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Registration No. 333-284580

PROSPECTUS

Up to 19,221,348 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 19,221,348 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 July 21, 2024. 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 July 21, 2024.

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 90 of this prospectus.

Our common stock is listed on the Nasdaq Capital Market under the symbol "CLRB." On January 28, 2025, the last reported sale price of our common stock was $0.2592.

Investing in our securities involves significant risks. We strongly recommend that you read carefully the risks we describe in "Risk Factors" beginning on page 8 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 February 6, 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 July 21, 2024, we entered into warrant exercise inducement offer letters (the "Inducement Letters") with certain holders (each a "Holder") of Tranche B warrants (the "Existing Warrants"), which were originally issued on September 8, 2023, pursuant to which the Holders agreed to immediately exercise for cash their Existing Warrants to purchase an amount of shares of the Company's Series E-4 Convertible Voting Preferred Stock, par value $0.00001 per share (the "Series E-4 Preferred Stock") which is convertible to 6,739,918 shares of our common stock, in the aggregate, at a reduced, as-converted common stock exercised price of $2.52 per share, in exchange for our agreement to issue the Inducement Warrants. We received aggregate gross proceeds of approximately $19.4 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 Company also agreed with one of the investors, Rosalind Advisors, Inc., not to effect or agree to effect certain common stock offerings until 60 days from the effectiveness of the Resale Registration Statement, unless waived by Rosalind Advisors, Inc. 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 three different tranches: Tranche A Inducement Warrants, the Tranche B Inducement Warrants and the Tranche C Inducement Warrants.

The Tranche A Inducement Warrants are immediately exercisable at an exercise price of $2.52 per share and will expire the earlier of (i) ten (10) Trading Days following the date of the Company's public announcement of written notification from the Food and Drug Administration (FDA) that the FDA has assigned a Prescription Drug User Fee Act goal date for review of iopofosine I 131 and (ii) July 20, 2029. The Tranche A Inducement Warrants are exercisable for up to 6,739,918 shares of our common stock, subject to adjustments as described below.

The Tranche B Inducement Warrants are immediately exercisable at an exercise price of $4.00 per share and will expire the earlier of (i) ten (10) Trading Days following the date of the Company's public announcement of its receipt of written approval from the FDA of its New Drug Application for iopofosine I 131 and (ii) July 20, 2029. The Tranche B Inducement Warrants are exercisable for up to 8,214,278 shares of our common stock, subject to adjustments as described below.

The Tranche C Inducement Warrants are immediately exercisable at an exercise price of $5.50 per share and will expire the earlier of (i) ten (10) Trading Days following the date of the Company's public announcement that it has recorded quarterly gross revenues from sales of iopofosine I 131 in the United States in excess of $10 million and (ii) July 20, 2029. The Tranche C Inducement Warrants are exercisable for up to 4,267,152 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

On December 10, 2024, our board of directors approved and management began implementing a workforce reduction plan to reduce operating costs and better align our workforce with the needs of our business following recent communications with the U.S. Food and Drug Administration (the "FDA") regarding our confirmatory study to support accelerated approval and the regulatory submission for iopofosine I 131. The implementation of the workforce reduction plan was completed by the end of the fourth quarter 2024.

Under the workforce reduction plan, the Company reduced its overall workforce by approximately 60%. Impacted employees are eligible to receive severance benefits, including: (a) salary continuation for period to be determined on an individual basis, but in no event for less than six weeks, (b) COBRA premium subsidies for the full months that encompass the severance period, and (c) a severance incentive. These severance benefits are contingent upon an impacted employee's execution (and non-revocation) of a separation agreement, which includes a general release of claims against the Company. In addition, any unvested and outstanding stock option grant held by impacted employees that would have vested within 90 days of the termination date were immediately fully vested and all vested stock options held by such employees shall remain exercisable for 180 days from date of such employee's termination.

The Company expects that the workforce reduction will decrease its annual operating costs by approximately $7.5 million. Additionally, the Company estimates that it will incur aggregate severance costs of approximately $1.7 million, which will be recorded primarily in the fourth quarter of 2024 and first quarter of 2025. The cost that the Company expects to incur in connection with the workforce reduction is subject to a number of assumptions, and actual results may differ materially. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the workforce reduction.

On January 30, 2025, the Company received notice from Nasdaq which indicated that under Nasdaq Listing Rule 5550(a)(2), the Company is required to maintain a minimum bid price for its common stock of $1.00 for continued listing. The notice does not have any immediate impact on the listing of the Company's stock on the Nasdaq exchange and the common stock remains listed on the Nasdaq Capital Market. In accordance with the Nasdaq Listing Rules, the Company has 180 calendar days, or until July 29, 2025, to regain compliance with the bid price requirement.

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)	19,221,348 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)	65,301,224 Shares
Selling stockholders	All of the shares of our common stock are being offered by the selling stockholders. See "Selling Stockholders" beginning on page 34 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 33 for additional information on the use of proceeds.
Risk Factors	See "Risk Factors" on page 8 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 46,079,876 shares of common stock outstanding as of January 27, 2025, and excludes, as of that date:

- an aggregate of 5,359,624 shares of common stock issuable upon the exercise of outstanding stock options issued to employees, directors and consultants;
- an aggregate of 391,209 shares of common stock issuable upon the conversion of outstanding shares of Series E-2 preferred stock;
- an aggregate of 111,111 shares of common stock issuable upon the conversion of outstanding shares of Series D preferred stock; and
- an aggregate of 24,582,748 additional shares of common stock reserved for issuance under outstanding warrants having expiration dates between October 2024 and July 2029, and exercise prices ranging from $12.075 to $1.96 per share.

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

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

- 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.

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

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

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

Risks Related to Manufacturing and Supply

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

Risks Related to Research and Development and the FDA

- We cannot assure the successful development and commercialization of our compounds in development.

- Failure to complete the development of our technologies, obtain government approvals, including required FDA approvals, or comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of proposed products and result in failure to achieve revenues or maintain our ongoing business.

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

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

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

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

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.

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

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

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.

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

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.

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

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

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

- The market for our proposed products is rapidly changing and competitive, and new therapeutics, drugs and treatments that may be developed by others could impair our ability to develop our business or become competitive.

- As a result of continued changes in marketing, sales and distribution, we may be unsuccessful in our efforts to sell our proposed products, develop a direct sales organization, or enter into relationships with third parties.

- If we are unable to convince physicians of the benefits of our intended products, we may incur delays or additional expense in our attempt to establish market acceptance.

- If our products are unable to obtain adequate reimbursement from third-party payors, or if additional healthcare reform measures are adopted, it could hinder or prevent the commercial success of our product candidates.

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

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

Risks Related to Internal Controls

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

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

Risks Related to Our Equity Securities

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

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

- Provisions of our certificate of incorporation, by-laws, and Delaware law may make an acquisition of us or a change in our management more difficult.

- 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.

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

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, 2024, our consolidated cash balance was approximately $34.3 million. We believe our cash balance as of September 30, 2024, is adequate to fund our basic budgeted operations into the fourth quarter of 2025.

During the third quarter ended September 30, 2023, the Company completed a private placement with certain institutional investors expected to result in gross proceeds of up to $102.9 million, including gross proceeds of $24.5 million which the Company received at closing. In January 2024, the Company's Tranche A warrants were all exercised resulting in gross proceeds of $44.1 million with net proceeds of approximately $42.8 million after deducting estimated offering expenses, and in July 2024 nearly all of the Company's Tranche B warrants were exercised and the Company sold the new warrants for gross proceeds of $19.4 million (see Note 13 in the Notes to Restated Consolidated Financial Statements included in this prospectus). 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.

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.

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

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

Risks Related to Manufacturing and Supply

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

We are in the preclinical study phase of product development and commercialization. We have closed manufacturing operations located at our former corporate headquarters in Wisconsin and have implemented a collaboration outsourcing model to more efficiently manage costs. We rely significantly on contracts with third parties to use their facilities to conduct our research, development and manufacturing.

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

In addition, we rely exclusively on contract research organizations to conduct research and development. Any inability of these organizations to fulfill the requirements of their agreements with us may delay or impair our ability to gain FDA approval and commercialization of our drug delivery technology and products.

Our reliance on third-party collaborators exposes us to risks related to not being able to directly oversee the activities of these parties. Furthermore, these collaborators, whether foreign or domestic, may experience regulatory compliance difficulties, mechanical shutdowns, employee strikes, or other unforeseeable acts that may delay fulfillment of their agreements with us. This may lead to the stopping or delay of our clinical trials or commercial manufacturing activity. Failure of any of these collaborators to provide the required services in a timely manner or on commercially reasonable terms could materially delay the development and approval of our products, increase our expenses, and materially harm our business, prospects, financial condition and results of operations.

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

arrangements based on their own business priorities, at a time that is costly or inconvenient for us. If we are unable to contract for the production of materials in sufficient quantity and of sufficient quality on acceptable terms, our planned clinical trials may be significantly delayed. Manufacturing delays could postpone the filing of our IND applications and/or the initiation or completion of clinical trials that we have currently planned or may plan in the future.

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

We believe that we have a good working relationship with our third-party collaborators. However, should the situation change, we may be required to relocate these activities on short notice, and we do not currently have access to alternate facilities to which we could relocate our research, development and/or manufacturing activities. The cost and time to establish or locate an alternate research, development and/or manufacturing facility to develop our technology would be substantial and would delay obtaining FDA approval and commercializing our products.

Furthermore, if our products are approved for commercial sale, we will need to work with our existing third-party collaborators to ensure sufficient capacity, or engage additional parties with the capacity, to commercially manufacture our products in accordance with FDA and other regulatory requirements. There can be no assurance that we would be able to successfully establish any such capacity or identify suitable manufacturing partners on acceptable terms.

Risks Related to Research and Development and the FDA

We cannot assure the successful development and commercialization of our compounds in development.

At present, our success is dependent on one or more of the following to occur: the successful development of iopofosine for the treatment of a hematologic or solid tumor cancer including Waldenstrom's macroglobulinemia, multiple myeloma and B-Cell lymphomas or the treatment of pediatric solid tumors and lymphomas; the development of new PDCs, specifically new products developed from our PDC program, and the advancement of our PDC agents through research and development; and/or commercialization partnerships.

We are a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer. We leverage our PDC platform to specifically target cancer cells. The PDC platform possesses the potential for the discovery and development of the next generation of cancer-targeting agents. The PDC platform features include the capacity to link with almost any molecule, the delivery of a significant increase in targeted oncologic payload, and the ability to target nearly all tumor cells. As a result, we believe that we can generate PDCs to treat a broad range of cancers with the potential to improve the therapeutic index of oncologic drug payloads, enhance or maintain efficacy while reducing adverse events by minimizing drug delivery to healthy cells, and increase delivery to cancerous cells and cancer stem cells.

Our proposed products and their potential applications are in clinical and manufacturing/process development and face a variety of risks and uncertainties inherent in the development of pharmaceutical products, including the following:

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

- Future clinical study results may show that our cancer-targeting and delivery technologies are not well-tolerated by patients at their effective doses or are not efficacious. In future clinical trials, we or our partners may discover additional side effects and/or a higher frequency of side effects than those observed in previously completed clinical trials.

- Future clinical study results may be inconsistent with testing results obtained to-date. The results of preliminary and mid-stage clinical trials do not necessarily predict clinical or commercial success, and larger later-stage clinical trials may fail to confirm the results observed in the previous clinical trials.

- A clinical trial may show that a product candidate is safe and effective for certain patient populations in a particular indication, but other clinical trials may fail to confirm those results in a subset of that population or in a different patient population, which may limit the potential market for that product candidate.

- Even if our cancer-targeting and delivery technologies are shown to be safe and effective for their intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities at reasonable prices or at all.

- Our ability to complete the development and commercialization of our cancer-targeting and delivery technologies for their intended use is substantially dependent upon our ability to raise sufficient capital or to obtain and maintain experienced and committed partners to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of, our products.

- Even if our cancer-targeting and delivery technologies are successfully developed, approved by all necessary regulatory authorities, and commercially produced, there is no guarantee that there will be market acceptance of our products.

- Our competitors may develop therapeutics or other treatments that are superior or less costly than our own with the result that our product candidates, even if they are successfully developed, manufactured and approved, may not generate sufficient revenues to offset the development and manufacturing costs of our product candidates.

If we are unsuccessful in dealing with any of these risks, or if we are unable to successfully advance the development of our cancer-targeting and delivery technologies for some other reason, our business, prospects, financial condition and results of operations may be adversely affected.

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

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

Failure to complete the development of our technologies, obtain government approvals, including required FDA approvals, or comply with ongoing governmental regulations could prevent, delay or limit introduction or sale of proposed products and result in failure to achieve revenues or maintain our ongoing business.

Our research and development activities and the manufacture and marketing of our intended products are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the U.S. and abroad. Before receiving approval to market our proposed products by the FDA, we will have to demonstrate that our products are safe and effective for the patient population for the diseases that are to be treated. Clinical studies, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug, and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacturing, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, clinical studies and regulatory approval can take many years to accomplish and require the expenditure of substantial financial, managerial and other resources.

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

research, development and commercialization of CLR 121225, CLR 121125, iopofosine and other future candidates in our pipeline must undergo extensive clinical trials, which can take many years and require substantial expenditures, subject to extensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. The process of obtaining regulatory approvals in the U.S. and other foreign jurisdictions is expensive, and lengthy, if approval is obtained at all.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Even if we do ultimately receive FDA approval for any of our products, these products will be subject to extensive ongoing regulation, including regulations governing manufacturing, labeling, packaging, testing, dispensing, prescription and procurement quotas, record keeping, reporting, handling, shipment and disposal of any such drug. Failure to obtain and maintain required registrations or to comply with any applicable regulations could further delay or preclude development and commercialization of our drugs and subject us to enforcement action.

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

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

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

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

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

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

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

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

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

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

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical studies will begin on time, need to be redesigned, or be completed on schedule, if at all. Clinical studies can be delayed for a variety of reasons,

including delays in obtaining regulatory approval to commence a study, reaching agreement on acceptable clinical study terms with prospective sites, obtaining institutional review board approval to conduct a study at a prospective site, recruiting patients to participate in a study, or obtaining sufficient supplies of clinical study materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, competing clinical studies, and new drugs approved for the conditions we are investigating. Prescribing physicians will also have to decide to use our product candidates over existing drugs that have established safety and efficacy profiles or other drugs undergoing development in clinical studies. Any delays in completing our clinical studies will increase our costs, slow down our product development and approval process, and delay our ability to generate revenue.

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

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

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

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

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

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

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

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

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

Risks Related to Legal Compliance and Litigation

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

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

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

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

Risks Related to Intellectual Property

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

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

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the US, or a patient population greater than 200,000 in the US where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the US. In the US, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first

FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Employees

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

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

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

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

be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade-secret protection could adversely affect our competitive position.

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

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

Risks Related to Commercialization of our Products

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

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

- receiving regulatory clearance of marketing claims for the uses that we are developing;
- the timing of market introduction of the product as well as competitive products;
- the clinical indications for which the product is approved;
- establishing and demonstrating the advantages, safety and efficacy of our technologies;
- relative convenience and ease of administration, and the convenience of prescribing, 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, and other regulators, to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and we may incur significant liability if it is determined that we are promoting the "off-label" use of any of our future product candidates if approved.

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

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

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

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

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

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

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

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

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

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

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

If any of our partners or contractors fail to fulfil their obligations in an adequate and timely manner or fail to comply with the FDA's rules and regulations, then the marketing and sales of our products could be delayed. The FDA may also take enforcement actions against us based on compliance issues identified with our contractors. If any of these events occur, we may incur significant liabilities,

which could decrease our revenues. For example, sales and medical science liaison or MSL personnel, including contractors, must comply with FDA requirements for the advertisement and promotion of products.

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

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

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

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

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

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

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

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

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

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

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

The market for our proposed products is rapidly changing and competitive, and new therapeutics, drugs and treatments that may be developed by others could impair our ability to develop our business or become competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our technologies and proposed products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and expected to increase. Most of these entities have significantly greater research and development capabilities and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase our competitors' financial, marketing, manufacturing and other resources.

