded them as a component of additional paid-in capital upon the closing of the transaction in October 2025.

We identified the assessment of the initial accounting for the October 2025 Inducement Warrants as a critical audit matter because of the complexity in applying the accounting framework and the significant judgments made by management in the determination of the classification and valuation of the securities. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of management's classification, as well as the valuation of the securities.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the classification and valuation of the October 2025 Inducement Warrants included the following, among others:

- We read the agreements associated with the October 2025 Inducement Warrants and tested the accuracy and completeness of the significant terms identified by management for the purpose of determining the appropriate accounting treatment and classification of the warrants.
- We evaluated the Company's conclusions regarding the accounting treatment applied to the October 2025 Inducement Warrants.
- With the assistance of our fair value specialists, we evaluated management's valuation of the October 2025 Inducement Warrants by:
    - Evaluating management's use of the valuation methodology
    - Testing the significant valuation assumptions, including the expected volatility, the risk-free interest rate, expected life and dividend yield
    - Independently calculating a fair value estimate for the October 2025 Inducement Warrants and comparing our estimates to management's estimates

/s/ Deloitte & Touche LLP

Morristown, New Jersey
March 4, 2026

We have served as the Company's auditor since 2024.

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 13,196,033	$ 23,288,607
Prepaid expenses and other current assets	842,432	961,665
Total current assets	14,038,465	24,250,272
Property, plant & equipment, net	549,405	757,121
Operating lease right-of-use asset	360,671	436,874
Other long-term assets	29,780	29,780
TOTAL ASSETS	$ 14,978,321	$ 25,474,047
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 4,423,548	$ 7,585,340
Warrant liability	226,000	1,718,000
Lease liability, current	100,189	84,417
Total current liabilities	4,749,737	9,387,757
Lease liability, net of current portion	309,397	409,586
TOTAL LIABILITIES	5,059,134	9,797,343
COMMITMENTS AND CONTINGENCIES (Note 10)		
MEZZANINE EQUITY:		
Series D convertible preferred stock, 111.11 shares authorized; 111.11 shares issued and outstanding as of December 31, 2025 and 2024	1,382,023	1,382,023
STOCKHOLDERS' EQUITY:		
Series E-2 preferred stock, 1,225.00 shares authorized; 35.60 and 35.60 shares issued and outstanding as of December 31, 2025 and 2024, respectively	520,778	520,778
Common stock, $0.00001 par value; 170,000,000 shares authorized; 4,240,129 and 1,535,996 shares issued and outstanding as of December 31, 2025 and 2024, respectively	42	15
Additional paid-in capital	277,149,844	261,116,351
Accumulated deficit	(269,133,500)	(247,342,463)
Total stockholders' equity	8,537,164	14,294,681
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 14,978,321	$ 25,474,047

See accompanying notes to the consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2025	2024
OPERATING EXPENSES:		
Research and development	$ 11,498,761	$ 26,136,246
General and administrative	11,481,083	25,641,452
Total operating expenses	22,979,844	51,777,698
LOSS FROM OPERATIONS	(22,979,844)	(51,777,698)
OTHER INCOME (EXPENSE):		
Warrant issuance expense	—	(7,743,284)
Gain on valuation of warrants	753,707	13,794,683
Interest income	435,100	1,210,853
Total other income (expense), net	1,188,807	7,262,252
LOSS BEFORE INCOME TAXES	(21,791,037)	(44,515,446)
INCOME TAX PROVISION (BENEFIT)	—	66,000
NET LOSS	$ (21,791,037)	$ (44,581,446)
NET LOSS PER SHARE — BASIC	$ (8.35)	$ (36.52)
NET LOSS PER SHARE — DILUTED	$ (8.35)	$ (41.89)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC	2,608,317	1,220,749
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — DILUTED	2,608,317	1,238,125

See accompanying notes to the consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

	Series D Preferred Stock		Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Par Amount			
Balance at December 31, 2023	111.11	$ 1,382,023	319.76	$ 4,677,632	691,470	$ 7	$ 182,924,410	$(202,761,017)	$ (15,158,968)
Stock-based compensation	—	—	—	—	—	—	4,272,780	—	4,272,780
Exercise of pre-funded warrants into common shares	—	—	—	—	35,971	—	3,972,540	—	3,972,540
Exercise of warrants for preferred stock, net of issuance costs (Note 2)	—	—	2,205.00	47,577,000	—	—	—	—	47,577,000
Conversion of Series E-3 preferred stock into common stock	—	—	(2,205.00)	(47,577,000)	461,538	5	47,576,995	—	—
Exercise of warrants for common stock	—	—	—	—	18,239	—	2,298,143	—	2,298,143
Conversion of Series E-2 preferred stock into common stock	—	—	(284.00)	(4,156,854)	104,088	1	4,156,853	—	—
Issuance of E-4 preferred stock net of issuance costs	—	—	1,610.00	15,914,632	—	—	—	—	15,914,632
Conversion of Series E-4 preferred stock into common stock	—	—	(1,610.00)	(15,914,632)	224,664	2	15,914,630	—	—
Stock option exercise into common stock	—	—	—	—	26	—	—	—	—
Net loss	—	—	—	—	—	—	—	(44,581,446)	(44,581,446)
Balance at December 31, 2024	111.11	$ 1,382,023	35.60	$ 520,778	1,535,996	$ 15	$ 261,116,351	$(247,342,463)	$ 14,294,681
Stock-based compensation	—	—	—	—	—	—	2,263,703	—	2,263,703
Issuance of common stock, net of issuance costs	—	—	—	—	1,045,000	11	5,788,369	—	5,788,380
Exercise of warrants for common stock, net of issuance costs	—	—	—	—	1,659,138	16	7,981,421	—	7,981,437
Retired shares	—	—	—	—	(5)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(21,791,037)	(21,791,037)
Balance at December 31, 2025	111.11	$ 1,382,023	35.60	$ 520,778	4,240,129	$ 42	$ 277,149,844	$(269,133,500)	$ 8,537,164

See accompanying notes to the consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (21,791,037)	$ (44,581,446)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	213,597	291,653
Stock-based compensation	2,263,704	4,272,780
Loss on disposal of assets	—	145,726
Warrant issuance expense	—	7,743,284
Change in fair value of warrants	(753,707)	(13,794,683)
Change in operating lease right-of-use asset	76,202	65,409
Changes in:		
Prepaid expenses and other assets	119,233	(73,440)
Accounts payable and accrued liabilities	(3,161,792)	(1,593,305)
Lease liability	(84,417)	(58,979)
Cash used in operating activities	(23,118,217)	(47,583,001)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant & equipment	(5,880)	(104,195)
Cash used in investing activities	(5,880)	(104,195)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants and new warrants, net of issuance costs	7,243,143	61,410,815
Proceeds from issuance of common stock, pre-funded warrants and common warrants, net of issuance costs	5,788,380	—
Cash provided by financing activities	13,031,523	61,410,815
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(10,092,574)	13,723,619
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	23,288,607	9,564,988
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 13,196,033	$ 23,288,607
SUPPLEMENTAL DISCLOSURE OF NON-CASH INFORMATION		
Conversion of preferred stock to common stock	$ —	$ 67,648,487
Settlement of warrants to equity	$ 738,325	$ 12,608,199

See accompanying notes to the consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS AND ORGANIZATION

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

Going Concern — As an emerging growth company, the Company has, by design, incurred significant recurring losses and used net cash in its operations since its inception as it devotes substantially all of its efforts towards researching, developing and seeking approval for its product candidates to be commercialized in the marketplace. As a result of these efforts, the Company had an accumulated deficit of approximately $269,000,000 as of December 31, 2025, and incurred a net loss of approximately $21,791,000 and negative cash flows from operations of approximately $23,100,000, during the year ended December 31, 2025. The Company expects it will continue to generate significant losses and negative cash flows from operations for the foreseeable future, until such time that one or more of its product candidates are approved and successfully commercialized in the marketplace. While management believes one or more of the Company's product candidates will be approved and successfully commercialized in the marketplace, no assurance can be provided that any products will be approved or commercialized in a profitable manner.

As of the date the accompanying consolidated financial statements were issued (the "issuance date"), the Company's available liquidity to fund the Company's operations over the next twelve months beyond the issuance date was limited to approximately $9.7 million of unrestricted cash and cash equivalents. Absent further action taken by management to increase its liquidity, the Company may be unable to fund its operations under normal course beyond the third quarter of 2026. These conditions and events raise substantial doubt about the Company's ability to continue as a going concern.

To fund its research, development, and approval efforts, the Company has been heavily dependent on funding from private investors and public stockholders since its inception through the issuance of securities, such as common stock, convertible preferred stock, and warrants (collectively "outside capital"). The Company expects to remain heavily dependent on outside capital to fund the Company's operations for the foreseeable future until such time that one or more of its product candidates are approved and successfully commercialized in the marketplace. While management believes additional outside capital will be secured as needed, no assurance can be provided that it will be secured or on terms acceptable to the Company.

To improve the Company's liquidity, management plans to secure additional outside capital via the sale of equity and/or debt securities or execute a strategic transaction. Management also plans to preserve liquidity, as needed, by implementing temporary cost-saving measures. While management believes their plans will be successful, no assurance can be provided such plans will be effectively implemented over the next twelve months beyond the issuance date. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

In the event management's plans are not effectively implemented, the Company will 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 return of capital to stockholders, and/or filing for bankruptcy protection.

The accompanying consolidated financial statements are prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying consolidated financial statements reflect the application of certain accounting policies, as described in this note and elsewhere in the notes to the consolidated financial statements.

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All inter-company accounts and transactions have been eliminated in consolidation. The Company consists of one reportable segment.

