Filed Pursuant to Rule 424(b)(3)
Registration No. 333-290971

PROSPECTUS

Up to 2,096,188 Shares of Common Stock Offered by the Selling Stockholders

CELLECTAR BIOSCIENCES, INC.

Common Stock

This prospectus relates to the resale, from time to time by the selling stockholders named in this prospectus (the "selling stockholders"), of up to 2,096,188 shares of our common stock (the "Shares") issuable upon exercise of common stock purchase warrants (the "Inducement Warrants") issued to the selling stockholders in a warrant inducement transaction (the "Warrant Inducement") which closed on October 8, 2025. For additional information about the transaction, see "Summary-Description of the Warrant Inducement."

Our registration of the shares of common stock covered by this prospectus does not mean that the selling stockholders will offer or sell any such shares. We are registering the offer and resale of the Shares to fulfill our contractual obligations set forth in the Inducement Letters (as defined below) entered into on October 7, 2025.

We will not receive any of the proceeds from the sale of our Shares by the selling stockholders, although we will receive proceeds from the cash exercise of any Inducement Warrants.

Any shares of our common stock subject to resale hereunder will have been issued by us and received by the selling stockholders prior to any resale of such shares pursuant to this prospectus.

The selling stockholders, or their donees, pledgees, transferees or other successors-in-interest may offer or resell the Shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. The selling stockholders will bear all commissions and discounts and similar selling expenses, if any, attributable to the sale of Shares. We will bear all costs, expenses and fees (other than commissions and discounts and similar selling expenses) in connection with the registration of the Shares. For additional information on the methods of sale that may be used by the selling stockholders, see "Plan of Distribution" beginning on page 42 of this prospectus.

Our common stock is listed on the Nasdaq Capital Market under the symbol "CLRB." On November 20, 2025, the last reported sale price of our common stock was $2.86.

Investing in our securities involves significant risks. We strongly recommend that you read carefully the risks we describe in "Risk Factors" beginning on page 9 of this prospectus and in any accompanying prospectus supplement, as well as the risk factors that are incorporated by reference into this prospectus from our filings made with the Securities and Exchange Commission, before investing in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is November 21, 2025.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this prospectus and any applicable prospectus supplement. We have not, and the selling stockholders have not, authorized any other person to provide you with different or additional information. If anyone provides you with different or additional information, you should not rely on it. This prospectus is not an offer to sell, nor are the selling stockholders seeking an offer to buy, the shares offered by this prospectus in any jurisdiction where the offer and sale is not permitted. No offers or sales of any of the shares of our common stock are to be made in any jurisdiction in which such an offer or sale is not permitted. You should assume that the information contained in this prospectus or any applicable prospectus supplement is accurate only as of the date on the front cover thereof or the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any applicable prospectus supplement or any sales of the shares of our common stock offered hereby or thereby.

You should read the entire prospectus and any prospectus supplement and any related issuer free writing prospectus, as well as the documents incorporated by reference into this prospectus or any prospectus supplement or any related issuer free writing prospectus, before making an investment decision. Neither the delivery of this prospectus or any prospectus supplement or any issuer free writing prospectus nor any sale made hereunder shall under any circumstances imply that the information contained or incorporated by reference herein or in any prospectus supplement or issuer free writing prospectus, as applicable. You should assume that the information appearing in this prospectus, any prospectus supplement or any document incorporated by reference herein or therein is accurate only as of the date of the applicable documents, regardless of the time of delivery of this prospectus or any sale of securities. Our business, financial condition, results of operation and prospects may have changed since that date.

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

SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you need to consider in making your investment decision. You should carefully read the entire prospectus, any applicable prospectus supplement and any related free writing prospectus, including the risks of investing in our securities discussed under the heading "Risk Factors" contained in this prospectus, any applicable prospectus supplement and any related free writing prospectus.

Company Overview

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

Corporate Information

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

Description of the Warrant Inducement

On October 7, 2025, we entered into warrant exercise inducement offer letters (the "Inducement Letters") with certain holders (each a "Holder") of certain existing warrants (the "Existing Warrants"), which were originally issued on October 25, 2022, July 21, 2024, and July 2, 2025, pursuant to which the Holders agreed to exercise for cash their Existing Warrants to purchase 1,048,094 shares of our common stock, at an exercise price of $5.25 per share, and pay $0.125 per new warrant, in exchange for our agreement to issue the Inducement Warrants. The transactions contemplated by the Inducement Letters closed on October 8, 2025, and we received aggregate gross proceeds of approximately $5.8 million from the exercise of the Existing Warrants by the Holders and the sale of the Inducement Warrants.

The Company also agreed to file a registration statement covering the resale of the Shares (the "Resale Registration Statement"). The registration statement of which this prospectus is a part is being filed pursuant to the Company's contractual obligation under the Inducement Letters.

Terms of the Inducement Warrants

We issued the Inducement Warrants in two different series: the Series I Inducement Warrants and the Series II Inducement Warrants.

The Series I Inducement Warrants are immediately exercisable at an exercise price of $6.00 per share and will expire on October 8, 2030. The Series I Inducement Warrants are exercisable for up to 1,048,094 shares of our common stock, subject to adjustments as described below.

The Series II Inducement Warrants are immediately exercisable at an exercise price of $6.00 per share and will expire on April 8, 2027. The Series II Inducement Warrants are exercisable for up to 1,048,094 shares of our common stock, subject to adjustments as described below.

The exercise price and number of shares of common stock issuable upon exercise of the Inducement Warrants is subject to adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

Recent Developments

October 2025 Warrant Inducement

On October 7, 2025, the Company, entered into definitive agreements for investors to immediately exercise certain outstanding warrants to purchase an aggregate of 1,048,094 shares of common stock, issued by the company on October 25, 2022, July 21, 2024 and July 2, 2025 (the October Existing Warrants), at an exercise price of $5.25 per share. The shares of common stock issuable upon exercise of the October Existing Warrants are all registered, or their resale is registered, pursuant to effective registration statements. Other than the shares of common stock issued upon exercise of the Existing Warrants issued on July 2, 2025, the issuance of which was registered under an effective registration statement, the shares of common stock issued upon exercise of the October Existing Warrants were offered pursuant to the exemption from the registration requirements of the Securities Act available under Section 4(a)(2) of the Securities Act. In connection with the exercise of the October Existing Warrants, the Company issued new warrants (the 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 per Inducement Warrant. The Company issued the Inducement Warrants pursuant to the exemption from the registration requirements of the Securities Act available under Section 4(a)(2) of the Securities Act and intends to issue the shares underlying the Inducement Warrants pursuant to the same exemption or pursuant to the exemption provided by Section 3(a)(9) of the Securities Act. The Company agreed to file a registration statement on Form S-1 covering the resale of such shares within 15 calendar days of the date of closing of the transaction. The gross proceeds to the Company from the exercise of the October Existing Warrants and the issuance of the Inducement Warrants was approximately $5.8 million, prior to deducting placement agent fees and offering expenses.