Our resources are limited, and we may experience management, operational or technical challenges inherent in our activities and novel technologies. Competitors have developed, or are in the process of developing, technologies that are, or in the future may be, the basis for competition. Some of these technologies may accomplish therapeutic effects similar to those of our technology, but through different means. Our competitors may develop drugs and drug delivery technologies that are more effective than our intended products and, therefore, present a serious competitive threat to us.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our products even if they are commercialized. Many of our targeted diseases and conditions can also be treated by other medication or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for widespread acceptance of our technologies and products if commercialized.

As a result of continued changes in marketing, sales and distribution, we may be unsuccessful in our efforts to sell our proposed products, develop a direct sales organization, or enter into relationships with third parties.

We have not established marketing, sales or distribution capabilities for our proposed products. Until such time as our proposed products are further along in the development process, we will not devote any meaningful time and resources to this effort. At the appropriate time, we will determine whether we will develop our own sales and marketing capabilities or enter into agreements with third parties to sell our products.

We have limited experience in developing, training or managing a sales force. If we choose to establish a direct sales force, we may incur substantial additional expenses in developing, training and managing such an organization. We may be unable to build a sales force on a cost-effective basis or at all. In addition, we will compete with many other companies that currently have extensive marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a cost-effective or timely basis, if at all.

If we choose to enter into agreements with third parties to sell our proposed products, we may be unable to establish or maintain third-party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors.

We may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to adequately market our products;
- fail to satisfy financial or contractual obligations to us;
- offer, design, manufacture or promote competing products; or
- cease operations with little or no notice.

If we fail to develop sales, marketing and distribution channels, we would experience delays in product sales and incur increased costs, which would have a material adverse effect on our business, prospects, financial condition and results of operation.

If we are unable to convince physicians of the benefits of our intended products, we may incur delays or additional expense in our attempt to establish market acceptance.

Achieving use of our products in the target market of cancer diagnosis and treatment may require physicians to be informed regarding these products and their intended benefits. The time and cost of such an educational process may be substantial. Inability to successfully carry out this physician education process may adversely affect market acceptance of our proposed products. We may be unable to educate physicians, in sufficient numbers, in a timely manner regarding our intended proposed products to achieve our marketing plans and product acceptance. Any delay in physician education may materially delay or reduce demand for our proposed products. In addition, we may expend significant funds towards physician education before any acceptance or demand for our proposed products is created, if at all.

Efforts to educate the physicians, patients, healthcare payors and others in the medical community on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates are approved, if at all, but do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable on a sustained basis.

If our products are unable to obtain adequate reimbursement from third-party payors, or if additional healthcare reform measures are adopted, it could hinder or prevent the commercial success of our product candidates.

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

In both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. For example, the Affordable Care Act which was passed in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers, has been subject to judicial, legislative, and regulatory efforts to replace it or to alter its interpretation or implementation. Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been enacted. The Tax Cuts and Jobs Act of 2017 included a provision that repealed the tax-based shared responsibility payment imposed by the Affordable

Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the Consolidated Appropriations Act of 2020 fully repealed the Affordable Care Act's mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and also eliminated the health insurer tax. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the law. It is unclear how future actions before the Supreme Court, other such litigation, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act.

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

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

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

In the U.S., there have been several recent Congressional inquiries and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer-sponsored patient assistance programs, and reform government program reimbursement methodologies for drugs.

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.

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

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

Risks Related to Internal Controls

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

As discussed in the Explanatory Note and Notes 14 and 15 in the Notes to Restated Consolidated Financial Statements included in this prospectus, we have restated our previously issued audited financial statements as of and for the years ended December 31, 2022 and 2023 and our interim financial statements as of and for the quarterly periods ended March 31, 2024, March 31, 2023 through September 30, 2023 and March 31, 2022 through September 30, 2022.

As a result of the misstatements discussed and the Restatement, we have become subject to a number of additional risks and uncertainties and unanticipated costs for accounting, legal and other fees and expenses, including risks of lawsuits relating to securities offered by us in public and private offerings as well as claims by purchasers of our shares of common stock in the public market. Any actions, lawsuits 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. We have identified the following material weaknesses:

Management concluded that material weaknesses existed as of the year ended December 31, 2023. Specifically, management identified deficiencies in the principles associated with the control environment, risk assessment, control activities, information and communication and monitoring components of internal control, based on the criteria established by the COSO Framework, that constitute material weaknesses, either individually or in the aggregate.

- Control Environment: The Company lacked appropriate policies and resources to develop and operate effective internal control over financial reporting, which contributed to the Company's inability to properly analyze, record and disclose accounting matters accurately and timely. This was further impacted by the limited number of staff in the Company's accounting and finance function. This material weakness contributed to additional material weaknesses further described below.

- Risk Assessment: The Company does not have a formal process to identify, update, and assess risks, including risks around the accounting for complex transactions, that could significantly impact the design and operation of the Company's control activities.

- Control Activities: Management did not design and implement effective control activities and identified the following material weaknesses:

    - Management failed to design and implement adequate internal controls over financial reporting which resulted in the inaccurate accounting of preferred equity and warrants.

    - Management failed to design and implement adequate internal controls over the recording of stock-based compensation expense related to the restricted stock awards granted in December 2023.

    - Management failed to design and implement adequate internal controls over financial reporting as it relates to the proper fair value methodologies and assumptions used to value financial instruments, specific to the assumptions utilized in the valuation of the preferred warrants.

- Information and Communication: As noted above, the Company had a limited number of staff in its finance and accounting function, and therefore was unable to design and maintain appropriate segregation of duties in the initiation, recording, and approval of transactions within its financial systems. This, coupled with management having not designed and maintained user access controls that adequately restrict user and privileged access to financial applications, and the absence of sufficient other mitigating controls, created segregation of duties deficiencies.

- Monitoring Activities: Management did not appropriately select, develop, and perform ongoing evaluations to ascertain whether the components of internal controls are present and functioning.

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

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

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.

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

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

Our stock price has been and continues to be highly volatile. There can be no assurance that the market price for our common stock will remain at its current level, and a decrease in the market price could result in substantial losses for investors. The market price of our common stock may be significantly affected by one or more of the following factors:

- announcements or press releases relating to the biopharmaceutical sector or to our own business or prospects;
- regulatory, legislative or other developments affecting us or the healthcare industry generally;
- sales by holders of restricted securities pursuant to effective registration statements or exemptions from registration;
- market conditions specific to biopharmaceutical companies, the healthcare industry and the stock market generally; and
- our ability to maintain our listing on the Nasdaq exchange.

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

In the past, we have issued common stock, convertible securities (such as convertible preferred stock and notes payable) and warrants to raise capital. We have also issued equity as compensation for services and incentive compensation for our employees and directors. We have shares of common stock reserved for issuance upon the exercise of certain of these securities and may increase the shares reserved for these purposes in the future. Our issuance of additional common stock, convertible securities, options and warrants could dilute our common stock, affect the rights of our stockholders, reduce the market price of our common stock, result in adjustments to exercise prices of outstanding warrants (resulting in these securities becoming exercisable for, as the case may be, a greater number of shares of our common stock), or obligate us to issue additional shares of common stock to certain of our stockholders.

Provisions of our certificate of incorporation, by-laws, and Delaware law may make an acquisition of us or a change in our management more difficult.

Certain provisions of our certificate of incorporation and by-laws could discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which an investor might otherwise receive a premium for its shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our

common stock or warrants, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so.

Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions:

- provide for the division of the Board into three classes as nearly equal in size as possible with staggered three-year terms and further limit the removal of directors and the filling of vacancies;
- authorize our Board to issue without stockholder approval blank-check preferred stock that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our Board;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;
- establish advance notice requirements for stockholder nominations to our Board or for stockholder proposals that can be acted on at stockholder meetings;
- limit who may call stockholder meetings; and
- require the approval of the holders of 75% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our certificate of incorporation.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a prescribed period of time.

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 19,221,348 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.

FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended (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 continue development plans or to pursue strategic options for the further development and commercialization of iopofosine I-131 (also known as iopofosine or CLR 131);
- our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise;
- our ability to continue development plans for CLR 1900 series, CLR 2000 series and CLR 12120;
- our ability to continue development plans for our Phospholipid Drug Conjugates (PDC)™;
- our ability to advance our technologies into product candidates;
- our enhancement and consumption of current resources along with ability to obtain additional funding;
- our ability to maintain orphan drug designation in the U.S. for iopofosine as a therapeutic for the treatment of multiple myeloma, neuroblastoma, osteosarcoma, rhabdomyosarcoma, Ewing's sarcoma and lymphoplasmacytic lymphoma, and the expected benefits of orphan drug status;
- any disruptions 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 $73.3 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 January 27, 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)
ADAR1 Partners, LP (3)	3,261,770	2,716,062	545,708	*
Entities associated with Rosalind Advisors, Inc. (4)	7,472,745	5,849,983	1,622,762	2.42 %
Entities associated with AIGH Capital Management LLC (5)	4,202,288	2,924,988	1,277,300	1.92 %
Laurence W. Lytton (6)	3,955,470	2,674,277	1,281,193	1.94 %
Nantahala Capital Partners Limited Partnership (7)	433,896	433,896	—	*
NCP RFM LP (8)	497,413	497,413	—	*
Blackwell Partners LLC – Series A (9)	1,575,816	1,575,816	—	*
Bigger Capital Fund, LP (10)	1,010,861	438,748	572,113	*
District 2 Capital Fund, LP (11)	1,252,333	438,748	813,585	1.24 %
Healthcare Opportunities Master Fund, LP (12)	627,511	626,783	728	*
The Hewlett Fund, LP (13)	417,855	417,855	—	*
Triple Gate Partners, LP (14)	1,118,007	417,855	700,152	1.07 %
Boothbay Diversified Alpha Master Fund LP (15)	70,532	70,532	—	*
Boothbay Absolute Return Strategies, LP (16)	138,392	138,392	—	*

* 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 January 27, 2025, including through the exercise of a warrant or the conversion of a security.

(2) Based on 65,301,224 shares of Common Stock outstanding, which assumes the issuance of all the Warrant Shares upon exercise of the Warrants and does not take into account the date of, or any limitations on, the exercise of the Warrants.

(3) Consists of (i) 545,708 shares of Common Stock, (ii) 952,380 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (iii) 1,160,714 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iv) 602,968 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. The selling stockholder's address is 3503 Wild Cherry Drive, Building 9, Austin, TX 78738.

(4) Consists of (i) warrants to acquire 1,622,762 shares of Common Stock, (ii) 2,051,281 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (iii) 2,500,001 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iv) 1,298,701 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Each of Rosalind Advisors, Inc., Steven Salamon, and Gilad Aharon have shared voting and dispositive power with respect to these shares. The address for Rosalind Advisors, Inc., Rosalind Opportunities Fund I L.P., Mr. Salamon and Mr. Aharon is 15 Wellesley Street West, Suite 326, Toronto, Ontario, M4Y 0G7 Canada. The address for Rosalind Master Fund, L.P. is P.O. Box 309, Ugland House, Grand Cayman KY1-1104, Cayman Islands. The address of each of Investor Company ITF Rosalind Opportunities Fund I L.P and Investor Company ITF Rosalind Master Fund L.P. is c/o TD Waterhouse, 77 Bloor Street West, 3rd Floor, Toronto, ON M5S 1M2 Canada.

(5) Consists of (i) warrants to acquire 1,277,300 shares of Common Stock, (ii) 1,025,640 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (iii) 1,249,999 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iv) 649,349 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Mr. Orin Hirschman is the managing member of AIGH Capital Management, LLC, a Maryland limited liability company ("AIGH CM"), who is an advisor with respect to the securities held by AIGH Investment Partners, L.P. ("AIGH LP"), and a sub-advisor with respect to the securities held by WVP Emerging Manager Onshore Fund, LLC – AIGH Series. Mr. Hirschman has voting and investment control over the securities indirectly held by AIGH CM and directly held by Mr. Hirschman and his family directly. The address for AIGH CM, AIGH LP, WVP Emerging Manager Onshore Fund, LLC – AIGH Series and Mr. Hirschman is 6006 Berkeley Avenue, Baltimore, Maryland 21209.

(6) Consists of (i) 503,296 shares of Common Stock, (ii) warrants to acquire 777,897 shares of Common Stock, (iii) 937,728 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (iv) 1,142,857 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (v) 593,692 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. The address of the stockholder is 467 Central Park West, New York, NY 10025.

(7) Consists of (i) 152,145 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (ii) 185,426 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iii) 96,325 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Nantahala Capital Management, LLC is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of the selling stockholder as a General Partner, Investment Manager, or Sub-Advisor and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or the selling stockholder that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other purpose. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The business address for Nantahala Capital Partners Limited Partnership is 130 Main St., 2nd Floor, New Canaan, CT 06840.

(8) Consists of (i) 174,417 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (ii) 212,570 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iii) 110,426 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Nantahala Capital Management, LLC is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of the selling stockholder as a General Partner, Investment Manager, or Sub-Advisor and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or the selling stockholder that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other purpose. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The business address for NCP RFM LP is 130 Main St., 2nd Floor, New Canaan, CT 06840.

(9) Consists of (i) 552,556 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (ii) 673,428 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iii) 349,832 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Nantahala Capital Management, LLC is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of the selling stockholder as a General Partner, Investment Manager, or Sub-Advisor and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or the selling stockholder that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other purpose. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The business address for Blackwell Partners LLC – Series A is 280 South Mangum Street, Suite 210, Durham, NC 27701.

(10) Consists of (i) 572,113 shares of Common Stock, (ii) 153,846 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (iii) 187,500 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iv) 97,402 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Michael Bigger has the power to vote or dispose of the shares owned by Bigger Capital Fund, LP. The selling stockholder's address is 11700 W Charleston Blvd 170-659, Las Vegas, NV 89135.

(11) Consists of (i) 387,527 shares of Common Stock, (ii) warrants to acquire 426,058 shares of Common Stock, (iii) 153,846 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (iv) 187,500 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (v) 97,402 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Michael Bigger has the power to vote or dispose of the shares owned by District 2 Capital Fund LP. The selling stockholder's address is 14 Wall Street, 2nd Floor, Huntington, New York 11743.

(12) Consists of (i) 728 shares of Common Stock, (ii) 219,780 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (iii) 267,857 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iv) 139,146 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. The selling stockholder's address is 5425 Wisconsin Ave #600, Chevy Chase, MD 20815.

(13) Consists of (i) 146,520 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (ii) 178,571 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iii) 92,764 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Mr. Martin Chop is the General Partner of The Hewlett Fund LP. The selling stockholder's address is 100 Merrick Road – Suite 400W, Rockville Centre, NY 11570.

(14) Consists of (i) 700,152 shares of Common Stock, (ii) 146,520 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (iii) 178,571 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iv) 92,764 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. The selling stockholder's address is 961 Broadway, Suite 103, Woodmere, NY 11598.

(15) Consists of (i) 24,732 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (ii) 30,142 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iii) 15,658 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Boothbay Diversified Alpha Master Fund LP, a Cayman Islands limited partnership ("BBDAMF"), is managed by Boothbay Fund Management, LLC, a Delaware limited liability company ("Boothbay"). Boothbay, in its capacity as the investment manager of BBDAMF, has 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 selling stockholder's address is c/o Kingsbrook Partners LP, 689 Fifth Avenue, 12th Floor, New York, NY 10022.