Use of Estimates — The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and judgments that may affect the reported amounts of assets, liabilities and expenses and disclosure of contingent assets and liabilities. On an on-going basis, management evaluates its estimates including those related to potential accrued liabilities, valuation of warrant and equity-based instruments, and share-based compensation. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from those estimates under different assumptions or conditions. Changes in estimates are reflected in reported results in the period in which they become known.

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

Property, Plant & Equipment — Property, plant & equipment are stated at cost. Depreciation on property and equipment is provided using the straight-line method over the estimated useful lives of the assets (3 to 10 years). Leasehold improvements are depreciated over 64 months (their estimated useful life), which represented the full term of the lease at the time the leasehold improvements were capitalized. Our only long-lived assets are property, equipment and Right-of-Use (ROU) assets. The Company periodically, and at a minimum annually, evaluates long-lived assets for potential impairment. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. Such analyses necessarily involve judgement. The Company recorded disposal charges of approximately $0 and $146,000 during the years ended December 31, 2025 and 2024, respectively.

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

Stock-Based Compensation — The Company uses the Black-Scholes option-pricing model to calculate the grant-date fair value of stock option awards. The resulting compensation expense, net of expected forfeitures, for awards that are not performance-based, is recognized on a straight-line basis over the service period of the award, which for 2025 and 2024 ranged from twelve months to three years.

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

Income Taxes — Income taxes are accounted for using the liability method of accounting. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement basis and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more-likely-than-not that some portion of the deferred tax assets will not be realized. Management has provided a full valuation allowance against the Company's net deferred tax asset. Tax positions taken or expected to be taken in the course of preparing tax returns are required to be evaluated to determine whether the tax positions are more-likely-than-not to be sustained by the applicable tax authority. Tax positions deemed to not meet a more-likely-than-not threshold would be recorded as tax expense in the current year. There were no uncertain tax positions that require accrual to or disclosure in the consolidated financial statements as of December 31, 2025 and 2024.

Fair Value of Financial Instruments — The guidance under ASC Topic 825, Financial Instruments, requires disclosure of the fair value of certain financial instruments. Financial instruments in the accompanying consolidated financial statements consist of cash equivalents, prepaid expenses and other assets, accounts payable, accrued liabilities, warrant liabilities and long-term obligations. The carrying amount of cash equivalents, prepaid expenses, other current assets, accounts payable and accrued liabilities approximate their fair value as a result of their short-term nature. See Note 3.

Warrants — The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity and ASC 815, Derivatives and Hedging. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. For equity-classified warrants, the fair value is not remeasured. For warrants that are liability-classified, changes in fair value, as well as the cost to issue the warrants, are included in Other Income (Expense) in the accompanying Consolidated Statements of Operations. If these instruments are initially classified as either liabilities or equity and a subsequent assessment determines that the classification has changed, the Company reflects that change in the financial statements.

Preferred Stock — The Company accounts for preferred stock based upon their specific terms and the authoritative guidance in ASC 480 and ASC 815, including whether they are freestanding instruments, whether any redemption or conversion aspects exist and how they are required to be settled (for example, if there are features that may require cash settlement), contain characteristics that are predominantly debt-like or equity-like, have embedded derivatives, and if they have redemption features. Based upon analysis of these criteria, the preferred stock will be classified as either debt, temporary (or "mezzanine") equity, or permanent equity. The resultant classification is then evaluated quarterly to determine whether any change to the classification is required.

Concentration of Credit Risk — Financial instruments that subject the Company to credit risk consist of cash and cash equivalents on deposit with financial institutions. The Company's excess cash as of December 31, 2025 and 2024, is on deposit in interest-bearing accounts with well-established financial institutions. At times, such amounts may exceed the Federal Deposit Insurance Corporation (FDIC) insurance limits. As of December 31, 2025 and 2024, uninsured cash balances totaled approximately $12,946,000 and $22,837,000, respectively.

Government Assistance — In accordance with ASC 832, Government Assistance, the Company discloses certain types of government assistance they receive in the notes to the financial statements. Reimbursements of eligible expenditures pursuant to government assistance programs are recorded as reductions of operating costs when there is reasonable assurance that the Company will comply with the conditions attached to the grant arrangement and when the reimbursement has been claimed. The determination of the amount of the claim, and accordingly the receivable amount, requires management to make calculations based on its interpretation of eligible expenditures in accordance with the terms of the programs. The reimbursement claims submitted by the Company are subject to review by the relevant government agencies. The Company currently has a cancer treatment research award through the National Cancer Institute (NCI) totaling approximately $2.0 million over a period of approximately three years. In September 2022, the Company was awarded $1.98 million in additional grant funding to expand the Company's ongoing Phase 1 study of iopofosine I 131 in children and adolescents with inoperable relapsed or refractory high-grade gliomas (HGGs). The grant was awarded by the NCI based upon the initial signals of efficacy in the Phase 1 study, which is an international, open-label, dose escalation, safety study. The funding allows for an expansion from Part 1a into the Part 1b portion of the ongoing Phase 1 pediatric study.

During the twelve months ended December 31, 2025, the Company received $0 in NCI grant funding under the grants described above. During the twelve months ended December 31, 2024, the Company received approximately $602,000 in NCI grant funding under the grants described above, all of which was reported as a reduction of research and development (R&D) expenses.

Recently Issued Accounting Pronouncements Not Yet Adopted — In November 2025, the FASB issued ASU No. 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*, which introduced new guidance on disclosures to provide clarity about the current requirements for interim reporting. This guidance is effective for the Company for interim reporting periods within annual reporting periods beginning after December 15, 2027. The Company is currently evaluating the impact ASU 2025-11 will have on its consolidated financial statements.

In October 2025, the FASB issued ASU No. 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities*, which introduced authoritative guidance on the accounting for government grants received by business entities. This guidance is effective for the Company for annual reporting periods beginning after December 15, 2028, and interim reporting periods within those annual reporting periods. The Company is currently evaluating the impact ASU 2025-10 will have on its consolidated financial statements.

The Company evaluates all ASUs issued by the FASB for consideration of their applicability to the financial statements. The Company has assessed all ASUs issued but not yet adopted and concluded that those not disclosed are not relevant to the Company or are not expected to have a material impact.

Recently Adopted Accounting Pronouncements — In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. This standard increases the transparency and decision usefulness of income tax disclosures for investors by requiring information to better assess how an entity's operations and related tax risks, planning, and operational opportunities affect its tax rate and prospects for future cash flows. This standard requires entities to provide enhanced disclosures related to the income tax rate reconciliation and income taxes paid. This standard is effective for all entities that are subject to Topic 740, Income Taxes for annual periods beginning after December 15, 2024, but early adoption is permitted. The Company adopted this standard in fiscal year 2025, utilizing the retrospective application as permitted in the standard. See Note 8.

3. FAIR VALUE

In accordance with ASC 820, Fair Value Measurements and Disclosures, the Company groups its financial assets and financial liabilities generally measured at fair value in three levels, based on the markets in which the assets and liabilities are traded, and the reliability of the assumptions used to determine fair value:

- Level 1: Input prices quoted in an active market for identical financial assets or liabilities.
- Level 2: Inputs other than prices quoted in Level 1, such as prices quoted for similar financial assets and liabilities in active markets, prices for identical assets, and liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data.
- Level 3: Input prices quoted that are significant to the fair value of the financial assets or liabilities which are not observable or supported by an active market.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. The carrying value of cash and cash equivalents approximates fair value as maturities are less than three months. The carrying amounts reported for other current financial assets and liabilities approximate fair value because of their short-term nature.

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period, pursuant to the policy described in Note 2. This determination requires significant judgments be made. The following table summarizes the conclusions reached as of December 31, 2025 and 2024 for financial instruments measured at fair value on a recurring basis.

	Balance	Level 1	Level 2	Level 3
December 31, 2025				
Cash and cash equivalents	$ 13,196,033	$ 13,196,033	$ —	$ —
Total assets	$ 13,196,033	$ 13,196,033	$ —	$ —
Warrant liability	$ 226,000	$ —	$ —	$ 226,000
Total liabilities	$ 226,000	$ —	$ —	$ 226,000
December 31, 2024				
Cash and cash equivalents	$ 23,288,607	$ 23,288,607	$ —	$ —
Total assets	$ 23,288,607	$ 23,288,607	$ —	$ —
Warrant liability	$ 1,718,000	$ —	$ —	$ 1,718,000
Total liabilities	$ 1,718,000	$ —	$ —	$ 1,718,000

July 2024 Warrants

As part of the July 2024 financing the Company issued Tranche A, B, and C warrants (the 2024 Warrants) to purchase shares of common stock (see Note 2). The fair value of the 2024 warrants was determined using a probability-weighted expected return method (PWERM) with a scenario-based Monte Carlo simulation and Black-Scholes model. The PWERM is a scenario-based methodology that estimates the fair value of the Company's different classes of equity based upon an analysis of future values for the Company, assuming various outcomes. Under both models, assumptions and estimates are used to value the warrants. The Company assesses these assumptions and estimates on a quarterly basis as additional information that impacts the assumptions is obtained. The quantitative elements associated with the inputs impacting the fair value measurement of the 2024 Warrants include the value per share of the underlying common stock, the timing, form and overall value of the expected exits for the stockholders, the risk-free interest rate, the expected dividend yield and the expected volatility of the Company's shares. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared cash dividends. Expected volatility was determined based upon the historical volatility of the Company's common stock.

The 2024 Warrants are classified within the Level 3 hierarchy because of the nature of these inputs and the valuation technique utilized, and had a fair value of $180,000 and $1,200,000 as of December 31, 2025, and December 31, 2024, respectively, which is included in the warrant liability caption on the accompanying balance sheets.