Regulatory Pathway - EMA

On October 6, 2025, the Company announced that after a scientific advice procedure, SAWP advised that filing for a CMA for iopofosine I 131 as a treatment for post- BTKi refractory patients with WM could be acceptable for a CMA. While there is no guarantee of CMA approval, if iopofosine I 131 is granted CMA, it could potentially begin to be commercially available in the 30 countries represented by the EMA as early as 2027.

The Company's decision to file for CMA in Europe follows SAWP's advice on the patient population for which iopofosine I 131 is acceptable for a CMA, particularly a discussion on a post BTKi patient population, consistent with the majority of the patients (>70%) enrolled in the CLOVER WaM Phase 2 study. The Company's briefing document to the SAWP included iopofosine I 131's safety database, CLOVER WaM clinical study results, subset analyses, and manufacturing information. It is not within the remit of the SAWP to determine whether the data shows the sufficiency of safety and efficacy for a CMA; however, the SAWP advised that iopofosine I 131 met the eligibility requirements for a CMA submission for the proposed patient population. As in the U.S., there remains a significant unmet medical need for the treatment of WM in Europe, where the condition affects an estimated 35,000 to 45,000 patients.

July Public Offering

On July 2, 2025, we closed our 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 included 180,000 class A units issued pursuant to Ladenburg Thalmann & Co. Inc.'s, the sole bookrunner, 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, 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 and (b) one common warrant. The price per class A unit was $5.00 and the price per class B unit was $4.99999 (collectively, the July 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.

In connection with the July Offering, we agreed to issue representative warrants to the underwriter, or its designees, which entitled it to purchase up to 82,800 shares of common stock. The representative warrants have an exercise price equal to $7.75 per share of common stock.

The securities described in the July Offering were sold pursuant to a registration statement on Form S-1 (File No. 333-288333), which was declared effective by the SEC on July 1, 2025.

June 2025 Warrant Inducement

On June 5, 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 June Existing Warrants), at a reduced exercise price of $9.123 per share. The shares of common stock issuable upon exercise of the June Existing Warrants are all registered, or their resale is registered, pursuant to effective registration statements. Other than the shares of common stock issued upon exercise of the June Existing Warrants issued on June 5, 2020, the issuance of which was registered under an effective registration statement, the shares of common stock issued upon exercise of the June Existing Warrants were offered pursuant to the exemption from the registration requirements of the Securities Act available under Section 4(a)(2) of the Securities Act. The Company did not issue any new warrants as part of the agreements. The gross proceeds to the company from the exercise of the June Existing Warrants was approximately $2.5 million, prior to deducting placement agent fees and offering expenses.

Breakthrough Designation

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

Regulatory Pathway - FDA

We plan to submit an NDA to the FDA for accelerated approval of iopofosine I 131 as a treatment for WM subject to sufficient funding and once a confirmatory trial is underway. The submission would be supported by data from the Phase 2b CLOVER WaM clinical trial demonstrating a statistically significant major response rate compared to a null hypothesis of 20% and meaningful duration of response. The data set now includes the FDA-requested 12-month follow-up results on all patients from the trial and new subset analysis of data from patients immediately following Bruton Tyrosine Kinase inhibitor (BTKi) treatment failures regardless of line of therapy.

SELECTED FINANCIAL DATA

Reverse Stock Split

As previously disclosed, on June 24, 2025 we effected a reverse stock split of our outstanding shares of common stock at a ratio of one-for-thirty (the Reverse Stock Split).

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

	Twelve Months Ended December 31,		Three Months Ended March 31,
	2024	2023	2025
Weighted-average common shares outstanding, basic - previously reported	36,622,474	12,221,571	46,079,875
Weighted-average common shares outstanding, diluted - previously reported	37,143,769	12,221,571	46,079,875
Weighted-average common shares outstanding, basic - post-Reverse Split	1,220,749	407,386	1,535,996
Weighted-average common shares outstanding, diluted - post-Reverse Split	1,238,126	407,386	1,535,996
Net loss per share, basic - previously reported	$ (1.22)	$ (3.50)	$ (0.14)
Net loss per share, diluted - previously reported	$ (1.40)	$ (3.50)	$ (0.14)
Net loss per share, basic - post-Reverse Split	$ (36.52)	$ (104.99)	$ (4.20)
Net loss per share, diluted - post-Reverse Split	$ (41.89)	$ (104.99)	$ (4.20)

	As of Dec 31, 2024	As of Dec 31, 2023
Common stock - previously reported	$ 461	$ 207
Additional paid-in capital - previously reported	$ 261,115,905	$ 182,924,210
Common stock issued and outstanding - previously reported	46,079,875	20,744,110
Common stock - post-Reverse Split	$ 15	$ 7
Additional paid-in capital - post-Reverse Split	$ 261,116,351	$ 182,924,410
Common stock issued and outstanding - post-Reverse Split	1,535,996	691,470

THE OFFERING

Shares of common stock offered by us	None
Shares of common stock offered by the selling stockholders (assuming full exercise of Inducement Warrants and excluding any other anti-dilution or similar adjustments)	2,096,188 Shares
Shares of common stock outstanding after completion of this offering (assuming full exercise of Inducement Warrants and excluding any other anti-dilution or similar adjustments)	6,336,322 Shares
Selling stockholders	All of the shares of our common stock are being offered by the selling stockholders. See "Selling Stockholders" beginning on page 36 for additional information on the selling stockholders.
Use of Proceeds	We will not receive any proceeds from the resale of the shares of common stock by the selling stockholders. See "Use of Proceeds" beginning on page 35 for additional information on the use of proceeds.
Risk Factors	See "Risk Factors" on page 9 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding whether to purchase our securities.
Nasdaq symbol for common stock	"CLRB"

The number of shares of our common stock outstanding before and after this offering is based on 1,812,040 shares of common stock outstanding as of June 30, 2025, which is adjusted to 4,240,134 to give effect to 1,045,000 shares that were issued pursuant to the July Offering, 335,000 pre-funded warrants issued pursuant to the July Offering that have been exercised, and 1,048,094 shares that were issued pursuant to the exercise of the October Existing Warrants, and which excludes:

- any shares of common stock issuable upon the exercise of the underwriter's over-allotment option;
- any shares of common stock issuable upon the exercise of Pre-Funded Warrants issued in this offering;
- any shares of common stock issuable upon the exercise of Common Warrants issued in this offering;
- any shares of common stock issuable upon the exercise of the representative warrants issued as compensation to the underwriter in this offering;
- an aggregate of 211,816 shares of common stock issuable upon the exercise of outstanding stock options issued to employees, directors and consultants;
- an aggregate of 13,040 shares of common stock issuable upon the conversion of outstanding shares of Series E-2 preferred stock;
- an aggregate of 3,704 shares of common stock issuable upon the conversion of outstanding shares of Series D preferred stock;
- an aggregate of 417,904 additional shares of common stock reserved for issuance under outstanding warrants having expiration dates between October 2027 and July 2029, and exercise prices ranging from $58.80 to $165.00 per share;

- an aggregate of 436,000 shares of common stock issuable upon the exercise of common warrants issued in the July Offering; and

- an aggregate of 82,800 shares of common stock issuable upon the exercise of the representative warrants issued as compensation to the underwriter in the July Offering.