(16) Consists of (i) 48,527 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (ii) 59,142 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iii) 30,723 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Boothbay Absolute Return Strategies LP, a Delaware limited partnership ("BBARS"), is managed by Boothbay. Boothbay, in its capacity as the investment manager of BBARS, has the power to vote and the power to direct the disposition of all securities held by the Fund. Ari Glass is the Managing Member of BBARS. Each of BBARS, Boothbay and Mr. Glass disclaim beneficial ownership of these securities, except to the extent of any pecuniary interest therein. The selling stockholder's address is c/o Kingsbrook Partners LP, 689 Fifth Avenue, 12th Floor, New York, NY 10022.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis is intended to help the reader understand the Company's results of operations and financial condition. This discussion and analysis is provided as a supplement to, and should be read in conjunction with, the Company's Restated Consolidated Financial Statements and the Company's unaudited Condensed Consolidated Financial Statements and notes thereto included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to the Company's plans and strategy for the Company's business, includes forward-looking statements that involve risks and uncertainties. The Company's actual results may differ materially from management's expectations as a result of various factors, including but not limited to those discussed in the sections entitled "Risk Factors" and "Forward-Looking Statements." The objective of this section is to provide investors an understanding of the financial drivers and levers in the Company's business and describe the financial performance of the business.

Restatement

The accompanying Management's Discussion and Analysis of Financial Condition and Results of Operations gives effect to the restatement adjustments made to the previously reported consolidated financial statements for the fiscal years ended December 31, 2023 and 2022. For additional information and a detailed discussion of the restatement, see Note 14: Restatement of Previously Issued Financial Statements in the Notes to Restated Consolidated Financial Statements included in this prospectus.

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.

We are primarily focused on the development of our radioconjugate PDC programs, also known as phospholipid radioconjugates or PRCs, designed to provide targeted delivery of a radioisotope directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates our PRCs from many traditional on-market treatments and radiotherapeutics. The three lead programs are: CLR 121225, an actinium-225 based program; CLR 121125, an iodine-125 Auger-emitting program, both expected to enter clinical trials early in 2025; and iopofosine I 131 (iopofosine), a beta-emitting iodine-131 based program which has been studied extensively, as described below.

- CLR 121225, the alpha-emitting, actinium-225 based PRC has demonstrated activity in multiple solid tumor animal models, including pancreatic, colorectal, and breast cancer. CLR 121225 has been shown to be well tolerated in these models with the animals showing no adverse events at the highest doses tested. It was also shown that the compound has excellent biodistribution and uptake by the tumor. Furthermore, in multiple models of pancreatic adenocarcinoma, including highly refractory pancreatic cancer, the compound demonstrated a proportional dose response with a single dose providing either tumor stasis at the lowest dose tested or tumor volume reduction at the higher doses. We are currently planning to initiate a Phase 1 imaging and dose escalation safety study in the first half of 2025.

- CLR 121125, the Auger-emitting PRC, utilizes iodine-125 and has demonstrated excellent tolerability with no toxicities in animal models. Additionally, CLR 121125 has been shown to have good activity in multiple solid tumor models, especially in triple negative breast cancer. Auger emitters provide the greatest precision in targeted radiotherapy as the emission can only travel a few nanometers. This means that to cause the necessary breakage of the tumor cell DNA, the isotope most get inside the cell and near the cell nucleus to be effective. CLR 121125 achieves this due to our novel phospholipid ether drug conjugate platform. CLR 121125 is expected to initiate a Phase 1b dose finding study in the first half of 2025.

- Iopofosine, the beta-emitting PRC, utilizes iodine-131 and was studied in our CLOVER-WaM Phase 2 pivotal study of iopofosine in patients with relapsed/refractory (r/r) Waldenstrom's macroglobulinemia (WM), and our Phase 2b studies in r/r multiple myeloma (MM) patients and r/r central nervous system lymphoma (CNSL) are ongoing. The CLOVER-2 Phase 1a study for a variety of pediatric cancers has concluded and a Phase 1b study in pediatric patients with high grade glioma is enrolling. Additionally, a Phase 1 Investigator-initiated study conducted by the University of Wisconsin Madison

of iopofosine I 131 in combination with external beam radiation in patients with recurrent head and neck cancer has also completed. As with all clinical trials, adverse events, serious adverse events or fatalities may arise during a clinical trial resulting from medical problems that may not be related to clinical trial treatments.

Results of Operations

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

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

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

Three Months Ended September 30, 2024 and 2023

Research and Development. Research and development expenses for the three months ended September 30, 2024, were approximately $5,493,000, compared to approximately $7,035,000 for the three months ended September 30, 2023.

The following table is a summary comparison of approximate research and development costs for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		
	2024	2023	Variance
Clinical project costs	$ 1,510,000	$ 3,412,000	$ (1,902,000)
Manufacturing and related costs	2,469,000	2,832,000	(363,000)
Pre-clinical project costs	49,000	206,000	(157,000)
General research and development costs	1,465,000	585,000	880,000
	$ 5,493,000	$ 7,035,000	$ (1,542,000)

The overall decrease in research and development expense of approximately $1,542,000, or 22%, was primarily a result of decreased clinical project costs of approximately $1,902,000, driven by the conclusion of patient enrollment in our WM pivotal study having occurred earlier in the year, partially offset by increased activity in our ongoing pediatric trial and an increase in personnel.

General and administrative. General and administrative expense for the three months ended September 30, 2024, was approximately $7,834,000, compared to approximately $2,379,00 for the same period in 2023. The overall increase in general and administrative expense of approximately $5,455,000, or 229%, was driven by costs associated with the development of infrastructure necessary to support commercialization upon anticipated NDA approval, including the related market preparation and personnel cost.

Other income (expense), net. Other income (expense), net, for the three months ended September 30, 2024, was an expense of approximately $1,337,000, as compared to approximately $8,107,000 of expense in the same period of 2023, resulting almost exclusively from changes in warrant valuation. Fluctuations in the Company's common stock price are the primary aspect of warrant valuation changes. Interest income increased year-over-year to approximately $318,000 in 2024 as compared to approximately $51,000 in 2023. The Company's cash on hand and increased interest rates drove the improved return.

Nine Months Ended September 30, 2024 and 2023

Research and Development. Research and development expense for the nine months ended September 30, 2024, was approximately $19,927,000, compared to approximately $19,529,000 for the nine months ended September 30, 2023.

The following table is a summary comparison of approximate research and development costs for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		
	2024	2023	Variance
Clinical project costs	$ 8,154,000	$ 10,235,000	$ (2,081,000)
Manufacturing and related costs	8,410,000	7,007,000	1,403,000
Pre-clinical project costs	101,000	422,000	(321,000)
General research and development costs	3,262,000	1,865,000	1,397,000
	$ 19,927,000	$ 19,529,000	$ 398,000

The overall increase in research and development expenses of approximately $398,000, or 2%, was primarily a result of increased manufacturing and related costs of approximately $1,403,000 related to production sourcing and an increase in general research and development costs related to an increase in personnel. These increases were largely offset by a reduction in clinical project costs of approximately $2,081,000, resulting from the timing of the patient enrollment related to our pivotal WM trial.

General and administrative. General and administrative expense for the nine months ended September 30, 2024, was approximately $19,106,000, compared to approximately $6,884,000 for the same period in 2023. The overall increase in general and administrative expense of $12,222,000, or 178%, was primarily driven by costs associated with the development of infrastructure necessary to support commercialization upon anticipated NDA approval, including the related market preparation and personnel costs.

Other income (expense), net. Other income (expense), net, for the first nine months of 2024 was an expense of approximately $3,193,000, while the expense for the same period in 2023 was approximately $8,477,000. A significant portion of the expense comes from changes in the valuation of the Company's outstanding warrants. Warrant valuation consists of a number of aspects, but the most significant driver is the value at which the Company's common stock is trading at the end of each reporting period. Interest income was approximately $967,000 year-to-date in 2024, and approximately $248,000 in 2023. The Company's improved return on cash equivalents is a product of higher average cash balance and a higher interest rate environment.

Twelve Months Ended December 31, 2023 and 2022

Research and Development. Research and development expenses for the year ended December 31, 2023, were approximately $27,266,000, compared to approximately $18,266,000 for the year ended December 31, 2022.

The following table provides a summary of research and development costs by category for the years ended December 31, 2023 and 2022:

	Year Ended December 31,		
	2023	2022	Variance
Clinical project costs	$ 15,132,000	$ 12,964,000	$ 2,168,000
Manufacturing and related costs	9,341,000	4,238,000	5,103,000
Pre-clinical project costs	483,000	431,000	52,000
General research and development costs	2,310,000	633,000	1,677,000
	$ 27,266,000	$ 18,266,000	$ 9,000,000

The overall increase in research and development expenses of approximately $9,000,000, or 49%, was primarily a result of an increase in manufacturing and related costs related to greater production sourcing necessary to support clinical trials and establish commercial production capabilities of approximately $5,103,000 and clinical project costs of approximately $2,168,000, driven by the

timing of the activities related to our pivotal and pediatric trials, and an increase in general research and development costs of approximately $1,677,000 primarily attributable to increased personnel-related costs.

General and Administrative. General and administrative expenses for the year ended December 31, 2023, were approximately $11,694,000, compared to approximately $10,548,000 in 2022. The increase of $1,146,000, or 11% in general and administrative costs was primarily driven by an increase in personnel costs partially offset by a reduction in professional fees.

Other income (expense), net. Other income (expense), net for 2023 was an expense of approximately $3,870,000, as compared to approximately $3,039,000 of expense in 2022. The decrease was largely a result of the cost of the September 2023 financing being substantially lower than that of the October 2022 financing, partially offset by the impact of the warrant revaluation having an unfavorable impact in 2023, whereas in 2022 the impact was favorable. Interest income, net, improved to approximately $387,000 in 2023 as compared to approximately $153,000 in 2022. The increase in interest earned is a result of higher interest rates supporting stronger returns on money market cash equivalents coupled with higher average balances of cash on hand in 2023.

Liquidity and Capital Resources

Year Ended December 31, 2023, Compared to Year Ended December 31, 2022

As of December 31, 2023, we had cash and cash equivalents of $9.6 million, compared to $19.9 million as of December 31, 2022, a decrease of $10.3 million. This decrease was primarily a result of increased research and development expenses and general and administrative expenses, partially offset by funds raised through equity securities. The cash used in operating activities during the twelve months ended December 31, 2023, was approximately $32,377,000.

Investing activities consist exclusively of fixed asset purchases. The increase in 2023 over 2022 relates to development of the infrastructure necessary to support our manufacturing capabilities, particularly ensuring that we have redundancy in each aspect of the supply chain to eliminate disruptions to product availability upon commercialization.

Net cash proceeds from the issuance of common stock, preferred stock, warrants, and the exercise of warrants by investors during 2023 was approximately $22,940,000, as compared to approximately $9,611,000 for similar financing activities in 2022.

Our cash requirements have historically been for our research and development activities, finance and administrative costs, capital expenditures and overall working capital. We have experienced negative operating cash flows since inception and have funded our operations primarily from sales of common stock and other securities. As of December 31, 2023, we had an accumulated deficit of approximately $202,761,000.

Nine Months Ended September 30, 2024, Compared to Nine Months Ended September 30, 2023

As of September 30, 2024, we had cash and cash equivalents of $34.3 million, compared to $19.0 million as of September 30, 2023, an increase of $15.3 million. This increase was primarily a result of funds raised through the sale of equity securities and the exercise of outstanding warrants by investors, partially offset by research and development expenses and general and administrative expenses. The cash used in operating activities during the nine months ended September 30, 2024, was approximately $36,670,000.

Investing activities consist exclusively of fixed asset purchases. The decrease in 2024 from 2023 relates to the development of the infrastructure necessary to support our manufacturing capabilities during 2023, an effort that did not recur in 2024.

Net cash proceeds from the issuance of common stock, preferred stock, warrants, and the exercise of warrants by investors during the nine months ended September 30, 2024, was approximately $61,411,000, as compared to approximately $22,499,000 for such activities in the comparable period in 2023.

Our cash requirements have historically been for our research and development activities, finance and administrative costs, capital expenditures and overall working capital. We have experienced negative operating cash flows since inception and have funded our operations primarily from sales of common stock and other securities. As of September 30, 2024, we had an accumulated deficit of approximately $244,987,000.

Liquidity Outlook

We have incurred losses since inception in devoting substantially all of our efforts toward research and development of drug candidates for which we are seeking FDA approval. During the year ended December 31, 2023 and the nine months ended September 30, 2024, we generated net losses of approximately $42.8 million and $42.2 million, respectively. As of September 30, 2024, our consolidated cash balance was approximately $34.3 million. As of the date the accompanying consolidated financial statements were issued (the "issuance date"), the Company's available liquidity to fund the Company's operations over the next twelve months beyond the issuance date was limited to approximately $28.6 million of unrestricted cash and cash equivalents. Absent further action taken by management to increase its liquidity, the Company may be unable to fund its operations under normal course beyond the fourth quarter of 2025. To improve the Company's liquidity, management plans to secure additional outside capital via the sale of equity and/or debt securities or execute a strategic transaction. Management also plans to preserve liquidity, as needed, by implementing temporary cost saving measures. While management believes their plans will be successful, no assurance can be provided such plans will be effectively implemented over the next twelve months beyond the issuance date. In the event management's plans are not effectively implemented, the Company will be required to seek other alternatives which may include, among others, the sale of assets, discontinuance of certain operations, and/or filing for bankruptcy protection.

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

Critical Accounting Policies and Estimates

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

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

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

Fair value measurements. We account for certain financial assets at fair value, defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., exit price) in the principal, most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. As such, fair value is a market-based measurement that is determined based on assumptions that a market participant would use in pricing an asset or liability. In conjunction with the financings conducted in September 2023 and October 2022, we recorded the preferred stock and warrants separately based on the estimated fair values. Subsequent to their issuance, to the extent that such securities are liability classified, they are marked to market, with the change reflected

in the statement of operations at each reporting date. If management made different assumptions or judgments, material differences in measurements of fair value could occur.

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

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

BUSINESS

Business Overview

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

The Company is primarily focused on the development of its radioconjugate PDC programs, also known as phospholipid radioconjugates or PRCs, designed to provide targeted delivery of a radioisotope directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates our PRCs from many traditional on-market treatments and radiotherapeutics. Our three lead programs are: CLR 121225, an actinium-225 based program; CLR 121125, an iodine-125 Auger-emitting program, both expected to enter clinical trials early in 2025; and iopofosine I 131 (iopofosine), a beta-emitting iodine-131 based program which has been studied extensively, as described below.

- CLR 121225, the alpha-emitting, actinium-225 based PRC has demonstrated activity in multiple solid tumor animal models, including pancreatic, colorectal, and breast cancer. CLR 121225 has been shown to be well tolerated in these models with the animals showing no adverse events at the highest doses tested. It was also shown that the compound has excellent biodistribution and uptake by the tumor. Furthermore, in multiple models of pancreatic adenocarcinoma, including highly refractory pancreatic cancer, the compound demonstrated a proportional dose response with a single dose providing either tumor stasis at the lowest dose tested or tumor volume reduction at the higher doses. The Company is currently planning to initiate a Phase 1 imaging and dose escalation safety study in the first half of 2025.

- CLR 121125, the Auger-emitting PRC, utilizes iodine-125 and has demonstrated excellent tolerability with no toxicities in animal models. Additionally, CLR 121125 has been shown to have good activity in multiple solid tumor models, especially in triple negative breast cancer. Auger emitters provide the greatest precision in targeted radiotherapy as the emission can only travel a few nanometers. This means that to cause the necessary breakage of the tumor cell DNA, the isotope most get inside the cell and near the cell nucleus to be effective. CLR 121125 achieves this due to the Company's novel phospholipid ether drug conjugate platform. CLR 121125 is expected to initiate a Phase 1b dose finding study in the first half of 2025.

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

The CLOVER-1 Phase 2 study, conducted in r/r B-cell malignancies, met the primary efficacy endpoints from the Part A dose-finding portion. The CLOVER-1 Phase 2b study, where iopofosine remains under further evaluation in highly refractory MM and CNSL patients, is ongoing.