The following table summarizes the modified option-pricing assumptions used on December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Volatility	110.00-117.00 %	80.60-104.00 %
Risk-free interest rate	3.50-3.80 %	3.50-4.20 %
Expected life (years)	3.30-4.10	0.50-4.80
Dividend	0 %	0 %

September 2023 Warrants

The fair value of the 2023 Warrants was determined by utilizing a Black-Scholes option-pricing model. The quantitative elements associated with the inputs impacting the fair value measurement of the 2023 Warrants include the value per share of the underlying common stock, the risk-free interest rate, the expected dividend yield and the expected volatility of the Company's shares. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared cash dividends. Expected volatility was determined based upon the historical volatility of the Company's common stock. These warrants are classified within the Level 3 hierarchy because of the nature of these inputs and the valuation technique utilized.

The 2023 Warrants are classified within the Level 3 hierarchy because of the nature of the valuation technique utilized, and had a fair value of $5,000 and $26,000 as of December 31, 2025 and 2024, respectively, which is included in the warrant liability caption on the accompanying balance sheets.

The following table summarizes the modified option-pricing assumptions used on December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Volatility	100.17-125.50 %	105 %
Risk-free interest rate	3.55-3.89 %	4.20-4.30 %
Expected life (years)	2.69-3.44	0.80-4.20
Dividend	0 %	0 %

October 2022 Warrants

The fair value of the 2022 Common Warrants was determined by utilizing a Black-Scholes option-pricing model. The quantitative elements associated with the inputs impacting the fair value measurement of the 2022 Common Warrants include the value per share

of the underlying common stock, the risk-free interest rate, the expected dividend yield and the expected volatility of the Company's shares. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared cash dividends. Expected volatility was determined based upon the historical volatility of the Company's common stock. These warrants are classified within the Level 3 hierarchy because of the nature of these inputs and the valuation technique utilized.

The 2022 Common Warrants are classified within the Level 3 hierarchy because of the nature of these inputs and the valuation technique utilized, and had a fair value of $41,000 and $462,000 as of December 31, 2025, and December 31, 2024, respectively, which is included in the warrant liability caption on the accompanying balance sheets.

The following table summarizes the assumptions used at each financial reporting date:

	December 31, 2025	December 31, 2024
Volatility	147.20 %	117.50 %
Risk-free interest rate	3.47 %	4.27 %
Expected life (years)	1.80	2.80
Dividend	0 %	0 %

The following table summarizes the changes in the fair market value of all warrants which are classified within the Level 3 fair value hierarchy for the years ended December 31, 2025 and 2024:

	2025	2024
Beginning warrant fair value	$ 1,718,000	$ 13,131,691
Change in warrant fair value	(317,055)	(14,778,015)
Issuance of July 2024 inducement warrants	—	12,000,000
Settlement of warrants to equity	(1,174,945)	(7,410,000)
Exercise of October 2022 warrants	—	(1,225,676)
Ending warrant fair value	$ 226,000	$ 1,718,000

4. PROPERTY, PLANT & EQUIPMENT

Property, plant & equipment consisted of the following as of December 31:

	2025	2024
Office and laboratory equipment	$ 1,421,000	$ 1,467,000
Computer software	4,000	4,000
Leasehold improvements	310,000	310,000
Total property, plant & equipment	1,735,000	1,781,000
Less– accumulated depreciation and amortization	(1,186,000)	(1,024,000)
Property, plant & equipment, net	$ 549,000	$ 757,000

For the years ended December 31, 2025 and 2024, the Company recorded approximately $214,000 and $292,000 of fixed asset depreciation and amortization expense, respectively.

5. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following as of December 31:

	2025	2024
Accounts payable	$ 1,441,000	$ 4,105,000
Incentive compensation	1,090,000	611,000
Clinical project costs	1,079,000	1,339,000
Professional fees	315,000	219,000
Other	499,000	1,311,000
	$ 4,424,000	$ 7,585,000

6. STOCKHOLDERS' EQUITY

October 2025 Warrant Inducement

On October 7, 2025, the Company entered into warrant exercise inducements with certain holders of certain existing warrants, which were originally issued on October 25, 2022, July 21, 2024, and July 2, 2025, pursuant to which the holders agree to exercise for cash their existing warrants to purchase 1,048,094 shares of the Company's common stock, at an exercise price of $5.25 per share, and pay $0.125 per new warrant, in exchange for the Company's agreement to issue two new warrants for each warrant exercised. In connection with the exercise of these warrants, the Company issued new warrants (the October 2025 Inducement Warrants) in two different series: the Series I Inducement Warrants and the Series II Inducement Warrants. Each Inducement Warrant is immediately exercisable at an exercise price of $6.00 per share. The Series I Inducement Warrants will expire on October 8, 2030, and the Series II Inducement Warrants will expire on April 8, 2027. The investors paid $0.125 for each October 2025 Inducement Warrant. The gross proceeds to the Company from the warrant exercises and new warrant issuance was approximately $5.8 million, prior to deducting placement agent fees and offering expenses. Based upon an evaluation utilizing the criteria in ASC 480, Distinguishing Liabilities from Equity, the company concluded that the Common Warrants do not meet any of the conditions necessary to be classified as a liability. Furthermore, based upon an assessment utilizing ASC 815, Derivatives and Hedging, the Common Warrants meet all the necessary criteria to be classified as permanent equity.

July 2025 Underwritten Public Offering

On July 2, 2025, the Company completed an underwritten public offering for gross proceeds of approximately $6.9 million, prior to deducting underwriting commissions and offering expenses. The offering was composed of (i) 1,045,000 Class A Units (which includes 180,000 Class A Units issued pursuant to the Underwriter's exercise of the over-allotment option in full) with each Class A Unit consisting of (a) one share of common stock and (b) one common warrant to purchase one share of common stock (the Common Warrants), and (ii) 335,000 Class B Units with each Class B Unit consisting of (a) one pre-funded common stock purchase warrant to purchase one share of common stock (Pre-funded Warrants) and (b) one Common Warrant. The price per Class A Unit is $5.00 and the price per Class B Unit is $4.99999 (collectively, the Offering). The Common Warrants have an exercise price of $5.25 per share, are exercisable upon issuance, and have a term expiring five years from issuance. Based upon an evaluation utilizing the criteria in ASC 480, Distinguishing Liabilities from Equity, the company concluded that the Common Warrants do not meet any of the conditions necessary to be classified as a liability. Furthermore, based upon an assessment utilizing ASC 815, Derivatives and Hedging, the Common Warrants meet all the necessary criteria to be classified as permanent equity. The Company also issued 82,800 common stock purchase warrants (representative warrants) to the underwriter upon the closing of the July 2025 offering. The representative warrants have an exercise price equal to $7.75 per share of common stock, were exercisable immediately upon issuance and have a term expiring five years from issuance.

2025 Reverse Stock Split

At the annual stockholders' meeting held on June 23, 2025, the Company's stockholders approved an amendment to the Company's certificate of incorporation to effect a reverse split of the Company's common stock at a ratio between one-for-ten (1:10) to one-for-thirty (1:30) in order to satisfy requirements for the continued listing of the Company's common stock on Nasdaq. The board of directors authorized the 1:30 ratio of the reverse split on June 18, 2025, and effective at the close of business on June 24, 2025, the Company's certificate of incorporation was amended to effect a 1:30 reverse split of the Company's common stock (the Reverse Stock Split). The Reverse Stock Split did not impact authorized shares. The accompanying consolidated financial statements and notes to consolidated financial statements give retroactive effect to the Reverse Stock Split for all periods presented.

June 2025 Warrant Inducement

On June 6, 2025, the Company entered into definitive agreements for investors to immediately exercise certain outstanding warrants to purchase an aggregate of 276,044 shares of common stock, issued by the company on June 5, 2020, October 25, 2022, and July 21, 2024 (the Existing Warrants), at a reduced exercise price of $9.123 per share. The shares of common stock issuable upon exercise of the Existing Warrants are all registered, or their resale is registered, pursuant to effective registration statements. The Company did not issue any new warrants as part of the agreements. The gross proceeds to the Company from the exercise of the Existing Warrants was approximately $2.5 million, prior to deducting placement agent fees and offering expenses.

July 2024 Warrant Inducement

On July 21, 2024, the Company, entered into a warrant exercise inducement (the Inducement) with certain holders of its September 2023 Tranche B warrants, pursuant to which the holders agreed to exercise the warrants to purchase 1,610 shares of the Company's Series E-4 Convertible Voting Preferred Stock, par value $0.00001 per share (the Series E-4 preferred stock) which is convertible to 224,663 shares of the Company's common stock in the aggregate, at a reduced, as-converted common stock price of $75.60 per share, in exchange for the Company's issuance of new warrants (the July 2024 Inducement Warrants), with varying termination dates and exercise prices. The Company received gross proceeds of $19.4 million and net proceeds of $17.5 million.