- an aggregate of 2,096,188 shares of common stock issuable upon the exercise of common warrants issued in the October Offering.

Summary Risk Factors

An investment in our common stock involves substantial risk. The occurrence of one or more of the events or circumstances described in the section entitled "Risk Factors," alone or in combination with other events or circumstances, may have a material adverse effect on our business, cash flows, financial condition and results of operations. Important factors and risks that could cause actual results to differ materially from those in the forward-looking statements include, among others, the following:

Risks Related to Capital and Our Operations

- Our regulatory strategy may not result in the approval of iopofosine I 131 by the FDA, the European Commission (based on recommendation from the EMA) or any other regulatory authority. Regulatory authorities have substantial discretion in the approval process and may find that iopofosine I 131 does not meet approval requirements. In addition, we may not be able to raise additional funds required to execute our regulatory strategy.

- Although we have obtained feedback from the EMA through their scientific advice procedure, this feedback does not guarantee any particular outcome with respect to regulatory approval of iopofosine I 131.

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

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

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

Risks Related to Manufacturing and Supply

- We rely on a collaborative outsourced business model, and disruptions with our third-party collaborators may impede our ability to gain 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.

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.

- 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.

Risks Related to Legal Compliance and Litigation

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

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

Risks Related to Intellectual Property

- We expect to rely on our patents as well as specialized regulatory designations such as orphan drug classification for our product candidates, but regulatory drug designations may not confer marketing exclusivity or other expected commercial benefits.

- If we are unable to adequately protect or enforce our rights to intellectual property or to secure rights to third-party patents, we may lose valuable rights, experience reduced market share, assuming any, or incur costly litigation to protect our intellectual property rights.

Risks Related to Our Employees

- We rely on a small number of key personnel who may terminate their employment with us at any time, and our success will depend on our ability to hire additional qualified personnel.

- Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Risks Related to Commercialization of our Products

- Acceptance of our products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues.

- Regulatory approval for any approved product is limited by the FDA, the European Commission (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.

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

Risks Related to Internal Controls

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

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

RISK FACTORS

An investment in our securities involves a high degree of risk. Prior to making a decision about investing in our securities, prospective investors should consider carefully all of the information included in this prospectus, including the risk factors set forth herein, as updated by annual, quarterly and other reports and documents we file with the SEC after the date of this prospectus and that are incorporated by reference herein. Each of these risk factors could have a material adverse effect on our business, results of operations, financial position or cash flows, which may result in the loss of all or part of your investment.

Risks Related to Capital and Our Operations

Our regulatory strategy may not result in the approval of iopofosine I 131 by the FDA, the European Commission (based on recommendation from the EMA) or any other regulatory authority. Regulatory authorities have substantial discretion in the approval process and may find that iopofosine I 131 does not meet approval requirements. In addition, we may not be able to raise additional funds required to execute our regulatory strategy.

We plan to submit an NDA to the FDA for accelerated approval of iopofosine I 131 for the treatment of WM patients that have received two prior lines of therapy, including a BTKi. FDA, the European Commission (based on recommendation from the EMA) and other regulatory authorities have substantial discretion in the drug approval process. They may refuse to file, refuse to review, or reject our NDA, or equivalent application, for a variety of reasons. They may determine that the CLOVER WaM trial or our other clinical trials for iopofosine I 131 did not meet safety and efficacy endpoints. They may decide that our data, sample size, trial design and other information are insufficient for approval. They may also disagree with the design of our proposed confirmatory study. They may require additional preclinical, clinical or other studies.

Our existing cash and cash equivalents are not sufficient to execute our regulatory strategy. We view raising additional funds as a precursor to submission of an NDA and initiation of our proposed confirmatory study. Additional funds will also be required to continue our potential EMA review process.

We may not be able to raise additional funds. If we are able to raise additional funds, such funds may not be sufficient to execute our regulatory strategy. Even if we raise funds that we believe are sufficient to execute our regulatory strategy, the FDA, the European Commission (based on recommendation from the EMA) and other regulatory authorities may not approve iopofosine I 131. If we are unable to execute our regulatory strategy, our business, financial position, results of operations, prospects and stock price may be materially adversely affected and we may be required to seek other alternatives which may include, among others, the sale of the Company or its assets, discontinuance of certain operations, a wind-down of operations and/or filing for bankruptcy protection.

Although we have obtained feedback from the EMA through their scientific advice procedure, this feedback does not guarantee any particular outcome with respect to regulatory approval of iopofosine I 131.

Although during the scientific advice procedure SAWP advised that filing a CMA for iopofosine I 131 as a treatment for post-BTKi refractory patients with WM could be acceptable, this feedback is not a guarantee of final CMA approval, and we do not know how the EMA will interpret the data and results from our clinical trials and other elements of our development program. The EMA may raise issues of, for example, safety, efficacy, study conduct, bias, deviation from the protocol, statistical power and analyses, patient demographics, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. There is no guarantee that the EMA will not require that we conduct one or more additional clinical trials or nonclinical studies to support potential CMA approval, or that iopofosine I 131 will receive any regulatory approvals in the EU. Scientific advice is legally non-binding with regard to any future CMA application and it is beyond the remit of the SAWP to determine whether the data shows sufficient safety and efficacy for a CMA. Companies which have been provided with positive scientific advice by SAWP have ultimately failed to obtain approval of a CMA or marketing authorization for their drugs. If we do not obtain approval of a CMA or marketing authorization for iopofosine I 131, our business, financial position, results of operations, prospects and stock price may be materially adversely affected.

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

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

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

We expect that we will continue to generate operating losses for the foreseeable future. As of September 30, 2025, our estimated consolidated cash balance was approximately $12.6 million. We believe our cash balance as of September 30, together with net proceeds from the exercise of the Existing Warrants by the Holders and the sale of the Inducement Warrants of approximately $5.2 million in October 2025, but excluding any proceeds from this offering, will be sufficient to fund the Company's 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 CLR 121225, CLR 121125, iopofosine and other future candidates in our pipeline must undergo extensive clinical trials, which can take many years and require substantial expenditures, subject to extensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. The process of obtaining regulatory approvals in the U.S. and other foreign jurisdictions is expensive, and lengthy, if approval is obtained at all.

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

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

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

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

- the product candidate may not prove to be effective;

- the product candidate may cause harmful side effects;
- the clinical results may not replicate the results of earlier, smaller trials;
- we, or the FDA or similar foreign regulatory authorities, may delay, terminate or suspend the trials;
- our results may not be statistically significant;
- patient recruitment and enrollment may be slower than expected;
- patients may drop out of the trials or otherwise not enroll; and
- regulatory and clinical trial requirements, interpretations or guidance may change.

The FDA has substantial discretion in the approval process and may refuse to approve any NDA or sNDA and decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. Varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of our products for any individual, additional indications.