The CLOVER-WaM study was a pivotal registration study evaluating iopofosine in WM patients that were r/r to at least two prior lines of therapy including having failed or had a suboptimal response to a Bruton tyrosine kinase inhibitor (BTKi). The study completed enrollment in the fourth quarter of 2023, and initial top line data from the study was reported in January 2024. CLOVER-WaM was a single-arm study with a target enrollment of 50 patients. Topline safety data was reported on 45 patients meeting criteria for the modified Intent to Treat (mITT) population with a data cut-off date of January 3, 2024. Topline efficacy evaluable population (41) is defined as patients who are in the mITT and had follow up of at least 60 days post last dose. The CLOVER-WaM study met its

primary endpoint with a major response rate (MRR) of 61% (95% confidence interval [44.50%, 75.80%, two-sided p value < 0.0001]) exceeding the FDA agreed-upon statistical hurdle of 20%. The overall response rate (ORR) in evaluable patients was 75.6%, and 100% of patients experienced disease control. Responses were durable, with median duration of response not reached and 76% of patients remaining progression free at a median follow-up of eight months. These outcomes exceed real world data, which demonstrate a 4-12% MRR and a duration of response of approximately six months or less despite continuous treatment in a patient population that is less pretreated and not refractory to multiple classes of drugs. Notably, iopofosine I 131 monotherapy achieved an 7.3% complete remission (CR) rate in this highly refractory WM population. Iopofosine I 131 was well tolerated and its toxicity profile was consistent with the Company's previously reported safety data. There were no treatment-related adverse events (TRAEs) leading to discontinuation. The rates of Grade 3 or greater TRAEs observed in more than 10% of patients included thrombocytopenia (55%), neutropenia (37%), and anemia (26%). All patients recovered from cytopenias with no reported aplastic sequalae. Importantly, there were no clinically significant bleeding events, and the rate of febrile neutropenia was 2%. There were no treatment-related deaths in the study.

The CLOVER-2 Phase 1a pediatric study was an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of iopofosine in children and adolescents with relapsed or refractory malignant solid tumors (neuroblastoma, Ewing's sarcoma, osteosarcoma, and rhabdomyosarcoma) and lymphoma or recurrent or refractory malignant brain tumors (high grade glioma, glioblastoma, etc.) for which there are no standard treatments. The study was conducted internationally at seven leading pediatric cancer centers. The CLOVER-2 Phase 1b pediatric study is an open-label, dose finding study evaluating the activity of two different doses and dosing regimens of iopofosine in children and adolescents with r/r malignant brain tumors (high grade gliomas). This study is partially funded (~$2M) by a National Institutes of Health SBIR grant from the National Cancer Institute.

The U.S. Food and Drug Administration (FDA) granted iopofosine Fast Track Designation for lymphoplasmacytic lymphoma (LPL) and WM patients having received two or more prior treatment regimens, as well as r/r MM and r/r diffuse large B-cell lymphoma (DLBCL). Orphan Drug Designations (ODDs) have been granted for LPL/WM, MM, neuroblastoma, soft tissue sarcomas including rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Iopofosine was also granted Rare Pediatric Disease Designation (RPDD) for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. The European Commission granted ODD to iopofosine for treatment of r/r MM and WM, as well as PRIME designation for WM.

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

Our product pipeline also includes a PDC-based targeted alpha-emitter therapy utilizing actinium-225 as the payload (CLR 121225) currently in IND enabling studies. We are also evaluating other alpha emitting isotopes such as astatine-211 and lead-212 preclinical studies. Additionally, we have preclinical PDC programs seeking to deliver conjugated small molecule chemotherapeutic compounds, oligonucleotides and peptides to solid tumors.

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

Our PDC platform is designed to provide selective delivery of a diverse range of oncologic payloads to cancerous cells, whether a hematologic cancer or solid tumor; a primary tumor, or a metastatic tumor; and cancer stem cells. The PDC platform's mechanism of entry is designed not to rely upon a specific cell surface epitope or antigen as are required by other targeted delivery platforms but rather a unique change in the tumor cell membrane. Our PDC platform takes advantage of a metabolic pathway (beta oxidation) utilized by nearly all tumor cell types in all stages of the tumor cycle. Tumor cells modify the cell membrane to create specific, highly organized microdomains by which to transport lipids and long chain fatty acids into the cytoplasm, as a result of the utilization of this metabolic pathway. Our PDCs are designed to bind to these regions and directly enter the intracellular compartment. This mechanism allows the PDC molecules to accumulate in tumor cells over time, which we believe can enhance drug efficacy. The direct intracellular delivery allows our molecules to avoid the specialized, highly acidic cellular compartment known as lysosomes, which allows a PDC to deliver payloads that previously could not be delivered in this targeted manner. Additionally, molecules targeting specific cell surface epitopes face challenges in completely eliminating a tumor because the targeted antigens are limited in the total number presented on the cell

surface, limiting total potential uptake and resulting in heterogenous uptake across the tumor, have longer cycling time from internalization to relocation on the cell surface, again diminishing their availability for binding, and are not present on all of the tumor cells because of the heterogenous nature of cancer cells, further increasing the unequal distribution of the drug across the tumor. This means a subpopulation of tumor cells always exists that cannot be addressed by therapies targeting specific surface epitopes. Additionally, many epitopes utilized are also present on other normal tissue, resulting in off-target toxicities.

Beyond the benefits provided by the mechanism of entry, the PDC platform features include the capacity to link with almost any molecule, provide a significant increase in targeted oncologic payload delivery, a more uniform delivery, and the ability to target virtually all types of tumor cells. As a result, we believe that we can create PDCs to treat a broad range of cancers with the potential to improve the therapeutic index of oncologic drug payloads, enhance or maintain efficacy while also reducing adverse events by minimizing drug delivery to healthy cells, and increasing delivery to cancerous cells and cancer stem cells.

We employ a drug discovery and development approach that allows us to efficiently design, research and advance drug candidates. Our iterative process allows us to rapidly and systematically produce multiple generations of incrementally improved targeted drug candidates without the expense of having to generate significant compound libraries.

Clinical Pipeline

Our lead clinical programs are: CLR 121225, an actinium-225 based program; CLR 121125, an iodine-125 Auger-emitting program, both expected to enter clinical trials early in 2025; and iopofosine, an iodine-131 beta-emitting program. All three of these product candidates are designed to provide targeted delivery of the respective radioisotope directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates our PRCs from many traditional on-market treatments and treatments in development.

Iopofosine was evaluated in the recently completed CLOVER-WaM Phase 2 pivotal study in patients with r/r WM, while evaluation is ongoing in a Phase 2b study in r/r MM and CNS lymphoma patients and the CLOVER-2 Phase 1b study for pediatric patients with high grade gliomas. Adverse events across all studies have been largely restricted to fatigue (39%), and cytopenias; specifically, thrombocytopenia (75%), anemia (61%), neutropenia (54%), leukopenia (56%), and lymphopenia (34%). Fatalities have occurred in patients post-treatment with iopofosine.

The CLOVER-WaM pivotal Phase 2b study completed enrollment of WM patients that have received at least two previous lines of therapy including those that failed or had a suboptimal response to a BTKi therapy in 4Q 2023. Topline safety data was reported on 45 patients meeting the criteria for the mITT population with a data cut-off date of January 3, 2024. Topline efficacy evaluable population (n=41) was defined as patients who were in the mITT and had follow up of at least 60 days post last dose. The CLOVER-WaM study met its primary endpoint with a MRR of 61% (95% confidence interval [44.50%, 75.80%, two-sided p value < 0.0001]) exceeding the agreed-upon statistical hurdle of 20%. The ORR in evaluable patients was 75.6%, and 100% of patients experienced disease control. Responses were durable, with median duration of response not reached and 76% of patients remaining progression free at a median follow-up of eight months. These outcomes exceed real world data, which demonstrate a 4-12% MRR and a duration of response of approximately six months or less despite continuous treatment in a patient population that is less pretreated and not refractory to multiple classes of drugs. Notably, iopofosine monotherapy achieved a 7.3% complete remission (CR) rate in this highly refractory WM population. Iopofosine I 131 was well tolerated and its toxicity profile was consistent with the Company's previously reported safety data. There were no treatment-related adverse events (TRAEs) leading to discontinuation. The rates of Grade 3 or greater TRAEs observed in more than 10% of patients included thrombocytopenia (55%), neutropenia (37%), and anemia (26%). All patients recovered from cytopenias with no reported aplastic sequalae. Importantly, there were no clinically significant bleeding events, and the rate of febrile neutropenia was 2%. There were no treatment-related deaths in the study.

The CLOVER-1 Phase 2 study met the primary efficacy endpoints from the Part A dose-finding portion, conducted in r/r B-cell malignancies, and is now enrolling an MM and CNSL expansion cohort (Phase 2b). The Phase 2b study will evaluate highly refractory MM patients in triple class, quad- and penta-drug refractory patients, including post-BCMA immunotherapy patients and r/r CNSL patients. The initial Investigational New Drug (IND) application was accepted by the FDA in March 2014 with multiple INDs submitted since that time. The Phase 1 study was designed to assess the compound's safety and tolerability in patients with r/r MM and to determine maximum tolerated dose (MTD) and was initiated in April 2015. The study completed enrollment and the final clinical study report is expected in the first half of 2025. Initiated in March 2017, the primary goal of the Phase 2a study was to assess the compound's efficacy in a broad range of hematologic cancers.

The CLOVER-2 Phase 1a pediatric study was conducted internationally at seven leading pediatric cancer centers. The study was an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of iopofosine in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). The maximum tolerated dose was determined to be greater than 60mCi/m2 administered as a fractionated dose. CLOVER-2 Phase 1b study is an open-label, international dose-finding study evaluating two different doses and dosing regiments of iopofosine in r/r pediatric patients with high grade gliomas. These cancer types were selected for clinical, regulatory and commercial rationales, including the radiosensitive nature and continued unmet medical need in the r/r setting, and the rare disease determinations made by the FDA based upon the current definition within the Orphan Drug Act.

In December 2014, the FDA granted ODD for iopofosine for the treatment of MM. In 2018, the FDA granted ODD and RPDD for iopofosine for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma, and osteosarcoma. In May 2019, the FDA granted Fast Track Designation for iopofosine for the treatment of MM and in July 2019 for the treatment of DLBCL. In September 2019 iopofosine received ODD from the European Union for MM. In December 2019, the FDA and the European Union each granted ODD for iopofosine for the treatment of WM. In September 2023, the European Union granted PRIME designation for iopofosine for the treatment of r/r WM. The FDA granted Fast Track designation for iopofosine for the treatment of r/r LPL and WM in May 2020.

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

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

We participated in a Type C guidance meeting with the FDA in September 2020. The results of that guidance meeting provided us with an agreed upon path for conducting the CLOVER-WaM study; a single arm, pivotal study in WM patients that have received and relapsed or were refractory to two prior lines of therapy, including having failed or had a suboptimal response to BTKi therapy. WM is a rare, indolent, and incurable form of non-Hodgkin's lymphoma (NHL) that is composed of a patient population in need of new and better treatment options.

The study enrolled 65 WM patients who have received at least two prior lines of therapy, failed both lines of therapy including having failed or had a suboptimal response to a BTKi (i.e. ibrutinib). Patients in the trial received 4-doses of iopofosine over two cycles (cycle one: days 1, 15, and cycle two: days 57, 71) with each dose administered as a 15mCi/m2 infusion. The primary endpoint of the trial is major response rate (MRR) defined as a partial response (a minimum of a 50% reduction in IgM) or better in patients that receive a minimum total body dose (TBD) of 60 mCi with secondary endpoints of treatment-free survival (treatment-free remission), duration of response and progression-free survival. An independent data monitoring committee (iDMC) performed an interim safety and futility evaluation on the first 10 patients enrolled. If three of the 10 patients experienced a Clinically Significant Toxicity (CST) then the dose would have been reduced to 12.5 mCi/m2. We believe this design aligned with the feedback received from the FDA during the guidance meeting held in September 2020 and subsequent interactions. The FDA accepted the dose to be tested, our proposal for a safety and futility assessment to be conducted on the first 10 patients, the endpoint to be assessed, the statistical analysis plan and study size of approximately 50 patients in the mITT population (>60mCi TBD). Based upon this agreement, the pivotal study was initiated. The interim futility and safety assessment occurred in 2022 and the iDMC determined the study exceeded the futility threshold and that the CST threshold was not met, therefore the study should continue to enroll with no change to the dosing regimen. The study achieved full enrollment in the fourth quarter 2023 and topline safety data was reported on 45 patients meeting the criteria for the mITT population with a data cut-off date of January 3, 2024. Among mITT patients, median age was 71 years, median IgM level prior to treatment with iopofosine was 2,185, 90% were refractory to either a BTKi (18/36 50%) or anti-CD20 therapy (18/41 40%), with 26.7% multiclass

refractory, and 80% of patients were previously treated with a BTKi therapy. Topline efficacy evaluable population (n=41) was defined as patients who were in the mITT and had follow up of at least 60 days post last dose. The CLOVER WaM study met its primary endpoint with a major response rate (MRR) of 61% (95% confidence interval [44.50%, 75.80%, two-sided p value < 0.0001]) exceeding the agreed upon statistical hurdle of 20%. The overall response rate (ORR) in evaluable patients was 75.6%, and 100% of patients experienced disease control. Responses were durable, with median duration of response not reached and 76% of patients remaining progression free at a median follow-up of eight months. These outcomes exceed real world data, which demonstrate a 4-12% MRR and a duration of response of approximately six months or less despite continuous treatment in a patient population that is less pretreated and not refractory to multiple classes of drugs. Notably, iopofosine monotherapy achieved an 7.3% complete remission (CR) rate in this highly refractory WM population. Iopofosine I 131 was well tolerated and its toxicity profile was consistent with the Company's previously reported safety data. There were no treatment-related adverse events (TRAEs) leading to discontinuation. The rates of Grade 3 or greater TRAEs observed in more than 10% of patients included thrombocytopenia (55%), neutropenia (37%), and anemia (26%). All patients recovered from cytopenias with no reported aplastic sequalae. Importantly, there were no clinically significant bleeding events, and the rate of febrile neutropenia was 2%. There were no treatment-related deaths in the study.

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

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

In July 2016, we were awarded a $2,000,000 National Cancer Institute (NCI) Fast-Track Small Business Innovation Research grant to further advance the clinical development of iopofosine. The funds supported the Phase 2 study initiated in March 2017 to define the clinical benefits of iopofosine in r/r MM and other niche hematologic malignancies with unmet clinical need. These niche hematologic malignancies include CLL, SLL, MZL, LPL/WM and DLBCL. The study was conducted in approximately 10 U.S. cancer centers in patients with orphan-designated relapse or refractory hematologic cancers. The planned study enrollment was up to 80 patients.

The study's primary endpoint was clinical benefit response (CBR), with secondary endpoints of ORR, PFS, time to next treatment (TtNT), median Overall Survival (mOS), DOR and other markers of efficacy following patients receiving one of three TBDs of iopofosine (<50mCi, ~50mCi and >60mCi), with the option for a second cycle approximately 75-180 days later. Dosages were provided either as a single bolus or fractionated (the assigned dose level split into two doses) given day 1 and day 15. Over the course of the study the dosing regimen of iopofosine advanced from a single bolus dose to two cycles of fractionated administrations of 15 mCi/m2 per dose on days 1, 15 (cycle 1), and days 57, 71 (cycle 2). Adverse events occurring in at least 25% of subjects were fatigue (39%) and cytopenias, specifically, thrombocytopenia (75%), anemia (61%), neutropenia (54%), leukopenia (51%), and lymphopenia (25%). Serious adverse events occurring in greater than 5% of subjects were restricted to thrombocytopenia (9%) and febrile neutropenia (7.5%).

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

Patients in the r/r WM cohort all received TBD of ≥ 60 mCi (25 mCi/m2 single bolus, 31.25 mCi/m2 fractionated, 37.5 mCi/m2 fractionated, or two cycles of mCi/m2 fractionated) either as a bolus dose or fractionated. Current data from our Phase 2a CLOVER-1 clinical study show a 100% ORR in six WM patients and an 83.3% major response rate with one patient achieving a complete response (CR), which reached 39 months post-last treatment. While median treatment free survival (TFS), also known as treatment free remission (TFR), and DOR have not been reached, the average treatment TFS/TFR is currently at 330 days. We believe this may represent an important improvement in the treatment of r/r WM as we believe no approved or late-stage development treatments for second- and third-line patients have reported a CR to date. Based on study results to date, patients continue to tolerate iopofosine well, with the most common adverse events being cytopenias and fatigue.