The July 2024 Inducement Warrants have the following terms:

- The 2024 Tranche A warrants have an exercise price of $75.60 and expire at the earlier of (i) ten (10) trading days following the date of the Company's public announcement that the FDA has assigned a Prescription Drug User Fee Act goal date for review of iopofosine I 131, and (ii) July 21, 2029.
- The 2024 Tranche B warrants have an exercise price of $120.00 and expire at the earlier of (i) ten (10) trading days following the date of the Company's public announcement of its receipt of written approval from the FDA of its New Drug Application for iopofosine I 131, and (ii) July 21, 2029.
- The 2024 Tranche C warrants have an exercise price of $165.00 and expire at the earlier of (i) ten (10) trading days following the date of the Company's public announcement that it has recorded quarterly gross revenues from sales of iopofosine I 131 in the United States in excess of $10 million and (ii) July 21, 2029.
- The July 2024 Inducement Warrants do not qualify under the equity classification guidance because of a cash settlement feature that requires cash settlement in event of a fundamental transaction that is outside the Company's control resulting in a form of settlement inconsistent with that which would be received by other security holders. As a result, and in accordance with the guidance in ASC 815, the warrants issued in July 2024 are deemed to be liabilities. All such liabilities are required to be presented at fair value, with changes reflected in financial results for the period. In accordance with the guidance above, the Company recorded the July 2024 Inducement Warrants and preferred stock at their respective fair values. See Note 3 for the related valuation.

September 2023 Private Placement

On September 8, 2023, in a private placement with certain institutional investors, the Company issued 1,225 shares of Series E-1 preferred stock, along with Tranche A warrants to purchase 2,205 shares of Series E-3 preferred stock and Tranche B warrants to purchase 1,715 shares of Series E-4 preferred stock.

The Series E-1 preferred stock automatically converted either to Series E-2 preferred or common stock upon stockholder approval, which occurred on October 25, 2023.

The July 2024 Warrant Inducement described above resulted in 105.000 Tranche B warrants remaining outstanding, which are convertible into 14,652 shares of common stock. The Tranche B warrants do not qualify as derivatives; however, they also do not meet the requirements necessary to be considered indexable in the Company's stock. As a result, and in accordance with the guidance in ASC 815, the warrants are deemed to be liabilities. All such liabilities are required to be presented at fair value, with changes reflected in financial results for the period. See Note 3 for the related valuation.

There are 35.60 shares of Series E-2 preferred stock outstanding as of December 31, 2025.

October 2022 Public Offering and Private Placement

On October 25, 2022, the Company completed a registered direct offering and concurrent private placement transaction. As of December 31, 2025, there remain 75,939 warrants outstanding that are immediately exercisable at an exercise price of $58.80 per share and will expire on the fifth anniversary of the closing date. Due to a cash settlement feature, the warrants are liability classified. See Note 3 for the related valuation.

The following table summarizes information with regard to outstanding warrants to purchase stock as of December 31, 2025:

Offering	Number of Common Shares Issuable Upon Exercise of Outstanding Warrants	Exercise Price	Expiration Date
2025 October Series I Common Warrants	1,048,094	$ 6.00	October 8, 2030
2025 October Series II Common Warrants	1,048,094	$ 6.00	April 8, 2027
2025 July Common Warrants	436.000	$ 5.25	July 2, 2030
2025 Representative Warrants	82,800	$ 7.75	July 2, 2030
2024 Tranche A Warrants	114,773	$ 75.60	July 21, 2029
2024 Tranche B Warrants	139,877	$ 120.00	July 21, 2029
2024 Tranche C Warrants	72,663	$ 165.00	July 21, 2029
2023 Tranche B Preferred Warrants	14,652	$ 143.25	September 8, 2028
2022 Common Warrants	75,939	$ 58.80	October 25, 2027
Total	3,032,892		

The 2025 October Series I and Series II Common Warrants, the 2025 July Common Warrants, and the 2025 Representative Warrants are classified as equity. All other warrants in the table above are liability classified.

7. STOCK-BASED COMPENSATION

Accounting for Stock-Based Compensation

2021 Stock Incentive Plan

The Company maintains the 2021 Stock Incentive Plan (the “2021 Plan”). The Company utilizes stock-based compensation incentives as a component of its employee and non-employee director and officer compensation philosophy. A committee of the Board of Directors determines the terms of the awards granted and may grant various forms of equity-based incentive compensation. Currently, these incentives consist principally of stock options and restricted shares. All outstanding awards under the 2015 Stock Incentive Plan (the “2015 Plan”) remained in effect according to the terms of the 2015 Plan. Any shares that are currently available under the 2015 Plan and any shares underlying 2015 Plan awards which are forfeited, cancelled, reacquired by the Company or otherwise terminated are added to the shares available for grant under the 2021 Plan.

Under the current stock option award program, all options become exercisable between one and three years after issuance and expire after ten years. The fair value of each stock option award is estimated on the grant date using the Black-Scholes option-pricing model. Volatility is based on the Company’s historical common stock volatility. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time. The expected term of stock options granted is based on an estimate of when options will be exercised in the future. Forfeitures are recorded as they occur. No dividends have been recorded historically.

During the twelve months ended December 31, 2025 and 2024, stock options granted were 77,331 and 102,116, respectively. The following table summarizes amounts charged to expense for stock-based compensation related to employee and director stock option grants:

	Twelve Months Ended December 31,	
	2025	2024
Employee and director stock option and stock grants:		
Research and development	$ 413,022	$ 3,486,168
General and administrative	1,850,682	786,612
Total stock-based compensation	$ 2,263,704	$ 4,272,780

In December 2023, the Company granted 92,533 contingent, non-statutory stock option awards at an exercise price of $78.90 per share to employees and directors, and in March 2024 the Company granted 6,666 contingent, non-statutory stock option awards at an exercise price of $108.90 and $100.50 per share to our employees. Each of these grants was contingent on approval of an increase in the shares available in the 2021 Stock Incentive Plan that was approved by the stockholders at the annual meeting of stockholders held on June 14, 2024. In accordance with the removal of the contingency, the Company began recognizing the expense for these awards in June 2024.

Assumptions Used in Determining Fair Value

Valuation and amortization method. The fair value of each stock award is estimated on the grant date using the Black-Scholes option-pricing model. The estimated fair value of employee stock options is amortized to expense using the straight-line method over the required service period which is generally the vesting period. The estimated fair value of the non-employee options is amortized to expense over the period during which a non-employee is required to provide services for the award (usually the vesting period).

Volatility. The Company estimates volatility based on the Company's historical volatility since its common stock has been publicly traded.

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption.

Expected term. The expected term of stock options granted is based on an estimate of when options will be exercised in the future. The Company applied the simplified method of estimating the expected term of the options, as described in the SEC's Staff Accounting Bulletins 107 and 110, as the historical experience is not indicative of the expected behavior in the future. The expected term, calculated under the simplified method, is applied to groups of stock options that have similar contractual terms. Using this method, the expected term is determined using the average of the vesting period and the contractual life of the stock options granted. The Company applied the simplified method to non-employees who have a truncation of term based on termination of service and utilizes the contractual life of the stock options granted for those non-employee grants which do not have a truncation of service.

Forfeitures. The Company only records stock-based compensation expense for those awards that are expected to vest. The Company accounts for forfeitures as they occur.

Dividends. The Company has not historically issued dividends.

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

	Year Ended December 31,	
	2025	2024
Volatility	100.17 %	82.13 %
Risk-free interest rate	4.37 %	4.21-4.64 %
Expected life (years)	6.0	6.0
Dividend	0 %	0 %

Exercise prices for all grants made during the twelve months ended December 31, 2025 and 2024 were equal to the market value of the Company's common stock on the date of grant.

Stock Option Activity

A summary of stock option activity is as follows:

	Number of Shares Issuable Upon Exercise of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term in Years	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	78,397	$ 163.80	8.64	$ 1,682,667
Granted	102,116	$ 81.60		
Expired	(53)	$ 600.00		
Forfeited	(27,503)	$ 75.30		
Exercised	(55)	$ 50.40		
Outstanding as of December 31, 2024	152,902	$ 123.00	7.37	$ —
Granted	77,331	$ 8.70		
Expired	(18,066)	$ 125.25		
Outstanding as of December 31, 2025	212,167	$ 80.47	5.35	$ —
Exercisable as of December 31, 2025	113,080	$ 129.93		$ —
Unvested as of December 31, 2025	99,087	$ 24.03		$ —

The aggregate intrinsic value of options outstanding is calculated based on the positive difference between the estimated per-share fair value of common stock at the end of the respective period and the exercise price of the underlying options. Shares of common stock issued upon the exercise of options are from authorized but unissued shares. At December 31, 2025, we had 100,651 shares available for grant under the 2021 Option Plan.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2025 and 2024, was $21.30 and $73.50, respectively. The total fair value of options vested during the years ended December 31, 2025 and 2024, was $2,039,819 and $5,342,685, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2025, was $113.91 and $21.30 respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2024, was $110.70 and $65.70, respectively.

The weighted average grant date fair value of options forfeited during the years ended December 31, 2025 and 2024, was $60.65 and $53.10, respectively. The number of options vested during the years ended December 31, 2025 and December 31, 2024, was 33,156 and 80,295, respectively. The number of options unvested at December 31, 2025 and December 31, 2024, was 99,087 and 55,130, respectively.

As of December 31, 2025, there was approximately $5,470,000 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, the Company expects to recognize approximately $1,969,000, $1,820,000, and $1,681,000 during 2026, 2027 and 2028, respectively. The Company's expense estimates are based upon the expectation that all unvested options will vest in the future.