To be commercially viable, we must successfully research, develop, manufacture, introduce, and obtain the required regulatory approval described above for our product candidates, in order to market and distribute our product candidates. This includes meeting a number of critical developmental milestones, including:

- demonstrating benefit from delivery of each specific drug for specific medical indications;
- demonstrating through preclinical and clinical studies that each drug is safe and effective; and
- demonstrating that we have established viable FDA cGMPs capable of potential scale-up.

The timeframe necessary to achieve these developmental milestones may be long and uncertain, and we may not successfully complete these milestones for any of our intended products in development.

In addition to the risks previously discussed, our technology is subject to developmental risks that include the following:

- uncertainties arising from the rapidly growing scientific aspects of drug therapies and potential treatments;
- uncertainties arising as a result of the broad array of alternative potential treatments related to cancer and other diseases; and
- expense and time associated with the development and regulatory approval of treatments for cancer and other diseases.

In addition, delays or rejections may be encountered based upon additional government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Failure to comply with applicable FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, adverse publicity, as well as other regulatory action against our potential products or us.

To conduct the clinical studies that are necessary to obtain approval by the FDA to market a product, it is necessary to receive clearance from the FDA to conduct such clinical studies. The FDA can halt clinical studies at any time for safety reasons or because we or our clinical investigators do not follow the FDA's requirements for conducting clinical studies. If any of our studies are halted, we will not be able to obtain FDA approval until and unless we can address the FDA's concerns. If we are unable to receive clearance to conduct clinical studies for a product, we will not be able to achieve any revenue from that product in the U.S., as it is illegal to sell any drug for use in humans in the U.S. without FDA approval.

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

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.

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

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

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

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

Iopofosine has received RPDD designation from the FDA for the treatment of neuroblastoma, rhabdomyosarcoma, osteosarcoma and Ewing's sarcoma. The FDA defines a "rare pediatric disease" as a disease that affects fewer than 200,000 individuals in the U.S. primarily under the age of 18 years old, or a patient population greater than 200,000 in the U.S. when there is no reasonable expectation that the cost of developing and making available the drug in the U.S. will be recovered from sales in the U.S. for that drug or biological product. Under the FDA's Rare Pediatric Disease Priority Review Voucher Program, upon the approval of an NDA or a BLA for the treatment of a rare pediatric disease, the sponsor of such application could be eligible for a Rare Pediatric Disease Priority Review Voucher that can be redeemed to obtain priority review for a subsequent NDA or BLA. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application.

The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval. In addition, the priority review voucher is only awarded to an NCE. Thus, if iopofosine is approved first for an indication that is not a rare pediatric disease, our application may not be eligible to receive the voucher. There is no assurance we will receive a Rare Pediatric Disease Priority Review Voucher or that it will result in a faster development process, review or approval for a subsequent marketing application. Also, although Priority Review Vouchers may be sold or transferred to third parties, there is no guaranty that we will be able to realize any value if we were to sell a Priority Review Voucher. In December 2020, the Priority Review Voucher Program was extended by the FDA permitting additional grants through September 2026 for rare pediatric diseases. It is possible that even if we obtain approval for iopofosine and qualify for a priority review voucher, the program may no longer be in effect at the time of such approval.

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

Clinical studies involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

To obtain regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive clinical studies to demonstrate safety and efficacy of these product candidates. Clinical testing is expensive, it can take many years to complete, and its outcome is uncertain. Failure can occur at any time during the clinical study process.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical studies will begin on time, need to be redesigned, or be completed on schedule, if at all. Clinical studies can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, reaching agreement on acceptable clinical study terms with prospective sites, obtaining institutional review board approval to conduct a study at a prospective site, recruiting patients to participate in a study, or obtaining sufficient supplies of clinical study materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, competing clinical studies, and new drugs approved for the conditions we are investigating. Prescribing physicians will also have to decide to use our product candidates over existing drugs that have established safety and efficacy profiles or other drugs undergoing development in clinical studies. Any delays in completing our clinical studies will increase our costs, slow down our product development and approval process, and delay our ability to generate revenue.

Additionally, the results of preclinical studies and early clinical studies of our product candidates do not necessarily predict the results of later-stage clinical studies. Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. The data collected from clinical studies of our product candidates may not be sufficient to support the submission of an NDA or to obtain regulatory approval in the U.S. or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or will achieve sales or profits.

Furthermore, we typically rely on third-party clinical investigators to conduct our clinical trials and other third-party organizations to oversee the operations of such trials and to perform data collection and analysis. The clinical investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. Failure of the third-party organizations to meet their obligations could adversely affect clinical development of our products. As a result, we may face additional delaying factors outside our control if these parties do not perform their obligations in a timely fashion. For example, any number of those issues could arise with our clinical trials causing a delay. Delays of this sort could occur for the reasons identified above or other reasons. If we have delays in conducting the clinical trials or obtaining regulatory approvals, our product development costs will increase. For example, we may need to make additional payments to third-party investigators and organizations to retain their services or we may need to pay recruitment incentives. If the delays are significant, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to become profitable will be delayed. Moreover, these third-party investigators and organizations may also have relationships with other commercial entities, some of which may compete with us. If these third-party investigators and organizations assist our competitors at our expense, it could harm our competitive position.

Our clinical studies may not demonstrate sufficient levels of efficacy necessary to obtain the requisite regulatory approvals for our drugs, and our proposed drugs may not be approved for marketing.

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

We may be required to suspend or discontinue clinical studies because of unexpected side effects or other safety risks that could preclude approval of our product candidates.

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

Administering any product candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical studies of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical studies.

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

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

Risks Related to Legal Compliance and Litigation

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

We and our third-party collaborators are subject to federal, state and local laws and regulations governing the storage, use and disposal of hazardous materials and waste products. Current or future regulations may impair our research, development, manufacturing and commercialization efforts. The inability of our third-party collaborators to maintain the required licenses and permits for any reason will negatively impact our manufacturing, and research and development activities. In addition, we may be required to indemnify third-party collaborators against certain liabilities arising out of any failure by them to comply with such regulations and/or laws. If we or our third-party collaborators fail to comply with any of these regulations and/or laws, a range of consequences could result, including the suspension or termination of clinical studies, failure to obtain approval of a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs, or other sanctions or litigation.

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

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. In addition, the use in our clinical studies of pharmaceutical products that we, or our current or potential collaborators, may develop and then subsequently sell, may cause us to bear a portion of, or all, product liability risks. While we carry an insurance policy covering up to $5,000,000 per occurrence and $5,000,000 in the aggregate for liability incurred in connection with such claims should they arise, there can be no assurance that our insurance will be adequate to cover all situations. Moreover, there can be no assurance that such insurance, or additional insurance if required, will be available or, if available, will be available on commercially reasonable terms. Furthermore, our current and potential partners with whom we have collaborative agreements, or our future licensees, may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have a net worth sufficient to satisfy any product liability claims. A successful product liability claim or series of claims brought against us could have a material adverse effect on our business, prospects, financial condition and results of operations.

Risks Related to Intellectual Property

We expect to rely on our patents as well as specialized regulatory designations such as orphan drug classification for our product candidates, but regulatory drug designations may not confer marketing exclusivity or other expected commercial benefits.