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

In September 2020, we announced that a 40% ORR was observed in the subset of refractory MM patients deemed triple class refractory who received 60 mCi or greater TBD. Triple class refractory is defined as patients that are refractory to immunomodulatory, proteasome inhibitors and anti-CD38 antibody drug classes. The 40% ORR (6/15 patients) represents triple class refractory patients enrolled in Part A of Cellectar's CLOVER-1 study and additional patients enrolled in Part B from March through May 2020 and received

>60mCi TBD (25 mCi/m2 single bolus, 31.25 mCi/m2 fractionated, 37.5 mCi/m2 fractionated, or two cycles of mCi/m2 fractionated) either as a bolus dose or fractionated. Patients with MM received 40 mg of dexamethasone concurrently beginning within 24 hours of the first CLR 131 infusion. All MM patients enrolled in the expansion cohort are required to be triple class refractory. The additional six patients enrolled in 2020 were heavily pre-treated with an average of nine prior multi-drug regimens. Three patients received a TBD of > 60 mCi and three received less than 60 mCi. Consistent with the data released in February 2020, patients receiving > 60 mCi typically exhibit greater responses. Based on study results to date, patients continue to tolerate iopofosine well, with the most common and almost exclusive treatment-emergent adverse events are cytopenias, such as thrombocytopenia, neutropenia, and anemia.

In December 2021, we presented data from 11 MM patients from our ongoing Phase 2 CLOVER-1 study in a poster at the American Society of Hematology (ASH) Annual Meeting and Exposition. The MM patients were at least triple class refractory (defined as refractory to an immunomodulatory agent, proteasome inhibitor and monoclonal antibody) with data current as of May 2021. Patients had a median of greater than 7 prior therapies with 50% classified as high risk. Initial results in these patients showed an ORR of 45.5%, a CBR of 72.7%, and a disease control rate (DCR) of 100%. Median PFS was 3.4 months. In a subset of five quad/penta drug refractory patients, efficacy increased, demonstrating an ORR of 80% and CBR of 100% in this highly treatment refractory group. The most commonly observed treatment emergent adverse events were cytopenias that included Grade 3 or 4 thrombocytopenia (62.5%), anemia (62.5%), neutropenia (62.5%) and decreased white blood cell count (50%). Treatment emergent adverse events were mostly limited to bone marrow suppression in line with prior observations. No patients experienced treatment emergent adverse events of neuropathy, arrhythmia, cardiovascular event, bleeding, ocular toxicities, renal function, alterations in liver enzymes, or infusion-site reactions or adverse events. We continue to enrich the r/r MM patient cohort with patients that are even more refractory, specifically enrolling patients that are quad-class refractory (triple class plus refractory to any of the recent approved product classes) and have relapsed post-BCMA immunotherapy. We reported in the Blood Cancer Journal in August 2022 that iopofosine demonstrated a 50% ORR in patients receiving >60mCi total administered dose (3/6 patients).

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

In February 2020, we announced positive data from our Phase 2a CLOVER-1 study in patients with NHL patients were treated with three different doses (<50mCi, ~50mCi and >60mCi TBD. Patients in the r/r NHL cohort received TBD of either ≥ 60 mCi or < 60 mCi (25 mCi/m2 single bolus, 31.25 mCi/m2 fractionated, 37.5 mCi/m2 fractionated, or two cycles of mCi/m2 fractionated) either as a bolus dose or fractionated. Patients with r/r NHL who received <60mCi TBD and the >60mCi TBD had a 42% and 43% ORR, respectively and a combined rate of 42%. These patients were also heavily pre-treated, having a median of three prior lines of treatment (range, 1 to 9) with the majority of patients being refractory to rituximab and/or ibrutinib. The patients had a median age of 70 with a range of 51 to 86. All patients had bone marrow involvement with an average of 23%. In addition to these findings, subtype assessments were completed in the r/r B-cell NHL patients. Patients with DLBCL demonstrated a 30% ORR with one patient achieving a CR, which continues at nearly 24 months post-treatment. The ORR for CLL/SLL and MZL patients was 33%.

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

The most frequently reported adverse events in all patients were cytopenias, which followed a predictable course and timeline. The frequency of adverse events did not increase as doses were increased and the profile of cytopenias remained consistent. Importantly, our assessment is that these cytopenias have had a predictable pattern to initiation, nadir and recovery and are treatable. The most common grade ≥3 events at the highest dose (75mCi TBD) were hematologic toxicities including thrombocytopenia (65%), neutropenia (41%), leukopenia (30%), anemia (24%) and lymphopenia (35%). No patients experienced cardiotoxicities, neurological toxicities, infusion site reactions, peripheral neuropathy, allergic reactions, cytokine release syndrome, keratopathy, renal toxicities, or changes in liver enzymes. The safety and tolerability profile in patients with r/r NHL was similar to r/r MM patients except for fewer cytopenias of any grade. Based upon iopofosine being well tolerated across all dose groups, the observed response rate, and especially in difficult to treat patients such as high risk and triple class refractory or penta-refractory, and corroborating data showing the potential to further improve upon current ORRs and durability of those responses, the study has been expanded to test a two-cycle dosing optimization regimen with a target TBD >60 mCi/m2 of iopofosine.

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

Phase 1 Study in Patients with r/r Multiple Myeloma

In February 2020, final results from a multicenter, Phase 1 dose escalation clinical trial of iopofosine in r/r MM were presented. The trial was designed to evaluate the safety and potential initial efficacy of iopofosine administered in an up to 30-minute I.V. infusion either as a single bolus dose or as a fractionated dose in heavily pretreated MM patients. The study enrolled a total of 26 evaluable patients at three trial sites. For the trial, which used a modified three-plus-three dose escalation design, 15 evaluable patients were dosed in single bolus doses from 12.5mCi/m2 up to 31.25mCi/m2 (TBD 20.35-59.17 mCi) and 11 evaluable patients were dosed in fractionated dosing cohorts of 31.25mCi/m2 to 40mCi/m2 (TBD 54.915-89.107 mCi). An iDMC did not identify dose-limiting toxicities in any cohort. Of the 26 evaluable patients in the trial, a partial response was observed in 4 of 26 patients (15.4%) and stable disease or minimal response in 22 of 26 patients (84.6%), for a disease control rate of 100%. A significant decrease in M-protein and free light chain (FLC) was also observed.

Iopofosine in combination with dexamethasone was under investigation in adult patients with r/r MM. MM is an incurable cancer of the plasma cells and is the second most common form of hematologic cancer. Patients had to be refractory to or relapsed from at least one proteasome inhibitor and at least one immunomodulatory agent. The clinical study was a standard three-plus-three dose escalation safety study to determine the maximum tolerable dose. We use the International Myeloma Working Group (IMWG) definitions of response, which involve monitoring the surrogate markers of efficacy, M protein and FLC. The IMWG defines a PR as a 50% or greater decrease in M protein or to 50% or greater decrease in FLC levels (for patients in whom M protein is unmeasurable). Secondary objectives included the evaluation of therapeutic activity by assessing surrogate efficacy markers, which include M protein, FLC, PFS and OS. All patients were heavily pretreated with an average of five prior lines of therapy. An iDMC assessed the safety of iopofosine up to its planned maximum single, bolus dose of 31.25 mCi/m2 or a TBD of ~63 mCi. The four single dose cohorts examined were: 12.5 mCi/m2 (~25mCi TBD), 18.75 mCi/m2 (~37.5mCi TBD), 25 mCi/m2(~50mCi TBD), and 31.25 mCi/m2(~62.5mCi TBD), all in combination with low dose dexamethasone (40 mg weekly). Of the five patients in the first cohort, four were assessed as achieving stable disease and one patient progressed at Day 15 after administration and was taken off the study. Of the five patients admitted to the second cohort, all five were assessed as achieving stable disease; however, one patient progressed at Day 41 after administration and was taken off the study. Four patients were enrolled to the third cohort, and all were assessed as achieving stable disease. In September 2017, we announced safety and tolerability data for cohort 4, in which patients were treated with a single infusion up to 30-minutes of 31.25mCi/m2 of iopofosine, which was tolerated by the three patients in the cohort. Additionally, all three patients experienced CBR with one patient achieving a partial response (PR). The patient experiencing a PR had an 82% reduction in FLC. This patient did not produce M protein, had received seven prior lines of treatment including radiation, stem cell transplantation and multiple triple combination treatments including one with daratumumab that was not tolerated. One patient experiencing stable disease attained a 44% reduction in M protein. In January 2019, we announced that the pooled mOS data from the first four cohorts was 22.0 months. In late 2018, we modified this study to evaluate a fractionated dosing strategy to potentially increase efficacy and decrease adverse events.

Cohorts five and six received fractionated dosing of 31.25 mCi/m2(~62.5mCi TBD) and 37.5 mCi/m2 (~75mCi TBD), each administered on day 1 and day 8. Following the determination that all prior dosing cohorts were tolerated, we initiated a cohort seven utilizing a 40mCi/m2 (~95mCi TBD) fractionated dose administered 20mCi/m2 (~40mCi TBD) on days 1 and day 8. Cohort seven was the highest pre-planned dose cohort and subjects have completed the evaluation period. The study completed enrollment and the final clinical study report is expected in the first half of 2022. Adverse events occurring in at least 25% of subjects were fatigue (26%) and cytopenias, specifically, thrombocytopenia (90%), anemia (65%), neutropenia (55%), leukopenia (61%), and lymphopenia (58%). Serious adverse events occurring in greater than two subjects were restricted to febrile neutropenia n=3 (9.7%).

In May 2019, we announced that the FDA granted Fast Track Designation for iopofosine in fourth line or later r/r MM. Iopofosine is currently being evaluated in our ongoing CLOVER-1 Phase 2 clinical study in patients with r/r MM and other select B-cell lymphomas. Patients in the study received up to four, approximately 20-minute, IV infusions of iopofosine over 3 months, with doses given 14 days apart in each cycle and a maximum of two cycles. Low dose dexamethasone 40 mg weekly (20mg in patients ≥ 75), was provided for up to 12 weeks. The planned study enrollment was up to 80 patients. Its primary endpoint was clinical benefit rate (CBR), with additional endpoints of ORR, PFS, median overall survival (OS) and other markers of efficacy. Over the course of the study the dosing regimen of iopofosine advanced from a single bolus dose to two cycles of fractionated administrations of 15 mCi/m2 per dose on days 1, 15 (cycle 1), and days 57, 71 (cycle 2). Following treatment with iopofosine, approximately 91% of patients experience a reduction in tumor marker with approximately 73% experiencing greater than 37% reduction.

CLOVER 2: Phase 1 Study in r/r Pediatric Patients with select Solid tumors, Lymphomas and Malignant Brain Tumors

In December 2017, the Division of Oncology at the FDA accepted our IND and study design for the Phase 1 study of iopofosine in children and adolescents with select rare and orphan designated cancers. This study was initiated during the first quarter of 2019. In

December 2017, we submitted an IND application for r/r pediatric patients with select solid tumors, lymphomas and malignant brain tumors. The Phase 1 clinical study of iopofosine is an open-label, sequential-group, dose-escalation study evaluating the safety and tolerability of intravenous administration of iopofosine in children and adolescents with relapsed or refractory malignant solid tumors (neuroblastoma, Ewing's sarcoma, osteosarcoma, rhabdomyosarcoma) and lymphoma or recurrent or refractory malignant brain tumors for which there are no standard treatments. Secondary objectives of the study are to identify the recommended efficacious dose of iopofosine and to determine preliminary antitumor activity (treatment response) of iopofosine in children and adolescents.

In August 2020, based on data on four dose levels from 15mCi/m2 up to 60mCi/m2, the iDMC permitted the beginning of the evaluation of the next higher dose cohort, at 75mCi/m2. The iDMC advised, based upon the initial data, to enrich the 60 mCi/m2 dose level for patients over the age of 10 with HGG and Ewing sarcoma. Changes in various tumor parameters appeared to demonstrate initial response and tumor uptake. This includes patients with relapsed HGGs with over five months of PFS. In November 2020, we announced clinical data providing that iopofosine had been measured in pediatric brain tumors, confirming that systemic administration of iopofosine crosses the blood brain barrier and is delivered into tumors and that the data show disease control in heavily pretreated patients with ependymomas. In November 2021, we announced favorable data on changes in various tumor parameters in a Phase 1 study in children and adolescents with relapsed and refractory high-grade gliomas (HGGs) and soft tissue sarcomas. Pediatric HGGs are a collection of aggressive brain and central nervous system tumor subtypes (i.e. diffuse intrinsic pontine gliomas, glioblastomas, astrocytomas, ependymomas, etc.) with about 400 new pediatric cases diagnosed annually in the U.S. Children with these tumors have a poor prognosis and limited 5-year survival. Adverse events occurring in at least 25% of subjects were fatigue, headache, nausea and vomiting (28% respectively), and cytopenias, specifically, thrombocytopenia (67%), anemia (67%), neutropenia (61%), leukopenia (56%), and lymphopenia (33%). There were no serious adverse events occurring in more than 2 subjects. The Part A portion of this Phase 1 study has concluded, and part B has initiated to determine the appropriate dosing regimen in pediatric patients with r/r HGG. In 2022, the NCI awarded Cellectar a $1,900,000 SBIR Phase 2 grant to explore iopofosine in pediatric HGG.

In 2018, the FDA granted ODD and RPDD for iopofosine for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. If iopofosine should be approved for any of these pediatric indications, the first approved RPDD would enable us to receive a priority review voucher. Priority review vouchers can be used by the sponsor to receive priority review for a future New Drug Application (NDA) or Biologic License Application (BLA) submission, which would reduce the FDA review time from 12 months to six months. Currently, these vouchers can also be transferred or sold to another entity. In December 2020, the FDA extended the Priority Review Voucher Program through September 2026 for rare pediatric diseases.

Phase 1 Study in r/r Head and Neck Cancer

In August 2016, the University of Wisconsin Carbone Cancer Center (UWCCC) was awarded a five-year Specialized Programs of Research Excellence (SPORE) grant of $12,000,000 from the NCI and the National Institute of Dental and Craniofacial Research to improve treatments and outcomes for head and neck cancer (HNC) patients. HNC is the sixth most common cancer across the world with approximately 56,000 new patients diagnosed every year in the U.S. As a key component of this grant, the UWCCC researchers completed testing of iopofosine in various animal HNC models and initiated the first human clinical study enrolling up to 30 patients combining iopofosine and external beam radiation treatment (EBRT) with recurrent HNC in the fourth quarter of 2019. UWCCC has completed the part A portion of a safety and tolerability study of iopofosine in combination with EBRT and preliminary data suggest safety and tolerability in relapsed or refractory HNC. The reduction in the amount or fractions (doses) of EBRT has the potential to diminish the (number and severity of) adverse events associated with EBRT. Patients with HNC typically receive approximately 60-70 Grays (Gy) of EBRT given as 2 - 3 Gy daily doses over a six-week timeframe. Patients can experience long-term tumor control following re-irradiation in this setting; however, this approach can cause severe injury to normal tissue structures, significant adverse events and diminished quality of life. Part B of the study was to assess the safety and potential benefits of iopofosine in combination with EBRT in a cohort of up to 24 patients. This portion of the study has fully enrolled, and data were reported at the ASTRO 2024 conference on March 2, 2024. Complete remission was achieved in 64% of patients, with an ORR of 73% (n=11). Prior to treatment with iopofosine I 131, six patients had multiple recurrences, and one had metastatic disease, both of which are indicative of poor outcomes. Additionally, the study demonstrated durability of tumor control with an overall survival of 67% and progression free survival of 42% at 12 months. Eleven patients (92%) experienced a treatment-related adverse event. Treatment-related adverse events of grade 3 or higher occurring in 20% or more patients were thrombocytopenia (75%), lymphopenia (75%), leukopenia (75%), neutropenia (67%), and anemia (42%). Observed adverse events were consistent with the known toxicity profile of iopofosine I 131, with cytopenias being the most common. All patients recovered. We believe that these data support the notion of enhanced patient outcomes when combining the use of iopofosine I 131 in combination with external beam radiation for a treatment of solid tumors.