8. INCOME TAXES

	2025	2024
Tax provision (benefit)		
Current		
Federal	$ —	$ —
State	—	66,000
Total current	—	66,000
Deferred		
Federal	(5,245,000)	(16,106,000)
State	(1,609,000)	(3,458,000)
Total deferred	(6,854,000)	(19,564,000)
Change in valuation allowance	6,854,000	19,564,000
Total	$ —	$ 66,000

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

	2025	2024
Deferred tax assets		
Federal net operating loss	$ 61,791,000	$ 47,909,000
Federal research and development tax credit carryforwards	22,530,000	21,359,000
State net operating losses and tax credit carryforwards	14,935,000	10,191,000
Capitalized research and development expenses	9,632,000	22,658,000
Stock-based compensation expense	5,092,000	5,072,000
Other	457,000	419,000
Total deferred tax assets	114,437,000	107,608,000
Deferred tax liabilities		
Depreciable assets	(98,000)	(123,000)
Total deferred tax liabilities	(98,000)	(123,000)
Net deferred tax assets	114,339,000	107,485,000
Less- valuation allowance	(114,339,000)	(107,485,000)
Total deferred tax assets	$ —	$ —

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

	Year ended December 31,			
	2025		2024	
Income tax benefit using U.S. federal statutory rate	$ (4,605,000)	21.00 %	$ (9,357,000)	21.00 %
State income taxes	$ (122,000)	0.56 %	$ 136,000	(0.31)%
Permanent nondeductible items	$ —	0.00 %	$ —	0.00 %
Federal tax credits				
Orphan Drug Credit	$ (1,176,000)	5.36 %	$ (4,582,000)	10.28 %
Research and development credits	$ 6,000	(0.03)%	$ (811,000)	1.82 %
Change in valuation allowance	$ 5,401,000	(24.63)%	$ 16,113,000	(36.15)%
Nontaxable or nondeductible items				
Warrant cost/Revaluation	$ (130,000)	0.59 %	$ (1,276,000)	2.86 %
Share-based compensation	$ 617,000	(2.81)%	$ —	—
Other	$ 4,000	(0.02)%	$ 40,000	(0.09)%
Other	$ 5,000	(0.02)%	$ (197,000)	0.44 %
Total	$ —	(0.00)%	$ 66,000	(0.15)%

As of December 31, 2025, the Company had federal net operating loss (NOL) carryforwards of approximately $109,370,000 generated as of December 31, 2017, and NOL carryforwards of approximately $184,873,000 after December 31, 2017. Federal NOLs generated as of December 31, 2017, will expire in 2025 through 2037, while NOLs generated during 2018 and later will be carried forward indefinitely until utilized. As of December 31, 2025, the Company had state NOL carryforwards of approximately $203,341,000. State NOL carryforwards will expire in 2030 through 2045.

In July 2025, the OBBBA was signed into law. The OBBBA makes permanent or introduces certain changes to the Internal Revenue Code, including 100% bonus depreciation, the deductibility of business interest expense, and expensing of domestic research costs. ASC 740 requires that the effect of changes in tax rates and laws be recognized in the period in which the legislation is enacted. The impact of this change is primarily reflected in deferred taxes.

As of December 31, 2025, the Company had federal research and development (R&D) and orphan drug credit carryforwards of approximately $22,530,000 which will expire in 2025 through 2044. As of December 31, 2025, the Company also had state credit carryforwards of approximately $781,000 which will expire in 2025 through 2039.

The Company had federal NOLs and R&D credit carryforwards of $274,000 and $50,000, respectively, that expired in 2025. Additionally, $49,000 of WI R&D credits carryforward expired in 2025.

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

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

The Company did not have unrecognized tax benefits or accrued interest and penalties at any time during the years ended December 31, 2025 or 2024, and does not anticipate having unrecognized tax benefits over the next twelve months. The Company is subject to audit by the Internal Revenue Service and state taxing authorities for tax periods commencing January 1, 2022, as a result of its NOLs. However, any adjustment related to these periods would be limited to the amount of the NOL generated in the year(s) under examination.

Upon the adoption of ASU 2023-09 we are required to disclose income taxes paid, net of refunds for 2025. All amounts for federal, state and foreign are zero for the year ended December 31, 2025.

9. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock and pre-funded warrants outstanding during the period. The pre-funded warrants are considered common shares outstanding for the purposes of the basic net loss per share calculation to the nominal cash consideration and lack of other contingencies for issuance of the underlying common shares. Diluted net loss attributable to common stockholders per share is computed by dividing net loss attributable to common stockholders, as adjusted, by the sum of the weighted average number of shares of common stock and the dilutive potential common stock equivalents then outstanding. Potential common stock equivalents consist of stock options, warrants, and convertible preferred shares. In accordance with ASC Topic 260, Earnings per Share, diluted earnings per share are the amount of earnings for the period available to each share of common stock outstanding during the reporting period and to each share that would have been outstanding assuming the issuance of common shares for all dilutive potential common shares outstanding during the reporting period. In the quarters ended June 30, 2024, and September 30, 2024, the common warrants issued in October 2022 were dilutive. In all other periods presented, all outstanding warrants were antidilutive. As a result, there is no difference between basic and diluted earnings per share for the year ended December 31, 2025.

Year ended December 31, 2024		
Net loss	$	(44,581,446)
Dilutive effect of warrant liability		(7,283,786)
Net loss allocated to common shares	$	(51,865,232)
Weighted average common shares outstanding - basic		1,220,749
Dilutive effect of warrant liability		17,376
Weighted average common shares outstanding - diluted		1,238,125
Net loss per share - diluted	$	(41.89)

The following potentially dilutive securities have been excluded from the computation of diluted net loss per share since their inclusion would have been antidilutive:

	Year Ended December 31,	
	2025	**2024**
Warrants	3,032,892	679,390
Stock options	212,167	152,902
Convertible preferred shares	16,743	16,743
Total potentially dilutive shares	3,261,802	849,035

10. COMMITMENTS AND CONTINGENCIES

Legal

The Company may be involved in legal matters and disputes in the ordinary course of business. We do not anticipate that the outcome of such matters and disputes will materially affect the Company’s financial statements.

Workforce Reduction

In December 2024, the Company implemented a workforce reduction plan impacting approximately 60% of employees. The total expense charge related to the plan was approximately $1,510,000. There is no remaining liability related to the workforce reduction as of December 31, 2025.

11. LEASES

Operating Lease Liability

In June 2018, the Company executed an agreement for office space in the Borough of Florham Park, Morris County, New Jersey to be used as its headquarters (HQ Lease). The HQ Lease commenced upon completion of certain improvements in October 2018.

On December 30, 2022, the Company entered into an Amended Agreement of Lease, with CAMPUS 100 LLC (the "Landlord"). Under the Amended Lease, which was accounted for as a modification of the initial lease, as the Company will continue to lease 3,983 square feet of rentable area on the second floor of a building located at 100 Campus Drive in Florham Park, New Jersey, for the period commencing on March 1, 2023, and ending on April 30, 2029. The Company also has an option to extend the term of the Amended Lease for one additional 60-month period.

Under the terms of the Amended Lease, the Company's previously paid security deposit of $75,000 was reduced to $23,566 and the aggregate rent over the term of the Amended Lease is approximately $918,000, which will be reduced to approximately $893,000 after certain rent abatements. The Company will also be required to pay its proportionate share of certain operating expenses and real estate taxes applicable to the leased premises. After certain rent abatements the rent is approximately $11,800 per month for the first year and then escalates thereafter by 2% per year for the duration of the term. The Company has not entered into any leases with related parties.

Discount Rate

The Company has determined an appropriate interest rate to be used in evaluating the present value of the Amended Lease liability considering factors such as the Company's credit rating, borrowing terms offered by the U.S. Small Business Administration, amount of lease payments, quality of collateral and alignment of the borrowing term and lease term. The Company considers 14% per annum as reasonable to use as the incremental borrowing rate for the purpose of calculating the liability under the Amended Lease. In conjunction with the June 2018 lease, the Company had previously used a 10% per annum incremental borrowing rate.

Maturity Analysis of Short-Term and Operating Leases

The following table approximates the dollar maturity of the Company's undiscounted payments for its short-term leases and operating lease liabilities as of December 31, 2025:

Years ending December 31,		
2026	$	150,000
2027		153,000
2028		155,000
2029		53,000
Total undiscounted lease payments		511,000
Less: Imputed interest		(101,000)
Present value of lease liabilities	$	410,000

12. EMPLOYEE RETIREMENT PLAN

The Company maintains a defined contribution plan under Section 401(k) of the Internal Revenue Code that allows eligible employees to contribute a portion of their annual compensation on a pre-tax basis. The Company has not made any matching contributions under this plan.

13. OPERATING SEGMENT

The Company has one operating and reportable segment focused on utilizing its PDC platform to develop drugs for the treatment of cancer. The accounting policies of the single operating segment are the same as those of the Company. The chief operating decision maker is the Company's president and CEO, who manages the Company's operations on a consolidated basis, assesses performance for the operating segment and decides how to allocate resources based on consolidated operating expenses, which are reported in the consolidated statements of operations. The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets. Expenditures for additions to long-lived assets, which include purchases of property and equipment, are included in total consolidated assets reviewed by management and are reported on the consolidated statements of cash flows.

Management uses consolidated cash used in operations and budget-to-actual variances for consolidated net loss to assess the performance of the operating segment and evaluate performance and to allocate resources.

The following table presents certain financial data for the Company's one reportable segment:

	Year Ended December 31,	
	2025	2024
Research and development:		
Phase 2 study in WM	$ 1,308,000	$ 7,422,000
Phase 1 study in pediatric tumors	1,345,000	3,040,000
Phase 1 study in Triple Negative Breast Cancer	933,000	—
Manufacturing and related costs	4,220,000	10,582,000
Pre-clinical projects costs	823,000	228,000
General research and development costs	2,870,000	4,864,000
General and administrative	11,481,000	25,641,000
Other segment items	(1,189,000)	(7,196,000)
Segment and consolidated net loss	$ 21,791,000	$ 44,581,000

Other segment items consist of warrant issuance expense, (gain) loss on valuation of warrants, and interest income.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision, and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), in connection with the period ending December 31, 2025. Based on that evaluation, management has concluded that as of the respective period, our disclosure controls and procedures were not effective to the material weaknesses in internal control over financial reporting described below.