We expect to file for ODD or other regulatory designations (fast track, break-through, priority review, etc.) as appropriate for our product candidates. We have been granted ODD in the U.S. for iopofosine as a therapeutic for the treatment of multiple myeloma, neuroblastoma, osteosarcoma, rhabdomyosarcoma, Ewing's sarcoma and lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia. Additionally, we have been granted ODD in Europe for iopofosine as a therapeutic for the treatment of multiple myeloma and Waldenstrom's macroglobulinemia.

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

Even though we have received ODD as described above, we may not be the first to obtain marketing approval for the orphan-designated indication because of the uncertainties associated with developing pharmaceutical products. For any product candidate for which we have been or will be granted ODD in a particular indication, it is possible that another company also holding ODD for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. In addition, exclusive marketing rights in the US for iopofosine for an orphan-designated indication or any future product candidate may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. We will not be able to rely on it to exclude other companies from manufacturing or selling products using the same principal molecular structural features for the same indication beyond these timeframes without our patent portfolio. Even if we were the first to obtain marketing authorization for an orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during the seven-year period of marketing exclusivity, such as if the later product is shown to be clinically superior to the product with orphan exclusivity. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. In addition, exclusive marketing rights in the US for iopofosine or any future product candidate may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Further, the seven-year marketing exclusivity, if granted, would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted ODD, or for other indications if not for our patent portfolio, or for the use of other types of products in the same indications as our orphan product. Furthermore, although the ODD and exclusivity are in effect right now, the FDA has the authority to modify this assessment at any time. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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

We may face litigation from third parties claiming our products infringe on their intellectual property rights, particularly because there is often substantial uncertainty about the validity and breadth of medical patents.

We may be exposed to future litigation by third parties based on claims that our technologies, products or activities infringe on the intellectual property rights of others or that we have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in medical technology patents, and the breadth and scope of trade-secret protection, involve complex legal and factual questions for which important legal principles are unresolved. Any litigation or claims against us, whether valid or not, could result in substantial costs, place a significant strain on our financial and managerial resources, and harm our reputation. License agreements that we may enter into in the future would likely require that we pay the costs associated with defending this type of litigation. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease selling, incorporating or using any of our technologies and/or products that incorporate the challenged intellectual property, which would adversely affect our ability to generate revenue;
- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our products, which would be costly and time-consuming.

If we are unable to adequately protect or enforce our rights to intellectual property or to secure rights to third-party patents, we may lose valuable rights, experience reduced market share, assuming any, or incur costly litigation to protect our intellectual property rights.

Our ability to obtain licenses to patents, maintain trade-secret protection, and operate without infringing the proprietary rights of others will be important to commercializing any products under development. Therefore, any disruption in access to the technology could substantially delay the development of our technology.

The patent positions of biotechnology and pharmaceutical companies, such as ours, for products that involve licensing agreements are frequently uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued or in subsequent legal proceedings. Consequently, our patent applications and any issued and licensed patents may not provide protection against competitive technologies or may be held invalid if challenged or circumvented. To the extent we license patents from third parties, the early termination of any such license agreement would result in the loss of our rights to use the covered patents, which could severely delay, inhibit or eliminate our ability to develop and commercialize compounds based on the licensed patents. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued or licensed to us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

We also rely on trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. Although we generally require our employees, consultants, advisors, and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology.

We may have to resort to litigation to protect our rights for certain intellectual property or to determine the scope, validity or enforceability of our intellectual property rights. Enforcing or defending our rights would be expensive, could cause diversion of our resources, and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technology to develop or sell competing products.

Risks Related to Our Employees

We rely on a small number of key personnel who may terminate their employment with us at any time, and our success will depend on our ability to hire additional qualified personnel.

Our success depends to a significant degree on the continued services of our executive officers, including our Chief Executive Officer, James V. Caruso. Our management and other employees may voluntarily terminate their employment with us at any time, and there can be no assurance that these individuals will continue to provide services to us. Our success will depend on our ability to attract and retain highly skilled personnel. We may be unable to recruit such personnel on a timely basis, if at all. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our products, loss of sales and diversion of management resources.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

We operate in the highly technical field of research and development of small-molecule drugs and rely, in part, on trade-secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that our competitors will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. Also, we typically obtain agreements from these parties that inventions conceived by them in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party has illegally obtained, and is using our trade secrets or know-how, is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade-secret protection could adversely affect our competitive position.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their current or former employers.

As is common in the biotechnology and pharmaceutical industry, we engage individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors or who are employed by academic research institutions. Although no claims against us are currently pending, we may be subject to claims that we, or these employees, have used or disclosed trade secrets or other proprietary information of their current or former employers, either inadvertently or otherwise. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Commercialization of our Products

Acceptance of our products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenues.

Our future financial performance will depend, at least in part, on the introduction and customer acceptance of our proposed products. Even if approved for marketing by the necessary regulatory authorities, our products may not achieve market acceptance. The degree of market acceptance will depend on several factors, including:

- receiving regulatory clearance of marketing claims for the uses that we are developing;
- the timing of market introduction of the product as well as competitive products;
- the clinical indications for which the product is approved;
- establishing and demonstrating the advantages, safety and efficacy of our technologies;
- relative convenience and ease of administration, and the convenience of prescribing, 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 European Commission (through the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency) and other regulators. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

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

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

Any product for which we have obtained regulatory approval, or for which we obtain approval in the future, is subject to, or will be subject to, extensive ongoing regulatory requirements by the FDA, 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 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 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 any healthcare reform measures of the Trump administration will impact the Affordable Care Act.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and, a result of subsequent legislative amendments, will remain in effect into 2031, unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022 with a subsequent reduction to 1% implemented from April 1, 2022 until June 30, 2022. To offset the temporary suspension during the COVID-19 pandemic, in 2030, reductions in Medicare payments will be 2.25% for the first half of the year, and 3% in the second half of the year. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (ATRA), which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

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

In the U.S., there have been several recent Congressional inquiries and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer-sponsored patient assistance programs, and reform government program reimbursement methodologies for drugs. See Part I, Item 1, Business-Regulation-Reimbursement and Pricing Controls in our Annual Report on Form 10-K for the year ended December 31, 2024 for more information on recent healthcare reform measures that may affect our ability to operate.

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

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

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payers and customers, may expose us to broadly applicable federal, state and foreign fraud and abuse and other healthcare laws and regulations including anti-kickback and false claims laws, data privacy and security laws, and transparency reporting laws. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any product for which we have obtained regulatory approval, or for which we obtain regulatory approval in the future. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws and regulations intended to prevent fraud, misconduct, bribery kickbacks, self-dealing and other abusive or inappropriate practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, including promoting off-label uses of our products, commission compensation, certain customer incentive programs, certain patient support offerings, and other business arrangements generally. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of patient recruitment for clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. See “Part I, Item 1, Business - Regulation - Other U.S. Regulatory Requirements” of our Annual Report on Form 10-K for more information on the healthcare laws and regulations that may affect our ability to operate.