Preclinical Pipeline

We believe our PDC platform has potential to provide targeted delivery of a diverse range of oncologic payloads, as exemplified by our lead product candidates: iopofosine, CLR 121225 and CLR 121125 as discussed above. Additional pipeline product candidates, listed below, may also result in improvements to the current standard of care (SOC) for the treatment of a broad range of human cancers:

- The company has developed a series of proprietary small molecule phospholipid drug conjugates. These programs employ either novel payload or novel linkers. Many of these molecules have demonstrated efficacy and tolerability in preclinical mouse models. The collaboration with IntoCell Inc., successfully met its agreed upon endpoint. The collaboration provided significant data which has led Cellectar to select a series of highly potent cytotoxic small molecule payloads for further development.

- In collaboration with other parties, Cellectar has also validated that the PLE is capable of delivering peptide payloads and oligonucleotide (siRNA, mRNA, etc.) payloads to the tumors when delivered systemically. These molecules have also been shown to demonstrate activity and safety in multiple preclinical mouse models. Based upon these collaborations and the data, the company has initiated internal proprietary programs with each of these treatment modalities.

Technology Overview

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

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

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

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

pivotal role played by lipid rafts is underscored by the fact that disruption of lipid raft architecture significantly eliminates uptake of our PDC delivery vehicle into cancer cells.

Products in Development

CLR 121225

CLR 121225 is the Company's lead alpha emitting, actinium-225, based radioconjugate program. The compound has demonstrated activity in multiple solid tumor animal models, including pancreatic, colorectal, and breast cancer. CLR 121225 has been shown to be well tolerated in these models with the animals showing no adverse events at the highest doses tested. It was shown that the compound has excellent biodistribution and uptake by the tumor. Furthermore, the compound demonstrated in multiple models of pancreatic adenocarcinoma, including highly refractory pancreatic cancer, a proportional dose response with a single dose providing either tumor stasis at the lowest dose tested or tumor volume reduction at the higher doses. The Company is currently planning to initiate a Phase 1 imaging and dose escalation safety study in the first half of 2025.

CLR 121125

CLR 121125 is the Company's lead Auger-emitting radioconjugate program. The compound utilizes iodine-125 and has demonstrated excellent tolerability with no toxicities in animal models. Additionally, CLR 121125 has been shown to have good activity in multiple solid tumor models and especially in triple negative breast cancer. Auger emitters provide the greatest precision in targeted radiotherapy as the emission can only travel a few nanometers. This means to cause the necessary breakage of the tumor cell DNA, the isotope most get inside the cell and near the cell nucleus to be effective. CLR 121125 achieves this due to the Company's novel phospholipid ether drug conjugate platform. CLR 121125 is expected to initiate a Phase 1b dose finding study in the first half of 2025.

Iopofosine

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

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

Market Overview

Our target market is broad and represents the market for the treatment of cancer. The American Cancer Society estimates 1 in 3 people will develop cancer in their lifetime. Approximately 1.92 million new cancer cases will be diagnosed in the U.S. in 2022 and approximately 609,360 cancer deaths in the U.S. The global market for cancer drugs reached $148 billion in annual sales (2020), and with a compound annual growth rate (CAGR) of 7.7% could reach $288 billion by 2030, according to a report dated August 2022 by Straits Research. This growth will be driven by emerging targeted therapies, which are expected to change the cancer treatment landscape (Cowen Report 2020), and an increased use of cancer drug combination regimens.

Waldenstrom's Macroglobulinemia

WM is a rare and incurable disease defined by specific genotypic subtypes that define patient responses and long-term outcomes. The U.S. annual incidence is 1,500 - 1,900 with prevalence of approximately 26,000 and 110,000 patients globally. WM is a lymphoma, or cancer of the lymphatic system. The disease occurs in a type of white blood cell called a B-lymphocyte or B-cell, which

normally matures into a plasma cell that plays an important part in the body's immune system by manufacturing immunoglobulins (antibodies) to help the body fight infection. In WM, there is a malignant change to the B-cell in the late stages of maturing, and it continues to proliferate into a clone of identical cells, primarily in the bone marrow but also in the lymph nodes and other tissues and organs of the lymphatic system. These clonal cells over-produce an antibody of a specific class called IgM.

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

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

Multiple Myeloma

According to the National Cancer Institute SEER database, multiple myeloma is the second most common hematologic cancer with a U.S. incidence rate of 32,270 and a relapse or refractory patient population of 43,727. In 2022, Datamonitor Healthcare estimated the MM dollar market size to be over $23B in 2023 and is forecasted to increase to nearly $47B in 2031. The increase in drug sales over this period will be mainly driven by the increasing incidence of MM with the U.S. market remaining the largest potential market. It is believed the largest growth will occur in patients receiving at least three lines of treatment because of the expanding elderly population, increases in treatment population and increasing rates of survival from earlier lines of treatment. According to data obtained from Decision Resource Group, over 40% of patients in later lines of therapy, while eligible, refuse treatment because of higher treatment failure, severity of adverse events and difficulty of treatment dosing regimen. The average response rates for patients receiving their fourth and fifth-line treatment are 15% and 8% response rates, respectively. Additionally, the mOS for these patients also decreases by line of therapy and is less than 9 months post third-line treatment.

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

B-Cell Non-Hodgkin's Lymphoma

B-cell Non-Hodgkin's Lymphoma (BCNHL) represents cancers of the lymphatic system. BCNHL may be indolent or aggressive and circulate in the blood or form tumors in lymph nodes. According to the American Cancer Society, the estimated 2023 US incidence of BCNHL was 68,468 cases. Nine types of B-cell lymphomas include CLL, SLL, MCL, MZL, and the most common lymphoma, DLBCL. According to a report dated June 2019 by Global Data Research Group, the BCNHL market was valued at $7.2 billion for 2022, with a forecasted increase to $11.7 billion in 2032 at a CAGR of 4.9%.

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

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

Neuroblastoma

Neuroblastoma, a neoplasm of the sympathetic nervous system, is the most common extracranial solid tumor of childhood, accounting for approximately 7-10% of childhood cancers and 50% of infant cancers, in the U.S. The NCI states the incidence is about 10.54 cases per 1 million per year in children younger than 15 years and 90% are younger than 5 years at diagnosis. Over 800 new cases are diagnosed each year in North America. Approximately 50% of patients present with metastatic disease requiring systemic treatment. Clinical consequences include abdominal distension, proptosis, bone pain, pancytopenia, fever and paralysis.

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

High Grade Glioma

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

Sarcomas

Sarcomas represent a heterogeneous disease group. Sarcomas grow in connective tissue, or cells that connect or support other kinds of tissue in the body. These tumors are most common in the bones, muscles, tendons, cartilage, nerves, and blood vessels. Sarcomas represent 15% of all pediatric tumors and 21% of pediatric solid tumors. The National Cancer Institute SEER database estimates that there were 2,060 incidences in 2019. The median age at diagnosis was 3, the median age of death was 5.

We are focused on 3 subsets of sarcomas:

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

Based on information from Market Insights, Epidemiology, and Market Forecast, the global market value of the pediatric sarcoma market is expected to nearly double from $490 million in 2022 to $1.01 billion in 2029. This growth is expected to be driven by the high rate of recurrence in pediatrics, increased incidence in select markets and new high-priced therapies coming to the market.

Manufacturing

The Company has built a collaborative outsourcing model for supply of all of its drug candidates and the key components. This model allows the Company to source each isotope and finished product through a decentralized and distributed network of contract manufacturers. As it relates to CLR 121225, it was announced in late 2024 that the one of the sources for actinium would be Northstar Medical Radioisotopes. The Company continues to collaborate with other sources and expects to announce additional supply agreements in 2025. The finished PRCs are currently supplied by either Atomvie or SpectronRx. Both organizations specialize in radiopharmaceutical production and can supply multiple different finished, ready-to-use radiotherapeutics simultaneously. Similar to the source of the isotopes, the Company expects to identify additional manufacturers of its PRCs as they advance through the clinic.

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

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

Sales and Marketing

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

Pancreatic cancer is one of the leading causes of cancer death globally with the treatment market size valued at $2.86 billion in 2023. The market is projected to grow from $3.30 billion in 2024 to $10.69 billion by 2032, exhibiting a CAGR of 15.8%. The U.S. pancreatic cancer treatment market size is projected to grow significantly, reaching an estimated value of $5.25 billion by 2032 and will represent nearly 50% of the global market. According to the American Cancer Society, in the United States, pancreatic cancer is expected to affect 67,440 people in 2025, with 51,980 deaths. According to the Pancreatic Cancer Action Network, the 5-year relative survival rate for pancreatic cancer is 13%. Pancreatic cancer affects men and women nearly equally.

Triple-negative breast cancer (TNBC) is an aggressive type of invasive breast cancer. TNBC differs from other types of invasive breast cancer in that it tends to grow and spread faster, has fewer treatment options, and tends to have a worse prognosis. The term triple-negative breast cancer refers to the fact that the cancer cells don't have estrogen or progesterone receptors (ER or PR) and also don't make any or much of the protein called HER2. According to DelveInsight, TNBC represents 15-20% of all breast cancers and occurs most frequently in women under the age of 40. According to Fact.MR the global TNBC treatment market size is estimated at $670.5 million in 2024 and thereafter increase at a CAGR of 4.6%, to reach $1.04 billion by the end of 2034. In the US it is estimated that in 2023 there was around 298,000 newly diagnosed cases of TNB. The 5-year relative survival rate is 77% across all stages of the disease.

The US WM market represents approximately $2.1 billion and is a very concentrated market, with 10 states harboring 60% of the WM cases. We are currently exploring options for the WM opportunity outside of the US market, which will seek to establish an arrangement with one or more biotechnology or pharmaceutical companies having strong product development and commercialization expertise and distribution infrastructure in Europe and parts of global markets.

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

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

Intellectual Property

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

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

We have taken a broad approach to creating market exclusivity for iopofosine both within the U.S., and globally, including all major markets. This approach includes numerous patents, patent applications and regulatory filings to provide maximum market

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

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

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

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

Licenses / Collaborations

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

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

Research and Development

Our primary activity to date has been research and development. Clinical development has been completed primarily through contract research organizations at hospitals and academic centers. We have established a collaboration outsourcing model to leverage third-party expertise, accelerate project timelines, improve productivity and limit spend and fixed costs. Our research and development expenses were approximately $27,266,000 and $18,266,000 for 2023 and 2022, respectively.

Regulation

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

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

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

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

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

Pre-Clinical Testing

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

Submission of IND

An IND must be submitted to the FDA and become effective before studies in humans may commence. An IND is an exemption from the FDCA that allows an unapproved new drug to be shipped in interstate commerce for use in an investigational clinical trial and

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

Clinical Studies

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

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

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

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

Submission of NDA

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

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

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

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

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

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

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

Expedited Approval Pathways

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as Fast Track designation, Breakthrough Therapy designation and Priority Review designation. In addition, accelerated approval offers the potential for approval based on a surrogate or intermediate clinical endpoint. In May 2014, the FDA published a final Guidance for Industry titled "Expedited

Programs for Serious Conditions Drugs and Biologics," which provides guidance on the FDA programs that are intended to facilitate and expedite development and review of new drug candidates as well as threshold criteria generally applicable to concluding that a drug candidate is a candidate for these expedited development and review programs.

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

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

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

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

Accelerated Approval Pathway

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

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

treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

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

Post NDA Regulation

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

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

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

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

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

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

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition, generally meaning that it affects fewer than 200,000 individuals in the US, or more in cases in which there is no reasonable

expectation that the cost of developing and making a drug product available in the US for treatment of the disease or condition will be recovered from sales of the product. A company must request ODD before submitting an NDA for the drug and rare disease or condition. ODD does not shorten the goal dates for the regulatory review and approval process, although it does convey certain advantages such as tax benefits and exemption from the application fee. After the FDA grants ODD, the name of the drug and its potential orphan-designated use are disclosed publicly by the FDA.

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

Pediatric Studies and Exclusivity

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

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

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

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

Abbreviated New Drug Applications for Generic Drugs

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

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

505(b)(2) New Drug Applications

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

Hatch-Waxman Patent Certification and the 30-month Stay

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

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

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory process. The allowable patent term extension is typically calculated as one-half the time between the effective date of an IND application and the submission date of a NDA, plus the time between NDA submission date and the NDA approval date up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed

14 years from the date of product approval. Only one patent applicable to an approved drug is eligible for extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent in question. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements.

Exclusivity Under the Hatch-Waxman Amendments

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

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

Other U.S. Regulatory Requirements

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

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

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

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program, including any third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements or representations, or making false statements relating to healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

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

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

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

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

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

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

Foreign Regulatory Requirements

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

Reimbursement and Pricing Controls

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

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

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

In addition to participating in the MDRP, federal law requires manufacturers to participate in the Public Health Service's 340B drug pricing program for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities only include health care organizations that have certain federal designations or receive funding from specific federal programs, including Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and certain types of hospitals and specialized clinics, as well as certain hospitals that serve a disproportionate share of low-income patients. The Affordable Care Act expanded the 340B program to include additional types of covered entities: certain children's hospitals, certain free-standing cancer hospitals, critical access hospitals, certain rural referral centers and certain sole community hospitals, each as defined by the Affordable Care Act. However, "orphan drugs" i.e., those designated under

section 526 of the federal Food, Drug, and Cosmetic Act (FDCA) are exempted from the ceiling price requirements for these eligible entities added by the Affordable Care Act (except for certain children's hospitals). The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the MDRP, and in general, products subject to the MDRP are also subject to the 340B ceiling price calculation and discount requirement. In addition, after multiple delays, the final rule implementing civil monetary penalties against manufacturers for instances of overcharging 340B covered entities became effective on January 1, 2019. Accordingly, we could be subject to such penalties if the government were to find that we knowingly and intentionally overcharged a 340B covered entity.

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

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

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

Significant uncertainty exists as to the pricing and reimbursement of products approved by the FDA and other government authorities. There have been several recent US Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. For example, included in the Consolidated Appropriations Act of 2021 were several drug price reporting and transparency measures, such as a new requirement for certain Medicare plans to develop tools to display Medicare Part D prescription drug benefit information in real time and for group and health insurance issuers to report information on pharmacy benefit and drug costs to the Secretaries of the Departments of Health and Human Services, Labor and the Treasury. Additionally, on March 11, 2021, Congress enacted the American Rescue Plan Act of 2021, which included among its provisions a sunset of the Affordable Care Act's cap on pharmaceutical manufacturers' rebate liability under the MDRP. Under the Affordable Care Act, manufacturers' rebate liability was capped at 100% of the average manufacturer price for a covered outpatient drug. Effective January 1, 2024, manufacturers' MDRP rebate liability will no longer be capped, potentially resulting in a manufacturer paying more in MDRP rebates than it receives on the sale of certain covered outpatient drugs. On February 2, 2022, the Biden Administration signaled its continued commitment to the Cancer Moonshot initiative, which was initially launched in 2016. In its announcement, the administration noted that its new goals under the initiative include addressing inequities in order to ensure broader access to cutting-edge cancer therapeutics and investing in a robust pipeline for new treatments. Additionally, in August 2022, President Biden signed into law the Inflation Reduction Act of 2022, which implements substantial changes to the Medicare program, including drug pricing reforms and creation of new Medicare inflation rebates. Namely, the IRA imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that, beginning in 2025, will cap beneficiary annual out-of-pocket spending at

$2,000, while imposing new discount obligations for pharmaceutical manufacturers; and beginning in 2026, establishes a "maximum fair price" for a fixed number of high expenditure pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with CMS. On October 14, 2022, President Biden issued an Executive Order on Lowering Prescription Drug Costs for Americans, which instructed the Secretary of the Department of Health and Human Services to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs. Most recently, on February 14, 2023, the Department of Health and Human Services issued a report in response to the October 14, 2022 Executive Order, which, among other things, selects three potential drug affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the report addresses: (1) a model that would allow Part D Sponsors to establish a "high-value drug list" setting the maximum co-payment amount for certain common generic drugs at $2; (2) a Medicaid-focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi-state outcomes-based agreements or certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments.