Notwithstanding the material weaknesses in our internal control over financial reporting, management has concluded that the audited consolidated financial statements included in this Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States of America.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act for the Company. Management assessed the effectiveness of internal control over financial reporting as of the year ended December 31, 2025. In making this assessment, our management used the criteria set forth in the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO Framework"). Based on this evaluation, our management concluded that our internal control over financial reporting was not effective as of December 31, 2025, because of the material weaknesses described below.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm, as allowed by the SEC.

Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or interim consolidated financial statements would not be prevented or detected on a timely basis.

Management concluded that material weaknesses existed as of the year ended December 31, 2024. Specifically, management identified deficiencies in the principles associated with the control environment, risk assessment, control activities, information and communication and monitoring components of internal control, based on the criteria established by the COSO Framework, that constitute material weaknesses, either individually or in the aggregate.

- Control Environment: The Company lacked appropriate policies and resources to develop and operate effective internal control over financial reporting, which contributed to the Company's inability to properly analyze, record and disclose accounting matters accurately and timely. This was further impacted by the limited number of staff in the Company's accounting and finance function. This material weakness contributed to additional material weaknesses further described below.
- Risk Assessment: The Company does not have a formal process to identify, update, and assess risks, including risks around the accounting for complex transactions, that could significantly impact the design and operation of the Company's control activities.
- Control Activities: Management did not design and implement effective control activities and identified the following material weaknesses:
    - Management failed to design and implement adequate internal controls over financial reporting which resulted in the inaccurate accounting of preferred equity and warrants
    - Management failed to design and implement adequate internal controls over the recording of stock-based compensation expense related to the restricted stock awards granted in December 2023.
    - Management failed to design and implement adequate internal controls over financial reporting as it relates to the proper fair value methodologies and assumptions used to value financial instruments, specific to the assumptions utilized in the valuation of the preferred warrants.
- Information and Communication: As noted above, the Company had a limited number of staff in its finance and accounting function, and therefore was unable to design and maintain appropriate segregation of duties in the initiation, recording, and approval of transactions within its financial systems. This, coupled with management having not designed and maintained user access controls that adequately restrict user and privileged access to financial applications, and the absence of sufficient other mitigating controls, created segregation of duties deficiencies.
- Monitoring Activities: Management did not appropriately select, develop, and perform ongoing evaluations to ascertain whether the components of internal controls are present and functioning

These material weaknesses resulted in errors that required the restatement of the Company's consolidated financial statements as of and for the fiscal years ended December 31, 2023 and December 31, 2022, as well as the restatement of the Company's condensed consolidated financial statements as of and for the interim periods ended March 31, 2024, September 30, 2023, June 30, 2023, March 31, 2023, September 30, 2022, June 30, 2022, and March 31, 2022. Additionally, these material weaknesses could result in a misstatement of the account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or timely detected.

Management's Plan to Remediate the Material Weaknesses

The process of designing and maintaining effective internal control over financial reporting is a continuous effort that requires management to anticipate and react to changes in our business, economic and regulatory environments and to expend significant resources. In early 2024, the Company began recruiting and hired qualified accounting and financial reporting personnel to supplement our level of knowledge and experience with internal control over financial reporting in order to begin to design and implement a formal control environment and risk assessment process. Such process includes identification of risks, the level of detail in our risk assessment, and the clarity of the linkage between risks and internal controls. The results of this effort are expected to enable us to effectively identify, develop, evolve and implement controls and procedures to address risks. Additionally, the Company has also initiated the implementation of an ERP system, which will provide a system-based control structure for all financial transactions.

As our remediation efforts are still on-going, we will continue to consider the need for additional resources and implement further enhancements to our policies and procedures as necessary to further improve our internal control over financial reporting. As we work to improve our internal control over financial reporting, we may modify our remediation plan and may implement measures as we continue to review, optimize and enhance our financial reporting controls and procedures in the ordinary course. The material weaknesses will not be considered remediated until the remediated controls have been operating for a sufficient period of time and can be evidenced through testing that these are operating effectively.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the period ended December 31, 2025, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Certain information regarding annual incentive bonus is included under Item 11 of this Form 10-K.

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

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated herein by reference to our definitive proxy statement for our 2026 Annual Meeting of Stockholders under the captions “Election of Directors,” “Officers and Directors” and “Corporate Governance.”

Insider Trading Policy

We have adopted an Insider Trading Policy which governs the purchase, sale and/or any other dispositions of our securities by the Company and its directors, officers and employees and is reasonably designed to promote compliance with insider trading laws, rules and regulations and applicable exchange listing standards. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Code of Ethics

The board of directors has adopted a Code of Ethics applicable to all of our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. A copy of the Code of Ethics is available at our website www.cellectar.com.

Item 11. Executive Compensation.

Compensation of Directors and Executive Officers

Executive Compensation

This section provides information, in tabular and narrative formats specified in applicable SEC rules, regarding the amounts of compensation paid to each of our named executive officers, or NEOs, and related information. As a smaller reporting company, the Company has presented such information in accordance with the scaled disclosure requirements permitted under applicable SEC regulations.

The following table sets forth certain information concerning all cash and non-cash compensation awarded to, earned by or paid to our each of NEOs for the years ended December 31, 2025 and 2024:

2025 Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Option Awards ($) [1]	Incentive Plan Compensation ($) [2]	Total ($)
James V. Caruso	2025	676,000	210,600	169,000	1,055,600
President and Chief Executive Officer	2024	650,000	2,214,000	178,750	3,042,750
Jarrod Longcor	2025	520,000	116,995	130,000	766,995
Chief Operating Officer	2024	500,000	1,230,000	100,000	1,830,000
Chad J. Kolean	2025	442,000	67,855	110,500	620,355
Chief Financial Officer	2024	425,000	713,400	85,000	1,223,400

(1) The reported amounts represent the aggregate grant date fair value computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation-Stock Compensation (“ASC 718”). All assumptions made regarding the valuation of option awards can be referenced in Note 7 in the Notes to Restated Consolidated Financial Statements included in this Annual Report on Form 10-K. The amounts reported for 2025 represent stock option awards to Messrs. Caruso, Longcor and Kolean with respect to 30,000 shares, 16,666 shares, and 9,666 shares, respectively, which awards were approved by the Compensation Committee on February 14, 2025.

(2) Amounts in this column represent bonuses approved by the Compensation Committee based on its annual review of the performance of the executive officers against predetermined financial and strategic objectives established for the year. NEOs are

paid the same percentage upon the achievement of financial objectives and may be paid varied percentages upon the achievement of strategic objectives depending on the subject matter.

Equity Awards

As described in Note (1) to the 2025 Summary Compensation Table above, on February 14, 2025 the Compensation Committee approved stock option awards to Messrs. Caruso, Longcor and Kolean with respect to 30,000 shares, 16,666 shares, and 9,666 shares, respectively, subject to stockholder approval of an amendment to the 2021 Plan at the 2024 annual meeting of stockholders. These options are scheduled to vest one-third on the first anniversary of the grant date and in 24 equal monthly installments thereafter, subject to continuous employment with the Company through each vesting date.

Employment Agreements

James V. Caruso. We entered into an employment agreement with Mr. Caruso as of June 15, 2015, as amended and restated on April 15, 2019, and amended on March 12, 2025, pursuant to which Mr. Caruso serves as President and Chief Executive Officer of the Company. Under the agreement, the Company pays Mr. Caruso a base salary that is adjusted from time to time. Mr. Caruso is also eligible for an annual bonus, based on performance, with an initial target of up to 55% of his base salary at the discretion of the Compensation Committee. If Mr. Caruso is terminated other than for cause or by Mr. Caruso for good reason within 12 months after a change in control (i.e. double trigger), he is entitled to severance in an amount equal to (i) 24 months of base salary, (ii) his then applicable target bonus payable over 24 months (a total of 2.0x the annual target bonus payable at the time of termination) and (iii) 24 months of payment or reimbursement of health insurance (equal to the premium paid by the Company prior to the date of termination), each payable in installments over 24 months. Following a termination of employment by the Company without cause or by Mr. Caruso for good reason that is not within 12 months after a change in control, Mr. Caruso is entitled to severance in an amount equal to 12 months base salary plus payment or reimbursement of health insurance for 12 months (equal to the premium paid by the Company prior to the date of termination). Each of the foregoing severance benefits is conditioned on Mr. Caruso's execution of a release agreement in favor of the Company.

Jarrod Longcor. We entered into an employment agreement with Mr. Longcor as of July 15, 2016, as amended and restated on April 15, 2019, and amended on November 10, 2019, and March 12, 2025. Under the agreement, Mr. Longcor receives a base salary that may be adjusted from time to time. Mr. Longcor is eligible for an annual bonus, based on performance, with an initial target of up to 40% of his base salary. If Mr. Longcor's employment is terminated other than for cause or by Mr. Longcor for good reason, contingent upon the execution of a release agreement in favor of the Company, Mr. Longcor is entitled to (i) severance in an amount equal to nine months of Mr. Longcor's annual base salary, provided that if such termination occurs within 12 months after a change in control (i.e. double trigger), such severance is increased to 18 months of Mr. Longcor's full base salary, each payable in monthly installments, (ii) payment or reimbursement of health insurance (for nine or 18 months, as applicable), each payable in monthly installments, (iii) a payment amount equal to the annual bonus Mr. Longcor would have received for the calendar year in which the termination occurred prorated for the number of days elapsed in such year, and (iv) outplacement services not to exceed $7,500.