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

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

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

In the EU, the outcomes of the ongoing review of the existing EU legislation on pharmaceutical products (the EU General Pharmaceutical Legislation or EU GPL) are uncertain. The GPL will have a major impact on the EU legislation on pharmaceutical products, and could, for example, result in a reduction of our data protection and market exclusivity periods. The final content of the EU GPL and timing for its adoption remain unclear, but negotiations could in theory be completed as early as the end of 2025.

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

Risks Related to Our Equity Securities

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 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.

The sale of a substantial number of shares of our common stock in the public market, including resale of the Shares hereby, could adversely affect the prevailing market price for our common stock.

We are registering for resale up to 2,096,188 shares of our common stock to fulfill our contractual obligations in the Inducement Letters. Sales of substantial amounts of shares of our common stock in the public market, or the perception that such sales might occur, could adversely affect the market price of our common stock. We cannot predict if and when the selling stockholders may sell such shares in the public markets or if the selling stockholders will choose to exercise their Inducement Warrants for shares of common stock. In addition, the issuance of shares of common stock to the selling stockholders pursuant to the exercise of the Inducement Warrants could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

General Risk Factors

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

Conflicts, military actions, terrorist attacks, natural disasters, public health crises and cyber-attacks have precipitated economic instability and turmoil in financial markets. Instability and turmoil may result in raw material cost increases. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical manufacturing and distribution industry in particular are unclear, and changes in the supply, demand or available sources of energy and the regulatory and other costs associated with energy production and delivery may affect the availability or cost of goods and services, including raw materials and other natural resources, necessary to run our businesses. The uncertainty and economic disruption resulting from hostilities, military action, acts of terrorism, natural disasters, public health crises or cyber-attacks may impact our operations or those of our suppliers. Accordingly, any conflict, military action, terrorist attack, natural disasters, public health crises or cyber-attack that impacts us or any of our suppliers, could have a material adverse effect on our business, liquidity, prospects, financial condition and results of operations.

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

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

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

Despite the implementation of security measures, our internal computer systems, and those of our third-party manufacturers, contract research organizations and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, phishing attempts, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption in our business. For example, the loss of clinical study data from ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, loss of trade secrets, inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, lack of access to our clinical data, or disruption of the manufacturing process, we could incur liability and the further development of our drug candidates could be delayed. We may also be vulnerable to cyber-attacks or other malfeasance by hackers. This type of breach of our cybersecurity may compromise our confidential and financial information, adversely affect our business, or result in legal proceedings. Further, these cybersecurity breaches may inflict reputational harm upon us that may result in decreased market value and erode public trust.

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

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

FORWARD-LOOKING STATEMENTS

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

- our current views with respect to our business strategy, business plan and research and development activities;
- the progress of our product development programs, including clinical testing and the timing of commencement and results thereof;
- our projected operating results, including research and development expenses;
- our ability to identify a strategic partner with the resources to develop iopofosine I 31 (also known as iopofosine or CLR 131) or otherwise continue the development or pursue other strategic options in connection with iopofosine;
- our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise;
- our ability to initiate a Phase 1b dose finding study for CLR 121125 and obtain the necessary additional funding for such study;
- our ability to initiate a Phase 1 imaging and dose escalation safety study for CLR 121225 and obtain the necessary additional funding for such study;
- our ability to continue development plans for our clinical and preclinical assets;
- our ability to continue development plans for our Phospholipid Drug Conjugates (PDC)™;
- our ability to advance our technologies into product candidates;
- our ability to maintain orphan drug designation in the U.S. for iopofosine as a therapeutic for the treatment of multiple myeloma, neuroblastoma, osteosarcoma, rhabdomyosarcoma, Ewing's sarcoma and lymphoplasmacytic lymphoma/Waldenstrom macroglobulinemia, and the expected benefits of orphan drug status;
- any disruptions to our suppliers;
- our current view regarding general economic and market conditions, including our competitive strengths;
- uncertainty and economic instability resulting from conflicts, military actions, terrorist attacks, natural disasters, public health crises, including the occurrence of a contagious disease or illness, cyber-attacks and general instability;
- the future impacts of legislative and regulatory developments in the United States on the pricing and reimbursement of our product candidates;
- our ability to meet the continued listing standards of Nasdaq;
- assumptions underlying any of the foregoing; and
- any other statements that address events or developments that we intend or believe will or may occur in the future.

In some cases, you can identify forward-looking statements by terminology, such as "expects," "anticipates," "intends," "estimates," "plans," "believes," "seeks," "may," "should," "could," "would" or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Forward-looking statements also involve risks and uncertainties, many of which are beyond our control. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus.

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

USE OF PROCEEDS

All proceeds from the resale of the shares of common stock offered by this prospectus will belong to the selling stockholders. We will not receive any proceeds from the sale or other disposition by the selling stockholders of the shares of our common stock covered by this prospectus. However, we will receive proceeds upon any cash exercise of the Inducement Warrants. If the Inducement Warrants are all exercised for cash, we will receive gross proceeds of $12.6 million. We intend to use any proceeds from any such exercise for working capital and general corporate purposes.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

DETERMINATION OF OFFERING PRICE

The prices at which the shares of our common stock covered by this prospectus may actually be sold will be determined by the prevailing market price for shares of our common stock or by negotiations between the selling stockholders and buyers of the shares in private transactions or as otherwise described in “Plan of Distribution.”

SELLING STOCKHOLDERS

The Selling Stockholders will offer or sell the shares of common stock offered by this prospectus at market prices prevailing at the time of sale, at prices related to prevailing market price or at privately negotiated prices. We are registering the Shares in order to permit the selling stockholders to offer them for resale from time to time after their issuance. For additional information regarding the Shares being offered by the selling stockholders pursuant to this prospectus, see "Summary-Description of the Warrant Inducement" above. Except for the ownership of our securities, the selling stockholders have not had any material relationship with us within the past three years.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of Common Stock by each of the selling stockholders. The second column lists the number of shares of common stock beneficially owned by each selling stockholder, based on its ownership of the shares of common stock as of October 15, 2025, and assuming full exercise of the Inducement Warrants on that date. The third column lists the shares of common stock being offered by this prospectus by the selling stockholders.

The fourth column assumes the sale of all Shares offered by the selling stockholders pursuant to this prospectus.

The information in the following table has been provided to us by or on behalf of the selling stockholders and the selling stockholders may have sold, transferred or otherwise disposed of all or a portion of their securities after the date on which they provided us with information regarding their securities. The selling stockholders may sell all, some or none of their Shares in this offering. See "Plan of Distribution."

	Ownership Before Offering		Ownership After Offering	
Selling Stockholder	**Number of shares of common stock beneficially owned(1)**	**Maximum number of shares of common stock offered**	**Number of shares of common stock beneficially owned**	**Percentage of common stock beneficially owned(2)**
Armistice Capital, LLC[3]	1,736,000	1,200,000	536,000	8.5%
Laurence Lytton[4]	604,170	402,780	201,390	3.2%
Intracoastal Capital LLC[5]	363,872	300,000	63,872	1.4%
Red Hook Fund LP [6]	95,000	60,000	35,000	*
Lincoln Park Capital Fund, LLC[7]	63,848	39,086	24,762	*
District 2 Capital, LP[8]	30,791	26,242	4,549	*
Bigger Capital Fund, LP[9]	29,248	29,248	—	—
Warberg WF XIII LP[10]	28,000	28,000	—	—
Boothbay Absolute Return Strategies, LP[11]	7,176	7,176	—	—
Boothbay Diversified Alpha Master Fund LP[12]	3,656	3,656	—	—

* Represents ownership of less than one percent.