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

Employees and Human Capital

As of December 31, 2024, we had eleven employees, all of whom were full-time. Of these eleven employees, six employees were engaged in research and development. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

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

Legal Proceedings

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

Corporate Information

Cellectar Biosciences, Inc., formerly known as Novelos Therapeutics, Inc., was incorporated in Delaware in June 1996. On April 8, 2011, the Company entered into a business combination with Cellectar, Inc., a privately held Wisconsin corporation that designed and developed products to detect, treat and monitor a wide variety of human cancers. On February 11, 2014, we changed our name to Cellectar Biosciences, Inc.

Our principal executive offices are located at 100 Campus Drive, Florham Park, New Jersey 07932, and our telephone number is (608) 441-8120. Our corporate website address is www.cellectar.com. Information contained on or accessible through our website is not a part of this prospectus.

MANAGEMENT

Our executive officers and directors as of the date hereof are as follows:

Name	Age	Position
James V. Caruso	65	President, Chief Executive Officer and Director
Chad J. Kolean	60	Vice President, Secretary and Chief Financial Officer
Jarrod Longcor	51	Chief Operating Officer
Douglas J. Swirsky	54	Chairman of the Board(2)(3)
Asher Chanan-Khan, M.B.B.S., M.D.	56	Director(1)
Frederick W. Driscoll	74	Director(1)(3)
Stefan D. Loren, Ph.D.	60	Director(1)(2)
John Neis	69	Director(2)(3)

(1) Member of the Audit Committee.

(2) Member of the Nominating and Corporate Governance Committee.

(3) Member of the Compensation Committee.

James V. Caruso. Mr. Caruso has served as President, Chief Executive Officer and a director of the Company since June 2015. Mr. Caruso came to Cellectar from Hip Innovation Technology, a medical device company where he was a founder and served as Executive Vice President and Chief Operating Officer from August 2010 to June 2015, and he currently serves on their board. Prior to his time at Hip Innovation Technology, he was Executive Vice President and Chief Commercial Officer of Allos Therapeutics, Inc., an oncology company acquired by Spectrum Pharmaceuticals, from June 2006 to August 2010. He was also Senior Vice President, Sales and Marketing, from June 2002 to May 2005, at Bone Care International, Inc., a specialty pharmaceutical company that was acquired by Genzyme Corporation. In addition, Mr. Caruso has held key positions at several well-known pharmaceutical companies, including Novartis, where he was Vice President of Neuroscience Specialty Sales, BASF Pharmaceuticals-Knoll, where he was Vice President, Sales, and Bristol-Myers Squibb Company in several senior roles. Mr. Caruso earned a Bachelor of Science degree in Finance from the University of Nevada. Mr. Caruso's extensive experience in the biotechnology industry and his recent experience as our Chief Executive Officer make him a highly qualified member of our Board of Directors.

Chad J. Kolean. Mr. Kolean was appointed our Vice President and Chief Financial Officer in February 2022 and our Secretary in April 2022. Mr. Kolean has more than 30 years of experience at both public and private companies. Most recently, he served as Chief Financial Officer of Vivex Biologics, Inc., a developer, manufacturer and distributor of regenerative medical products from October 2019 to January 2022. Prior to his service at Vivex Biologics, Inc., Mr. Kolean served as Chief Financial Officer of Titan Spine, Inc., a designer, manufacturer and distributor of titanium spinal implants from September 2017 to September 2019 (Titan was acquired by Medtronic plc in June 2019). Prior to his time at Vivex, Mr. Kolean served as Chief Financial Officer of Cellectar from May 2014 to September 2017. Before that, Mr. Kolean served as Chief Financial Officer of Pioneer Surgical Technology, Inc., a global manufacturer and distributor of spinal, biological and orthopedic implants from April 2012 until its acquisition by RTI Biologics in July 2013, and Chief Accounting Officer from September 2011 to March 2012. Prior to Pioneer, Mr. Kolean was the Corporate Controller of TomoTherapy, Inc., a publicly traded developer and manufacturer of radiation oncology equipment from July 2010 to August 2011 (TomoTherapy merged with Accuray Incorporated in June 2011). Mr. Kolean also served as Director of Financial Reporting for Pioneer Surgical Technology, Inc. from March 2009 to July 2010. From 2001 to 2008, Mr. Kolean held a number of leadership positions at Metavante Corporation, a provider of banking and payments technologies and services to financial institutions, including: Director of Planning, Analysis and Reporting, Vice President and FSG Controller and Vice President of Shared Services. Prior to his tenure at Metavante, Mr. Kolean held leadership roles at Snap-On Inc., Herman Miller, Inc. and Kaydon Corporation. Mr. Kolean began his career at Arthur Andersen LLP where he practiced as a certified public accountant. Mr. Kolean holds a B.A. in Business Administration from Hope College.

Jarrod Longcor. Mr. Longcor was appointed Chief Operating Officer in February 2022. He previously served as Chief Business Officer from September 2017 to January 2022 and Senior Vice President of Corporate Development and Operations from July 2016 to August 2017. Mr. Longcor brings years of pharmaceutical and biotech experience to Cellectar and was previously the Chief Business Officer for Avillion LLP, a drug development company. In this role, he was responsible for executing the company's unique co-development partnership strategy. Prior to Avillion, Mr. Longcor was the Vice President of Corporate Development for Rib-X Pharmaceuticals, Inc. (now Melinta Therapeutics), a publicly-traded biopharmaceutical company where he was responsible for

identifying and concluding several critical collaborations for the company, including a major discovery collaboration with Sanofi Aventis valued over $700M. Prior to Rib-X, Mr. Longcor held key positions in several small to midsized biotech companies where he was responsible for business development, strategic planning and operations. Mr. Longcor holds a B.S. from Dickinson College, a M.S. from Boston University School of Medicine and an M.B.A. from Saint Joseph's University's Haub School of Business.

Douglas J. Swirsky. Mr. Swirsky has served as a director of the Company since April 2017 and as Chairman of the Board since August 2017. Since March 2023, Mr. Swirsky has served as Chief Financial Officer of MaxCyte, Inc., a publicly traded life sciences company. Prior to joining MaxCyte, Mr. Swirsky served as Chief Financial Officer and Treasurer of AavantiBio, Inc., a privately held biotechnology company from February 2021 to December 2022, and previously served as AavantiBio's Interim President and a director from May 2020 to October 2020. Prior to AavantiBio, Mr. Swirsky served as President, Chief Executive Officer and a director of Rexahn Pharmaceuticals, a clinical-stage biopharmaceutical company from November 2018 to November 2020, having previously served as Rexahn's President and Chief Financial Officer from January 2018 until his appointment as CEO. Prior to Rexahn, Mr. Swirsky served as President and Chief Executive Officer of GenVec, Inc., a clinical-stage biopharmaceutical company, from 2013 to June 2017. From 2006 until his appointment as CEO in 2013, Mr. Swirsky served as Senior Vice President, Chief Financial Officer, Treasurer and Corporate Secretary of GenVec. Mr. Swirsky previously held investment banking positions at Stifel, UBS, PaineWebber, Morgan Stanley, and Legg Mason. His experience also includes positions in public accounting and consulting. Mr. Swirsky received his undergraduate degree in business administration from Boston University and his M.B.A. from the Kellogg School of Management at Northwestern University. Mr. Swirsky is a Certified Public Accountant and a CFA® charterholder. Within the past five years, Mr. Swirsky has also served on the board of Fibrocell Science, Inc., Pernix Therapeutics Holdings, Inc. and NeuroBo Pharmaceuticals, Inc. Mr. Swirsky's distinguished career in financial services and corporate management, including his investment banking experience and his experience serving as a principal executive officer and principal financial officer, make him a highly qualified member of our Board of Directors. Mr. Swirsky has completed the NACD Directorship Certification® program, which is designed to enhance a director's ability to effectively contribute in the boardroom.

Asher Chanan-Khan, M.B.B.S., M.D. Dr. Chanan-Khan has served as a director of the Company since June 2021. Dr. Chanan-Khan currently serves as Professor of Medicine & Oncology at the Mayo Clinic School of Medicine, a position he has held since November 2011. He served as Chair, Department of Hematology & Oncology at the Mayo Clinic, Florida from October 2011 to January 2018. Prior to joining Mayo Clinic, Dr. Chanan-Khan spent over a decade as an attending physician at the Roswell Park Comprehensive Cancer Center. He was a tenured member of the Faculty of Medicine at the State University of New York (SUNY) Buffalo. Dr. Chanan-Khan received his Bachelor of Medicine and Bachelor of Surgery from the Allama Iqbal Medical College of Punjab University in Lahore Pakistan. He then completed an internship and residency in Internal Medicine from the College of Physicians & Surgeons at Columbia University in New York followed by fellowships in Hematology and Medical Oncology from New York University. In addition, he also completed a fellowship in translational research from Dr. Takeshita's laboratory at NYU. Dr. Chanan-Khan's extensive experience in oncology and hematology make him a highly qualified member of our Board of Directors.

Frederick W. Driscoll. Mr. Driscoll has served as a director of the Company since April 2017. Mr. Driscoll previously served as Interim CFO for Invivyd, Inc., a biopharmaceutical company developing antibody therapies for infectious diseases, a position he held from October 2022 until May 2023. Mr. Driscoll served as CFO of Renovacor from March to June in 2022, while the company was in the process of being sold to Rocket Pharmaceuticals. Mr. Driscoll served as Chief Financial Officer at Flexion Therapeutics, a biopharmaceutical company, from 2013 to 2017, spearheading an initial public offering in 2014. Prior to joining Flexion, he was Chief Financial Officer at Novavax, Inc., a publicly traded biopharmaceutical company, from 2009 to 2013. From 2008 to 2009, Mr. Driscoll served as Chief Executive Officer of Genelabs Technologies, Inc., a publicly traded biopharmaceutical and diagnostics company later acquired by GlaxoSmithKline. He previously served as Genelabs' Chief Financial Officer from 2007 to 2008. From 2000 to 2006, Mr. Driscoll served as Chief Executive Officer at OXiGENE, Inc., a biopharmaceutical company. Mr. Driscoll has also served as Chairman of the Board and Audit Committee Chair at OXiGENE and as a member of the Audit Committee for Cynapsus, a specialty central nervous system pharmaceutical company which was sold to Sunovion Pharmaceuticals in 2016. Mr. Driscoll earned a Bachelor's degree in accounting and finance from Bentley University. Mr. Driscoll is a member of the board of directors of Cue Biopharma and MEI Pharma and was a member of the board of directors of ImmunityBio, Inc. until March 2021. Mr. Driscoll's significant corporate management and board experience at multiple biotechnology companies as well as his strong financial background make him a highly qualified member of our Board of Directors.

Stefan D. Loren, Ph.D. Dr. Loren has served as a director of the Company since June 2015. Dr. Loren is currently a managing director with Oppenheimer and Company's healthcare investment banking group, a position he has held since November 2017. Prior to this position, he was the founder and managing member of Loren Capital Strategy (LCS), a strategic consulting and investment firm focused on life science companies since February 2014. Prior to LCS, he headed the life science practice of Westwicke Partners, a healthcare-focused consulting firm from July 2008 to February 2014. Prior to joining Westwicke, he worked as an Analyst/Portfolio Manager with Perceptive Advisors, a health care hedge fund, and MTB Investment Advisors, a long-term oriented family of equity funds. His focus areas included biotechnology, specialty pharmaceuticals, life science tools, and health care service companies. Prior to moving to the buy side, Dr. Loren was Managing Director, Health Care Specialist/Desk Analyst for Legg Mason where he discovered, evaluated, and communicated investment opportunities in the health care area to select clients. In addition, he assisted both advising management teams on strategic options. He started his Wall Street career as a sell side analyst at Legg Mason covering biotechnology, specialty pharmaceuticals, life science tools, pharmaceuticals, and chemistry outsourcing companies. In his research career, Dr. Loren was an early member of Abbott Laboratories Advanced Technologies Division, analyzing and integrating new technological advances in Abbott's pharmaceutical research. Prior to that, he was a researcher at The Scripps Research Institute, a nonprofit American medical research facility, working with Nobel Laureate K. Barry Sharpless on novel synthetic routes to chiral drugs. Dr. Loren received a doctorate in Organic Chemistry from the University of California at Berkeley and an undergraduate degree in Chemistry from UCSD. His scientific work has been featured in Scientific American, Time, Newsweek, and Discover, as well as other periodicals and journals. Dr. Loren's extensive experience in the biotechnology and financial industries make him a highly qualified member of our Board of Directors.

John Neis. Mr. Neis has served as a director of the Company since April 2011 and served as a director of our predecessor company since 2008. Mr. Neis is a Managing Director of Venture Investors LLC, a healthcare-focused venture capital firm, a position he has held since 2021. He led the firm and headed the firm's Health Care practice from 2000 to 2021. He serves on the Board of Directors of privately held Delphinus Medical Technologies, Inc. and Health Scholars, Inc. He also serves on the Board of Directors of the National Venture Capital Association and the Wisconsin Technology Council, the science and technology advisor to Wisconsin's Governor and Legislature. He serves on the Board of Trustees at the Morgridge Institute for Research. He also serves on the Weinert Applied Ventures Program Advisory Board in the School of Business and chairs the Tandem Press Advisory Board in the School of Education at the University of Wisconsin – Madison. He holds a B.S. in finance from the University of Utah, and received a M.S. in Marketing and Finance from the University of Wisconsin – Madison. He is a Chartered Financial Analyst. Mr. Neis' extensive experience leading emerging companies and his financial experience makes him a highly qualified member of our Board of Directors.

CORPORATE GOVERNANCE

Classified Board of Directors

Our Board consists of six members and is divided into three classes of directors that serve staggered three-year terms. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the same class whose term is then expiring. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

Director Independence

Our Board of Directors has determined that, with the exception of Mr. Caruso, who is our employee, all of the members of our Board of Directors are "independent directors" under the applicable rules and regulations of the SEC and the listing requirements of the Nasdaq Stock Market. Our Board of Directors has also determined that each member of our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee is an "independent director" under the rules of the Nasdaq Stock Market applicable to such committees.

Board Leadership Structure

The Board does not have a formal policy on whether the roles of Chairman of the Board and Chief Executive Officer should be separate and believes that it should retain the flexibility to make this determination in the manner it believes will provide the most appropriate leadership for our Company from time to time. Currently, we split these positions with Douglas Swirsky serving as Chairman of the Board and James V. Caruso serving as Chief Executive Officer. We believe that our current separation of the positions of Chairman of the Board and Chief Executive Officer reinforces the independence of our board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of our board of directors as a whole.

The duties of our independent Chairman include the following:

- Oversee that governance policies and practices are in place.
- Approve board of directors meeting agenda.
- Work with committee chairs to set committee agendas, considering strategic issues facing the Company, and with input from other directors and the CEO.
- Preside over board of directors and annual shareholder meetings.
- Attend committee meetings as appropriate.
- Coordinate effective communication between respective committee chairs and management.
- Oversee orientation for new directors and ongoing education for directors.
- Oversee that the board of directors receives accurate, timely, and clear information on:
    - The Company's performance;
    - The issues, challenges, and opportunities facing the Company; and
    - Matters reserved to it for decision.
- Facilitate effective communication and constructive relationships between the board of directors and management.
- Serve as spokesperson for the board of directors.

- Meet with shareholders when engagement requested.