Chad J. Kolean. We entered into an employment agreement with Mr. Kolean as of February 22, 2022. Pursuant to his employment agreement, Mr. Kolean receives a base salary that may be adjusted from time to time and is eligible to receive an annual performance bonus with a target amount equal to 40% of his base salary. In the event of a dismissal without cause or resignation by Mr. Kolean for good reason, contingent upon the execution of a release agreement in favor of the Company, Mr. Kolean is entitled to (i) severance in an amount equal to nine months of Mr. Kolean's annual base salary, provided that if such termination occurs within 12 months after a change in control (i.e. double trigger), such severance is increased to 18 months of Mr. Kolean's full base salary, each payable in monthly installments, (ii) payment or reimbursement of health insurance (for nine or 18 months, as applicable), each payable in monthly installments, and (iii) outplacement services not to exceed $7,500.

2025 Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information with respect to outstanding equity awards as of December 31, 2025, with respect to our NEOs, and reflects the reverse stock split of our common stock that occurred on June 24, 2025.

		Option Awards				Stock Awards	
Name	Date of Award	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option Exercise Price ($/share)	Option Expiration date	Number of Shares or Units of Stock that Have Not Vested (#)	Market Value of Shares or Units of Stock that Have Not Vested ($)
James V. Caruso	2/14/2025(1)	—	30,000	$ 8.70	2/14/2035	—	—
	11/30/2023(1)	20,000	10,000	$ 79.50	11/30/2033	—	—
	1/17/2023(1)	16,916	484	$ 50.40	1/17/2033	—	—
	1/25/2022	4,730	—	$ 165.00	1/25/2032	—	—
	3/4/2021	5,333	—	$ 522.00	3/4/2031	—	—
	2/3/2020	333	—	$ 813.00	2/3/2030	—	—
	1/17/2019	250	—	$ 597.00	1/17/2029	—	—
	10/12/2018	499	—	$ 783.00	10/12/2028	—	—
	5/12/2016	66	—	$ 4,440.00	5/12/2026	—	—
Jarrod Longcor	2/14/2025(1)	—	16,666	$ 8.70	6/15/2025	—	—
	11/30/2023(1)	11,110	5,556	$ 79.50	11/30/2033	—	—
	1/17/2023(1)	9,332	268	$ 50.40	1/17/2033	—	—
	1/25/2022	1,583	—	$ 165.00	1/25/2032	—	—
	3/4/2021	1,500	—	$ 522.00	3/4/2031	—	—
	2/3/2020	133	—	$ 813.00	2/3/2030	—	—
	1/17/2019	100	—	$ 597.00	1/17/2029	—	—
	10/12/2018	209	—	$ 783.00	10/12/2028	—	—
	9/18/2017	8	—	$ 5,490.00	9/18/2027	—	—
	7/15/2016	25	—	$ 8,790.00	7/15/2026	—	—
Chad J. Kolean	2/14/2025(1)	—	9,666	$ 8.70	2/14/2035	—	—
	11/30/2023(1)	6,444	3,222	$ 79.50	11/30/2033	—	—
	1/17/2023(1)	6,738	194	$ 50.40	1/17/2033	—	—
	2/22/2022	500	—	$ 147.00	2/21/2032	—	—

(1) These options are scheduled to vest one-third on the first anniversary of the grant date and in 24 equal monthly installments thereafter, subject to continuous employment with the Company through each vesting date.

Pursuant to the terms of the option award agreements, options granted pursuant to the 2021 Stock Incentive Plan become fully vested upon a termination event within one year following a change in control, as defined in such plan. A termination event is defined as either termination of employment other than for cause or constructive termination resulting from a significant reduction in either the nature or scope of duties and responsibilities, a reduction in compensation or a required relocation.

Risks Related to Compensation Policies and Practices

When determining our compensation policies and practices, the Compensation Committee considers various matters relevant to the development of a reasonable and prudent compensation program, including whether the policies and practices are reasonably likely to have a material adverse effect on us. We believe that the mix and design of our executive compensation plans and policies do not encourage management to assume excessive risks and are not reasonably likely to have a material adverse effect on us.

2025 Director Compensation

The following table sets forth certain information about the compensation of our non-employee directors who served during the year ended December 31, 2025:

Name	Year	Director Fees ($)[1]	Option Awards ($)[2]	Total ($)
Asher Chanan-Khan, M.B.B.S., M.D.	2025	$ 60,000	$ 14,040	$ 74,040
Frederick W. Driscoll	2025	60,000	14,040	74,040
Stefan D. Loren, Ph.D.	2025	60,000	14,040	74,040
John Neis	2025	60,000	14,040	74,040
Douglas J. Swirsky	2025	90,000	21,060	111,060

(1) Director fees consist of annual cash fees for service.

(2) Granted on February 14, 2025. These stock options have an exercise price of $8.70 per share and fully vested on the first anniversary of the grant date, subject to continued service through applicable vesting date. The reported amounts represent the aggregate grant date fair value computed in accordance with ASC 718. All assumptions made regarding the valuation of equity awards can be referenced in Note 7 in the Notes to Restated Consolidated Financial Statements included in this Annual Report on Form 10-K.

During 2025, we paid each of our non-employee directors a quarterly cash fee of $15,000 ($22,500 for Mr. Swirsky). In addition, in February 2025, we granted to each non-employee director stock options to purchase 2,000 shares (3,000 shares for Mr. Swirsky) (in each case, adjusted to reflect the reverse stock split of our common stock that occurred on June 24, 2025). Mr. Swirsky receives additional cash remuneration and option awards for his service as Chairman of the Board. We reimbursed directors for reasonable out-of-pocket expenses incurred in attending Board and committee meetings and undertaking certain matters on our behalf. Directors who are our employees do not receive additional fees for their service as directors.

The aggregate number of option awards outstanding as of December 31, 2025, for each non-employee director was as follows:

Name	Stock Options Outstanding
Asher Chanan-Khan, M.B.B.S., M.D.	5,353
Frederick W. Driscoll	5,585
Stefan D. Loren, Ph.D.	5,592
John Neis	5,592
Douglas J. Swirsky	8,395

Clawback Policy

Under the Sarbanes-Oxley Act, in the event of misconduct that results in a financial restatement that would have reduced a previously paid incentive amount, we can recoup those improper payments from our executive officers. We have adopted our Policy on Recoupment of Incentive Compensation (the "Clawback Policy") in order to comply with the final clawback rules adopted by the SEC under the Rule, and the listing standards, as set forth in the Nasdaq Listing Rule 5608 (the "Final Clawback Rules").

The Clawback Policy provides for the mandatory recovery of erroneously awarded incentive-based compensation from our current and former executive officers as defined in the Final Clawback Rule ("Covered Officers") in the event that we are required to prepare an accounting restatement, in accordance with the Final Clawback Rules. The recovery of such compensation applies regardless of whether a Covered Officer engaged in misconduct or otherwise caused or contributed to the requirement of an accounting restatement. Under the Clawback Policy, our Board may recoup from the Covered Officers erroneously awarded incentive compensation received within a lookback period of the three completed fiscal years preceding the date on which we are required to prepare an accounting restatement. The foregoing description of the Clawback Policy does not purport to be complete and is qualified in its entirety by the terms and conditions of the Clawback Policy, a copy of which is attached hereto as Exhibit 97 and is incorporated herein by reference.

Timing of Grants of Options

We do not grant option awards in anticipation of the release of material nonpublic information and we do not time the release of material nonpublic information based on option award grant dates or for the purpose of affecting the value of executive compensation. In addition, we do not take material nonpublic information into account when determining the timing and terms of such awards. In fiscal year 2025, we did not grant option awards to our named executive officers during the time period outlined in Item 402(x) of Regulation S-K

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

The information required by this item with respect to the security ownership of certain beneficial owners and the security ownership of management is incorporated herein by reference to our definitive proxy statement for our 2026 Annual Meeting of Stockholders under the caption "Security Ownership of Certain Beneficial Owners and Management."

Equity compensation plans

The following table provides information as of December 31, 2025, regarding shares authorized for issuance under our equity compensation plans, including individual compensation arrangements.

Equity compensation plan information

Plan category	Number of shares to be issued upon exercise of outstanding options and rights (#) (a)	Weighted-average exercise price of outstanding options and rights ($) (b)	Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a)) (#) (c)
Equity compensation plans approved by stockholders	211,642	$ 79.28	100,651
Equity compensation plans not approved by stockholders	525	$ 558.57	n/a
Total	212,167	$ 80.47	100,651

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item with respect to certain relationships and related transactions is incorporated herein by reference to our definitive proxy statement for our 2026 Annual Meeting of Stockholders under the caption "Certain Relationships and Related-Person Transactions." The information required by this item with respect to director independence is incorporated herein by reference to our definitive proxy statement for our 2026 Annual Meeting of Stockholders under the caption "Corporate Governance — Director Independence."

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated herein by reference to our definitive proxy statement for our 2026 Annual Meeting of Stockholders under the captions "Ratification of Appointment of our Independent Registered Public Accounting Firm" and "Audit Committee Matters — Audit and Other Fees."

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

(1) Financial Statements

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

(2) Exhibits – The exhibits to this annual report on Form 10-K are listed on the Exhibit Index below.