(1) "Beneficial ownership" is a term broadly defined in Rule 13d-3 under the Exchange Act, and includes more than the typical form of stock ownership, that is, stock held in a person's name. The term also includes what is referred to as "indirect ownership," meaning ownership of shares as to which a person has or shares investment power. For purposes of this column, a person or group of persons is deemed to have "beneficial ownership" of any shares that such person or group of persons has the right to acquire within 60 days after October 15, 2025, including through the exercise of a warrant or the conversion of a security.

(2) Based on 6,336,322 shares of Common Stock outstanding, which assumes the issuance of all the Shares upon exercise of the Inducement Warrants and does not take into account the date of, or any limitations on, the exercise of the Inducement Warrants.

(3) Consists of 290,000 shares of common stock, 246,000 shares of common stock issued or issuable upon exercise of pre-funded warrants, and 1,200,000 Inducement Warrants. The securities are directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the "Master Fund"), and may be deemed to be beneficially owned by: (i) Armistice Capital, LLC ("Armistice Capital"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. The warrants are subject to a beneficial ownership limitation of 4.99%, which such limitation restricts the Selling Stockholder from exercising that portion of the warrants that would result in the Selling Stockholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The address of Armistice Capital Master Fund Ltd. is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

(4) Consists of 201,390 shares of common stock and 402,780 Inducement Warrants. The business address of Mr. Lytton is 467 Central Park West 17-A New York, NY 10025.

(5) Consists of 63,872 shares of common stock and 300,000 Inducement Warrants. Mitchell P. Kopin ("Mr. Kopin") and Daniel B. Asher ("Mr. Asher"), each of whom are managers of Intracoastal Capital LLC ("Intracoastal"), have shared voting control and investment discretion over the securities reported herein that are held by Intracoastal. As a result, each of Mr. Kopin and Mr. Asher may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of the securities reported herein that are held by Intracoastal. The business address of Intracoastal, Mr. Kopin and Mr. Asher is 245 Palm Trail, Delray Beach, FL 33483.

(6) Consists of 35,000 shares of common stock and 60,000 Inducement Warrants held by Red Hook Fund LP (the "Red Hook Fund"). Red Hook Asset Management LLC (the "Investment Manager"), a Delaware limited liability company, is the investment advisor to the Red Hook Fund and Red Hook Fund GP LLC ("General Partner") is the general partner of the Red Hook Fund. Mathew Lazarus and Jeff Lopatin are the managing members of the Investment Manager and the General Partner, and may each be deemed to beneficially own the shares beneficially owned by the Red Hook Fund LP. Mathew Lazarus and Jeff Lopatin each disclaims beneficial ownership of securities beneficially owned by the Red Hook Fund LP. The principal business address of the Red Hook Fund LP is 44 Ball Road, Mountain Lakes, NJ 07046.

(7) Consists of 24,762 shares of common stock and 39,086 Inducement Warrants. Joshua Scheinfeld and Jonathan Cope, the principals of Lincoln Park Capital Fund, LLC ("Lincoln Park") are deemed to be beneficial owner of all the securities owned by Lincoln Park. Messrs. Scheinfeld and Cope have shared voting and disposition power. The business address of Lincoln Park and Messrs. Scheinfeld and Cope is 415 N. LaSalle Dr., Suite 700B, Chicago, IL 60654

(8) Consists of 4,549 shares of common stock and 26,242 Inducement Warrants. Michael Bigger, managing member of the general partner of District 2 Capital, LP ("District 2") may be deemed to be beneficial owner of the securities owned by District 2. The business address of District 2 and Mr. Bigger is 14 Wall Street, 2nd Floor, Huntington NY 11743.

(9) Consists of 29,248 Inducement Warrants. Michael Bigger, managing member of the general partner of Bigger Capital Fund, LP ("Bigger Capital") may be deemed to be beneficial owner of the securities owned by Bigger Capital. The business address of Bigger Capital is 11700 W Charleston Blvd 170-659, Las Vegas, NV 89135.

(10) Consists of 28,000 Inducement Warrants. Daniel Warsh, manager of Warberg WF XIII LP ("Warberg") may be deemed to be beneficial owner of the securities owned by Warberg. The business address of Warberg and Mr. Warsh is 716 Oak St., Winnetka, IL 60093.

(11) Consists of 7,176 Inducement Warrants. Boothbay Absolute Return Strategies, LP, a Delaware limited partnership ("BBARS"), is managed by Boothbay Fund Management, LLC, a Delaware limited liability company ("Boothbay"). Boothbay, in its capacity as the investment manager of BBARS, has delegated to Kingsbrook Partners LP, a Delaware limited partnership ("Kingsbrook"), the power to vote and the power to direct the disposition of all securities held by BBARS that are being registered hereby. Ari Glass is the Managing Member of Boothbay. Each of BBARS, Boothbay and Mr. Glass disclaim beneficial ownership of these securities, except to the extent of any pecuniary interest therein. The business address of each of BBARS, Boothbay and Mr. Glass is c/o Kingsbrook Partners LP, 689 Fifth Avenue, 12th Floor, New York, NY 10022.

(12) Consists of 3,656 Inducement Warrants. Boothbay Diversified Alpha Master Fund LP, a Cayman Islands limited partnership ("BBDAMF"), is managed by Boothbay. Boothbay, in its capacity as the investment manager of BBDAMF, has delegated to Kingsbrook the power to vote and the power to direct the disposition of all securities held by BBDAMF. Ari Glass is the Managing Member of Boothbay. Each of BBDAMF, Boothbay and Mr. Glass disclaim beneficial ownership of these securities, except to the extent of any pecuniary interest therein. The business address of each of BBDAMF, Booothbay and Mr. Glass is c/o Kingsbrook Partners LP, 689 Fifth Avenue, 12th Floor, New York, NY 10022.

DESCRIPTION OF SECURITIES TO BE REGISTERED

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

Authorized Capital Stock

Our authorized capital stock consists of 170,000,000 shares of common stock, $0.00001 par value per share and 7,000 shares of preferred stock, $0.00001 par value per share. Our certificate of incorporation authorizes us to issue shares of our preferred stock from time to time in one or more series without stockholder approval, each such series to have rights and preferences, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences as our board of directors may determine. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of holders of any preferred stock, including our Series D and Series E Convertible Preferred Stock and any other series of preferred stock we may issue in the future. The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for others to acquire, or of discouraging others from attempting to acquire, a majority of our outstanding voting stock.

Common Stock

On October 17, 2025, there were 12 holders of record of our common stock. This number does not include stockholders for whom shares were held in a "nominee" or "street" name.

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

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

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

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

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

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

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

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

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

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

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

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

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

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty owed by any current or former director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders;
- any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to the Delaware General Corporation Law, our restated certificate, or our amended and restated bylaws;
- any action asserting a claim against us that is governed by the internal affairs doctrine; or
- asserting an "internal corporate claim," as defined in Section 115 of the Delaware General Corporation Law.

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

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

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

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

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

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

Concentration of Ownership

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

Listing

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

Transfer Agent and Registrar

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

Inducement Warrants

The Inducement Warrants overlying shares offered for resale under this prospectus were issued in two different series: the Series I Inducement Warrants and the Series II Inducement Warrants.

The Series I Inducement Warrants are immediately exercisable at an exercise price of $6.00 per share and will expire on October 8, 2030. The Series I Inducement Warrants are exercisable for up to 1,048,094 shares of our common stock, subject to adjustments as described below.

The Series II Inducement Warrants are immediately exercisable at an exercise price of $6.00 per share and will expire on April 8, 2027. The Series II Inducement Warrants are exercisable for up to 1,048,094 shares of our common stock, subject to adjustments as described below.

The exercise price and number of shares of common stock issuable upon exercise of the Inducement Warrants is subject to adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

PLAN OF DISTRIBUTION

The selling stockholders, including their pledgees, donees, transferees, distributees, beneficiaries or other successors in interest, may from time to time offer some or all of the shares of our common stock offered under this prospectus. We will not receive any of the proceeds from the sale of the shares of our common stock offered under this prospectus by the selling stockholders. We will bear all fees and expenses incident to our obligation to register the shares of our common stock offered under this prospectus.

The selling stockholders may sell all or a portion of the shares of our common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of our common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of our common stock may be sold on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market or in transactions otherwise than on these exchanges or systems or in the over-the-counter market and in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at privately negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions.

The selling stockholders may use any one or more of the following methods when disposing of shares of our common stock or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell shares of our common stock as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an over-the-counter distribution;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales effected after the effective date of the registration statement of which this prospectus forms a part;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of our common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of our common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee, or other successors in interest as selling stockholder under this prospectus. The selling stockholders also may transfer the shares of our common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of shares of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of shares of our common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out its short positions, or loan or pledge the shares of our common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares of our common stock offered under this prospectus, which shares of our common stock such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. If the selling stockholders effect certain transactions by selling shares of our common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of our common stock for whom they may act as agent or to whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with applicable rules of the Financial Industry Regulatory Authority, Inc. ("FINRA"); and in the case of a principal transaction a markup or markdown in compliance with applicable FINRA rules.

The aggregate proceeds to the selling stockholders from the sale of the shares of our common stock offered under this prospectus will be the purchase price of the shares of common stock less discounts or commissions, if any. The selling stockholders reserve the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of shares of our common stock to be made directly or through agents. We will not receive any of the proceeds from the offering under this prospectus.

The selling stockholders also may resell all or a portion of the shares of our common stock offered under this prospectus in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conforms to the requirements of that rule.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the shares of our common stock or interests therein may be deemed to be "underwriters" within the meaning of Section 2(a)(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares of our common stock may be underwriting discounts and commissions under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities. The selling stockholders are subject to the prospectus delivery requirements of the Securities Act.

To the extent required pursuant to Rule 424(b) under the Securities Act, the shares of our common stock to be sold, the name of the selling stockholders, the purchase price and public offering price, the names of any agents, dealer or underwriter, and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

We have agreed to keep this prospectus effective until the earliest to occur of the following events: (i) the date on which the selling stockholders shall have resold all the Securities covered hereby; and (ii) the date on which the Securities may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information requirement under Rule 144 under the Securities Act or any other rule of similar effect. In order to comply with the securities laws of some states, if applicable, the shares of our common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the shares of our common stock may not be sold unless the shares been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

The selling stockholders and any other person participating in a sale of shares of our common stock registered under this prospectus will be subject to applicable provisions of the Exchange Act, and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of our common stock by the selling stockholders and any other participating person. All of the foregoing may affect the marketability of the shares of our common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of our common stock. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares of our common stock against certain liabilities, including liabilities arising under the Securities Act.

LEGAL MATTERS

The validity of the securities being offered hereby will be passed upon for us by Sidley Austin LLP, New York, New York.

EXPERTS

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

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933, as amended (the "Securities Act"), with respect to the securities offered by this prospectus and any applicable prospectus supplement. This prospectus and any applicable prospectus supplement do not contain all of the information set forth in the registration statement and its exhibits and schedules in accordance with SEC rules and regulations. For further information with respect to us and the securities being offered by this prospectus and any applicable prospectus supplement, you should read the registration statement, including its exhibits and schedules. Statements contained in this prospectus and any applicable prospectus supplement, including documents that we have incorporated by reference, as to the contents of any contract or other document referred to are not necessarily complete, and, with respect to any contract or other document filed as an exhibit to the registration statement or any other such document, each such statement is qualified in all respects by reference to the corresponding exhibit. You should review the complete contract or other document to evaluate these statements. You may obtain copies of the registration statement and its exhibits via the SEC's website at http://www.sec.gov.

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

We are subject to the information and periodic reporting requirements of the Exchange Act, and we file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information are available for inspection and copying at the website of the Securities and Exchange Commission referred to above. We maintain a website at https://www.cellectar.com. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the Securities and Exchange Commission free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus.

INFORMATION INCORPORATED BY REFERENCE

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

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

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on March 13, 2025;
- our Quarterly Reports on Form 10-Q for the fiscal quarter ended March 31, 2025, filed with the SEC on May 13, 2025, the fiscal quarter ended June 30, 2025, filed with the SEC on August 14, 2025 and the fiscal quarter ended September 30, 2025, filed with the SEC on November 13, 2025;
- the portions of our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 28, 2025, that are incorporated by reference in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024;
- our Current Reports on Form 8-K, filed with the SEC on January 31, 2025, March 17, 2025, May 1, 2025, June 5, 2025 (excluding Item 7.01 and the related exhibit 99.1), June 13, 2025, June 18, 2025, June 25, 2025, June 26, 2025, October 6, 2025 (excluding Item 7.01 and the related exhibit 99.1) and October 10, 2025 (excluding Item 2.02); and
- the description of our common stock and warrants to purchase common stock included in our registration statement on Form 8-A filed on August 14, 2014, as the same may be updated by Exhibit 4.3 to Amendment No. 1 to our Annual Report on Form 10-K filed on April 1, 2024, including all other amendments and reports filed for the purpose of updating such description.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including those made after the date of the initial filing of the registration statement of which this prospectus is a part and those made after the effectiveness of such registration statement, until the termination of the offering of the common stock made by this prospectus, and such filings will become a part of this prospectus from the respective dates that such documents are filed with the SEC. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information herein or in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.You may request and obtain a copy of any of the filings incorporated herein by reference, at no cost, by writing or telephoning us at the following address or phone number:

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

Up to 2,096,188 Shares of Common Stock Offered by the Selling Stockholders

PROSPECTUS

November 21, 2025

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