Exhibit Index

Exhibit No.	Description	Incorporated by Reference		
		Form	Filing Date	Exhibit No.
2.1	Agreement and Plan of Merger by and among Novelos Therapeutics, Inc., Cell Acquisition Corp. and Cellectar, Inc. dated April 8, 2011	8-K	April 11, 2011	2.1
3.1	Second Amended and Restated Certificate of Incorporation	8-K	April 11, 2011	3.1
3.2	Certificate of Ownership and Merger of Cellectar Biosciences, Inc. with and into Novelos Therapeutics, Inc.	8-K	February 13, 2014	3.1
3.3	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	June 13, 2014	3.1
3.4	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	June 19, 2015	3.2
3.5	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	March 4, 2016	3.1
3.6	Certificate of Amendment of Second Amended and Restated Certificate of Incorporation	8-K	June 1, 2017	3.2
3.7	Certificate of Amendment of Second Amended and Restated Certificate of Incorporation	8-K	July 13, 2018	3.1
3.8	Certificate of Amendment of Second Amended and Restated Certificate of Incorporation	8-K	February 25, 2021	3.1
3.9	Certificate of Correction of Certificate of Amendment of Second Amended and Restated Certificate of Incorporation	10-Q	May 10, 2022	3.1
3.10	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	July 21, 2022	3.1
3.11	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	October 27, 2023	3.1
3.12	Amended and Restated By-laws	8-K	December 2, 2022	3.1
3.13	Certificate of Designation of Preferences, Rights and Limitations of the Series D Convertible Preferred Stock	8-K	December 28, 2020	3.1
3.14	Certificate of Elimination of the Series A Convertible Preferred Stock, the Series B Convertible Preferred Stock and the Series C Convertible Preferred Stock	8-K	September 8, 2023	3.1
3.15	Amendment No. 1 to Certificate of Designation of the Series D Preferred Stock	8-K	September 8, 2023	3.2
3.16	Certificate of Designation of Preferences, Rights and Limitations of the Series E Convertible Voting Preferred Stock	8-K	September 8, 2023	3.3
3.17	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	June 25, 2025	3.1
4.1	Form of common stock certificate	S-1/A	November 9, 2011	4.1
4.2	Form of Series D Preferred Stock certificate	8-K	December 28, 2020	4.1
4.3	Form of Tranche A Warrant	8-K	September 8, 2023	4.1
4.4	Form of Tranche B Warrant	8-K	September 8, 2023	4.2

4.5	Form of Common Stock Purchase Warrant A	8-K	July 22, 2024	4.1
4.6	Form of Common Stock Purchase Warrant B	8-K	July 22, 2024	4.2
4.7	Form of Common Stock Purchase Warrant C	8-K	July 22, 2024	4.3
4.8	Description of Securities Registered under Section 12(b) of the Securities Exchange Act of 1934	10-K/A	April 1, 2024	4.3
4.9	Form of Common Warrant	S-1/A	June 30, 2025	4.2
4.10	Form of Pre-Funded Warrant	S-1/A	June 30, 2025	4.3
4.11	Representative Warrant	S-1/A	June 30, 2025	4.4
4.12	Form of Series I Warrant	8-K	October 10, 2025	4.1
4.13	Form of Series II Warrant	8-K	October 10, 2025	4.2
10.1	Form of Restricted Common Stock Agreement**	10-Q	August 14, 2017	10.1
10.2	Form of Series D Common Stock Purchase Warrant	8-K	October 11, 2017	4.1
10.3	Registration Rights Agreement, dated as of October 10, 2017, by and among Cellectar Biosciences, Inc. and the Purchasers	8-K	October 11, 2017	10.2
10.4	Form of Non-Statutory Stock Option**	S-8	November 9, 2017	10.2
10.5	Stock Option Agreement with James V. Caruso**	S-8	November 9, 2017	10.4
10.6	Stock Option Agreement with Jarrod Longcor**	S-8	November 9, 2017	10.5
10.7	Series E Common Stock Purchase Warrant	S-1/A	July 18, 2018	4.5
10.8	Form of Warrant Agency Agreement	S-1/A	July 18, 2018	4.7
10.9	Agreement of Lease between the Company and KBS II 100-200 Campus Drive, LLC	S-1/A	July 18, 2018	10.35
10.10	Form of Non-Statutory Stock Option (Definitive/Contingent – Employees)**	10-Q	November 13, 2018	10.3
10.11	Form of Non-Statutory Stock Option (Definitive/Contingent – Directors)**	10-Q	November 13, 2018	10.4
10.12	Amended and Restated Employment Agreement between the Company and James Caruso, dated April 15, 2019**	8-K	April 19, 2019	10.1
10.13	Amended and Restated Employment Agreement between the Company and Jarrod Longcor, dated April 15, 2019**	8-K	April 19, 2019	10.2
10.14	Form of Series F Common Stock Purchase Warrant	8-K	May 20, 2019	4.1
10.15	Form of Series G Common Stock Purchase Warrant	8-K	May 20, 2019	4.2
10.16	Registration Rights Agreement, dated as of May 16, 2019, by and among Cellectar Biosciences, Inc. and the Purchasers	8-K	May 20, 2019	10.3
10.17	Cellectar Biosciences, Inc. Amended and Restated 2015 Stock Incentive Plan**	8-K	June 14, 2019	10.1
10.18	2021 Stock Incentive Plan**	8-K	June 24, 2021	10.1
10.19	Amendment 1 to the 2021 Stock Incentive Plan**	8-K	June 27, 2022	10.1
10.20	2021 Stock Incentive Plan, as Amended**	8-K	June 29, 2023	10.1
10.21	2021 Stock Incentive Plan, as Amended**	8-K	June 14, 2024	10.1
10.22	Amendment to Amended and Restated Employment Agreement between the Company and Jarrod Longcor dated November 10, 2019**	10-Q	November 12, 2019	10.2
10.23	Form of Underwriting Agreement	S-1/A	May 20, 2020	1.1
10.24	Form of Series H Warrant	S-1/A	May 20, 2020	4.3
10.25	Form of Warrant Agency Agreement	8-K	June 5, 2020	4.3
10.26	Equity Distribution Agreement between Cellectar Biosciences, Inc. and Oppenheimer & Co. Inc., dated August 11, 2020	8-K	August 11, 2020	10.1
10.27	Form of Securities Purchase Agreement	8-K	December 28, 2020	10.1
10.28	Form of Registration Rights Agreement	8-K	December 28, 2020	10.2
10.29	Employment Agreement between the Company and Chad Kolean dated February 23, 2022	8-K	February 25, 2022	10.1
10.30	Form of First Amendment of Lease, dated December 30, 2022	8-K	January 4, 2023	
10.31	Form of Common Warrant	8-K	October 25, 2022	4.1

10.32	Form of Pre-Funded Warrant	8-K	October 25, 2022	4.2
10.33	Form of Registration Rights Agreement, dated as of October 20, 2022, by and between the Company and the purchasers named therein	8-K	October 25, 2022	10.3
10.34	Form of Indemnification Agreement	8-K	December 2, 2022	10.1
10.35	Inducement Letter in consideration for Exercise of the Tranche B warrants	8-K	July 22, 2024	10.1
10.36	Form of Indenture	S-3	May 24, 2024	4.7
16.1	Letter Regarding Change in Certifying Accountant	8-K	July 11, 2024	16.1
19.1	Insider Trading Policy	10-K	March 13, 2025	19.1
21.1	List of Subsidiaries	10-K	March 13, 2025	21.1
23.1*	Consent of Independent Registered Public Accounting Firm			
24.1*	Power of Attorney (included on the Signatures page of this Annual Report on Form 10-K)			
31.1*	Certification of chief executive officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
31.2*	Certification of chief financial officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
32.1*	Certification of chief executive officer and chief financial officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
97	Clawback Policy	10-K/A	April 1, 2024	97
101*	Interactive Data Files (formatted in Inline XBRL)			
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)			

* Filed herewith.
** Management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

CELLECTAR BIOSCIENCES, INC.

By: /s/ *James V. Caruso*
James V. Caruso
Title: Chief Executive Officer
March 4, 2026

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

POWER OF ATTORNEY

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

By: /s/ *James V. Caruso*
James V. Caruso
Title: Chief Executive Officer and Director (Principal Executive Officer)
March 4, 2026

By: /s/ *Chad J. Kolean*
Chad J. Kolean
Title: Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
March 4, 2026

By: /s/ *Frederick W. Driscoll*
Frederick W. Driscoll
Title: Director
March 4, 2026

By: /s/ *Asher Alban Chanan-Khan*
Asher Alban Chanan-Khan
Title: Director
March 4, 2026

By: /s/ *Stefan D. Loren*
Stefan D. Loren
Title: Director
March 4, 2026

By: /s/ *John L. Neis*
John L. Neis
Title: Director
March 4, 2026

By: /s/ *Douglas J. Swirsky*
Douglas J. Swirsky
Title: Director
March 4, 2026

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-208638, 333-214198, 333-214310, 333-221468, 333-225675, 333-231888, 333-238132, 333-268554, 333-284580, 333-288333 and 333-290971 on Form S-1, Registration Statement Nos. 333-226374 and 333-238892 on Form S-1 MEF, Registration Statement Nos. File Nos. 333-208189, 333-252309, 333-274880 and 333-279731 on Form S-3, and Registration Statement Nos. 333-164398, 333-195255, 333-221469, 333-233460, and 333-266594 on Form S-8 of our report dated March 4, 2026, relating to the financial statements of Cellectar Biosciences, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Deloitte & Touche LLP

Morristown, New Jersey
March 4, 2026

EXHIBIT 31.1

I, JAMES V. CARUSO, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cellectar Biosciences, Inc., a Delaware Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 4, 2026

/s/ James V. Caruso
James V. Caruso
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

I, CHAD J. KOLEAN, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cellectar Biosciences, Inc., a Delaware Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 4, 2026

/s/ Chad J. Kolean
Chad J. Kolean
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. § 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Cellectar Biosciences, Inc. (the "Company") for the quarter ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, James V. Caruso, President and Chief Executive Officer of the Company, and Chad J. Kolean, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to our knowledge, that:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James V. Caruso
James V. Caruso
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 4, 2026

/s/ Chad J. Kolean
Chad J. Kolean
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 4, 2026