Board Committees

Our Board has established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each committee operates pursuant to a written charter. The composition and responsibilities of each of the committees of our Board of Directors are described below and copies of the charters are available on our website at www.cellectar.com.

Audit Committee. Our Audit Committee is currently composed of Mr. Driscoll (Chairman), Dr. Chanan-Khan and Dr. Loren. The Board has determined that each member of our Audit Committee is independent within the meaning of Rule 10A-3 under the Exchange Act. The Board has also determined that Mr. Driscoll is an "audit committee financial expert" within the meaning of the applicable SEC rules and regulations. The Audit Committee provides the opportunity for direct contact between our independent registered public accounting firm and members of the Board, and the independent registered public accounting firm reports directly to the Audit Committee. The Audit Committee assists the Board in overseeing the integrity of our financial statements, our compliance with legal and regulatory requirements, and our independent registered public accounting firm's qualifications, independence and performance. The Audit Committee is directly responsible for appointing, compensating, evaluating and, when necessary, terminating our independent registered public accounting firm. The Audit Committee has established procedures for the treatment of complaints regarding accounting, internal accounting controls or auditing matters, including procedures for the confidential and anonymous submission by our employees of concerns regarding questionable accounting, internal accounting controls or auditing matters. Our Audit Committee met four times during the fiscal year ended December 31, 2024.

Compensation Committee. Our Compensation Committee is currently composed of Mr. Neis (Chairman), Mr. Driscoll and Mr. Swirsky. The Board has determined that each member of our Compensation Committee is independent under the Nasdaq listing standards and a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act. The Compensation Committee's responsibilities include providing recommendations to the Board regarding the compensation levels of directors; approving, or recommending for approval by the Board, the compensation levels of executive officers; providing recommendations to our Board regarding compensation programs; administering our incentive compensation plans and equity-based plans; authorizing grants under our 2021 Plan; and authorizing other equity compensation arrangements. Our Compensation Committee met two times during the fiscal year ended December 31, 2024. The Compensation Committee shall have the authority to retain, at Company expense, independent advisers (including legal counsel, accountants and independent compensation or other consultants) as it determines necessary to carry out its duties, and shall be directly responsible for the appointment, compensation and oversight of the work of any compensation consultant, legal counsel and other adviser retained by the Committee. In 2021, the Compensation Committee retained Aon/Radford as an independent consultant to advise it on compensation matters. Aon/Radford was engaged directly by and reported directly to our Compensation Committee and did no other work for the Company. The Compensation Committee considered the applicable Nasdaq listing rules and determined that Aon/Radford qualified as an independent compensation consultant in accordance with applicable SEC and Nasdaq listing rules and regulations.

Nominating and Corporate Governance Committee. Our Nominating and Corporate Governance Committee is currently composed of Dr. Loren (Chairman), Mr. Neis and Mr. Swirsky. The Board has determined that each member of our Nominating and Corporate Governance Committee is independent under the applicable Nasdaq listing standards. The Nominating and Corporate Governance Committee's responsibilities include, to the extent deemed necessary or appropriate by the committee: developing and recommending to the Board criteria for the selection of individuals to be considered as candidates for election to the Board; identifying individuals qualified to become members of the Board; making recommendations to the Board regarding its size and composition; approving director nominations to be presented for stockholder approval at the Company's annual meeting; approving nominations to fill any vacancies on the Board; and developing and recommending corporate governance principles to the Board. Our Nominating and Corporate Governance Committee met once during the fiscal year ended December 31, 2024.

Director Qualification Standards

The process followed by the Nominating and Corporate Governance Committee to identify and evaluate director candidates includes requests to the Board members and others for recommendations, meetings from time to time to evaluate biographical information and background materials relating to potential candidates, and interviews of selected candidates by members of the committee and other members of the Board. The committee may also solicit the opinions of third parties with whom the potential candidate has had a business relationship. Once the committee is satisfied that it has collected sufficient information on which to base a judgment, the committee votes on the candidate or candidates under consideration.

In evaluating the qualifications of any candidate for director, the Nominating and Corporate Governance Committee considers, among other factors, the candidate's depth of business experience, reputation for personal integrity, understanding of financial matters, familiarity with the periodic financial reporting process, reputation, degree of independence from management, possible conflicts of interest and willingness and ability to serve. The Nominating and Corporate Governance Committee also considers the degree to which the candidate's skills, experience and background complement or duplicate those of our existing directors and the long-term interests of our stockholders. The Nominating and Corporate Governance Committee considers factors such as gender, ethnicity/race and other characteristics when evaluating how a candidate for director could contribute to the diversity of the Board. In the case of incumbent directors whose terms are set to expire, the Nominating and Corporate Governance Committee also gives consideration to each director's prior contributions to the Board. In selecting candidates to recommend for nomination as a director, the Nominating and Corporate Governance Committee abides by our company-wide non-discrimination policy.

The Nominating and Corporate Governance Committee will consider director candidates recommended by stockholders and uses the same process to evaluate candidates regardless of whether the candidates were recommended by stockholders, directors, management or others. We suggest that stockholders make recommendations by writing to the chairman of the Nominating and Corporate Governance Committee, in care of our offices, with sufficient information about the candidate, his or her work experience, his or her qualifications for director, and his or her references to enable the Nominating and Corporate Governance Committee to evaluate the candidacy properly. We also suggest that stockholders make their recommendations well in advance of the anticipated mailing date of our next proxy statement so as to provide the Nominating and Corporate Governance Committee an adequate opportunity to complete a thorough evaluation of the candidacy, including personal interviews. Stockholders may also directly nominate director candidates through the procedures set forth in our by-laws.

Code of Business Conduct and Ethics

We have adopted a Code of Ethics (the "Code") applicable to our employees, officers and directors. A copy of our Code is available on our principal corporate website at *www.cellectar.com*. Amendments to the Code or waivers of this Code may be made only by the Audit Committee and the Board of Directors and must be promptly disclosed to stockholders as required by Nasdaq listing rules, SEC regulation or any other law or regulation.

Compensation Committee Interlocks and Insider Participation

None of the members of our Compensation Committee is or has been an officer or employee of us or any of our subsidiaries. In addition, none of our executive officers serves or has served as a member of the Board of Directors, Compensation Committee or other board committee performing equivalent functions of any entity that has one or more executive officers serving as one of our directors or on our Compensation Committee.

Role of the Board in Risk Oversight

Management is responsible for the day-to-day management of the risks that we face, while our Board, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, the Board is responsible for satisfying itself that our risk management processes are adequate and functioning as designed. Our Board's involvement in risk oversight includes receiving regular reports from members of management and evaluating areas of material risk, including operational, cybersecurity and technology, financial, legal and compliance, regulatory, strategic and competitive, and brand and reputational risks. As a smaller reporting company with a small Board of Directors, we believe it is appropriate to have the involvement and input of all of our directors in risk oversight matters. In addition, the Board has delegated risk oversight to each of its committees within their areas of responsibility. Our Compensation Committee assists the Board in its risk oversight function by overseeing strategies related to our incentive compensation programs and key employee retention. Our Audit Committee assists the Board in its risk oversight function by reviewing our system of disclosure controls and procedures and our internal control over financial reporting. Our Nominating and Corporate Governance Committee assists the Board in its risk oversight function by managing risks associated with director candidate selection, governance and succession matters. Our Nominating and Corporate Governance Committee also oversees the Company's environmental, sustainability and governance (ESG) efforts and related risks.

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

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

As of December 31, 2024, we had not identified any cybersecurity threats or intrusions that have materially affected our strategy, results of operations or financial condition. We and our third-party service providers have, however, been the target of cybersecurity threats and we expect these threats to continue.

Evaluations of the Board of Directors

The Board of Directors evaluates its performance and the performance of its committees and individual directors on an annual basis through an evaluation process administered by our Nominating and Corporate Governance Committee. The Board of Directors discusses each evaluation to determine what, if any, actions should be taken to improve the effectiveness of the Board of Directors or any committee thereof or of the directors.

Meetings of the Board of Directors

Board Meetings. Our Board of Directors held five meetings during the fiscal year ended December 31, 2024. Each of our directors attended all of the meetings held by the Board and the committees of the Board on which he served during the fiscal year ended December 31, 2024.

Meetings of Independent Directors. Our independent directors are expected, but not required, to meet without management present at least twice per year.

Director Attendance at the Annual Meeting of Stockholders

We encourage our director to attend our annual meetings of stockholders. All of our directors attended the 2024 annual meeting of stockholders.

Prohibition on Hedging and Pledging of Company Securities

We maintain an insider trading policy that applies to our officers, directors and employees that prohibits them from engaging in speculative transactions in our securities, such as short sales, puts, calls, straddles, hedging or monetization transactions, including but not limited to prepaid variable forwards, equity swaps, collars and exchange funds, or similar transactions. Since the adoption of our insider trading policy, the Audit Committee has not granted any such exemptions to the policy's general prohibition on hedging and pledging.

Communications with the Board

Stockholders and interested parties wishing to communicate with the Board or any director or group of directors should direct their communications to: Secretary, Cellectar Biosciences, Inc., 100 Campus Drive, Florham Park, New Jersey 07932. The Secretary will forward the stockholder or interested-party communication to the Board or to any individual director or directors to whom the communication is directed; provided, however, that if the communication is unduly hostile, profane, threatening, illegal or otherwise inappropriate, the Secretary has the authority to discard the communication and take any appropriate legal action.

COMPENSATION OF EXECUTIVE OFFICERS AND DIRECTORS

Executive Compensation

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

The following table sets forth certain information concerning all cash and non-cash compensation awarded to, earned by or paid to our each of NEOs for the years ended December 31, 2024 and 2023:

2024 Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Stock Awards ($)(1)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($) (2)	All Other Compensation ($)	Total ($)
James V. Caruso	2024	650,000	––	2,214,000	––	––	2,864,000
President and Chief Executive Officer	2023	600,000	107,582	715,140	450,000	92,418	1,965,140
Jarrod Longcor	2024	500,000	––	1,230,000	––	––	1,730,000
Chief Operating Officer	2023	480,000	113,758	394,560	288,000	86,242	1,362,560
Chad J. Kolean	2024	425,000	––	713,400	––	––	1,138,400
Chief Financial Officer	2023	390,000	112,770	284,960	234,000	87,230	1,108,960

(1) The reported amounts represent the aggregate grant date fair value computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation-Stock Compensation ("ASC 718"). In the case of stock awards, the grant date fair value was determined based on the stock price on the grant date. All assumptions made regarding the valuation of option awards can be referenced in Note 7 in the Notes to Restated Consolidated Financial Statements included in this prospectus. The amounts reported for 2024 include stock option awards to Messrs. Caruso, Longcor and Kolean with respect to 900,000 shares, 500,000 shares, and 290,000 shares, respectively, which awards were approved by the Compensation Committee on November 30, 2023, subject to stockholder approval of an amendment to the Company's 2021 Stock Incentive Plan (the "2021 Plan") at the 2024 annual meeting of stockholders. Because stockholder approval was received in 2024, these stock option awards are considered granted in 2024 under ASC 718 and are reflected as 2024 compensation in the 2024 Summary Compensation Table.

(2) Amounts in this column represent bonuses approved by the Compensation Committee based on its annual review of the performance of the executive officers against predetermined financial and strategic objectives established for the year. NEOs are paid the same percentage upon the achievement of financial objectives and may be paid varied percentages upon the achievement of strategic objectives depending on the subject matter. Annual incentive bonuses for 2024 are not determinable as of the date of this prospectus. These determinations are expected to be made in February 2025 and will be disclosed on a Form 8-K.

Equity Awards

As described in Note (1) to the 2024 Summary Compensation Table above, on November 30, 2023 the Compensation Committee approved stock option awards to Messrs. Caruso, Longcor and Kolean with respect to 900,000 shares, 500,000 shares, and 290,000 shares, respectively, subject to stockholder approval of an amendment to the 2021 Plan at the 2024 annual meeting of stockholders. These options are scheduled to vest one-third on the first anniversary of the grant date and in 24 equal monthly installments thereafter, subject to continuous employment with the Company through each vesting date.

Employment Agreements

James V. Caruso. We entered into an employment agreement with Mr. Caruso as of June 15, 2015, as amended and restated on April 15, 2019, pursuant to which Mr. Caruso serves as President and Chief Executive Officer of the Company. Under the agreement, the Company pays Mr. Caruso a base salary that is adjusted from time to time. Mr. Caruso is also eligible for an annual bonus, based on performance, with an initial target of up to 50% of his base salary at the discretion of the Compensation Committee. If Mr. Caruso is terminated other than for cause or by Mr. Caruso for good reason within 12 months after a change in control (i.e. double trigger), he is entitled to severance in an amount equal to (i) 18 months of base salary, (ii) his then applicable target bonus payable over 18 months (a total of 1.5x the annual target bonus payable at the time of termination) and (iii) 18 months of payment or reimbursement of health insurance (equal to the premium paid by the Company prior to the date of termination), each payable in installments over 18 months. Following a termination of employment by the Company without cause or by Mr. Caruso for good reason that is not within 12 months after a change in control, Mr. Caruso is entitled to severance in an amount equal to 12 months base salary plus payment or reimbursement of health insurance for 12 months (equal to the premium paid by the Company prior to the date of termination). Each of the foregoing severance benefits is conditioned on Mr. Caruso's execution of a release agreement in favor of the Company.

Jarrod Longcor. We entered into an employment agreement with Mr. Longcor as of July 15, 2016, as amended and restated on April 15, 2019, and amended on November 10, 2019. Under the agreement, Mr. Longcor receives a base salary that may be adjusted from time to time. Mr. Longcor is eligible for an annual bonus, based on performance, with an initial target of up to 30% of his base salary. If Mr. Longcor's employment is terminated other than for cause or by Mr. Longcor for good reason, contingent upon the execution of a release agreement in favor of the Company, Mr. Longcor is entitled to (i) severance in an amount equal to nine months of 75% of Mr. Longcor's annual base salary, provided that if such termination occurs within 12 months after a change in control (i.e. double trigger), such severance is increased to 12 months of Mr. Longcor's full base salary, each payable in monthly installments, (ii) payment or reimbursement of health insurance (for nine or 12 months, as applicable), each payable in monthly installments, (iii) a payment amount equal to the annual bonus Mr. Longcor would have received for the calendar year in which the termination occurred prorated for the number of days elapsed in such year, and (iv) outplacement services not to exceed $7,500.

Chad J. Kolean. We entered into an employment agreement with Mr. Kolean as of February 22, 2022. Pursuant to his employment agreement, Mr. Kolean receives a base salary that may be adjusted from time to time and is eligible to receive an annual performance bonus with a target amount equal to 40% of his base salary. In the event of a dismissal without cause or resignation by Mr. Kolean for good reason, Mr. Kolean will be entitled to nine months of severance. In the event of dismissal without cause or resignation by Mr. Kolean for good reason, within the twelve months following a change in control, Mr. Kolean will be entitled to eighteen months of severance.

2024 Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information with respect to outstanding equity awards as of December 31, 2024, with respect to our NEOs.

		Option Awards				Stock Awards	
Name	Date of Award	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option Exercise Price ($/share)	Option Expiration date	Number of Shares or Units of Stock that Have Not Vested (#)	Market Value of Shares or Units of Stock that Have Not Vested ($)
James V. Caruso	11/30/2023(1)	300,060	599,940	$ 2.65	11/30/2033	—	—
	1/17/2023(1)	333,518	188,482	$ 1.68	1/17/2033	—	—
	1/25/2022(1)	137,958	3,942	$ 5.50	1/25/2032	—	—
	3/4/2021	160,000	—	$ 17.40	3/4/2031	—	—
	2/3/2020	10,000	—	$ 27.10	2/3/2030	—	—
	1/17/2019	7,500	—	$ 19.90	1/17/2029	—	—
	10/12/2018	15,000	—	$ 26.10	10/12/2028	—	—
	5/12/2016	2,000	—	$ 148.00	5/12/2026	—	—
	6/15/2015	375	—	$ 2,640.00	6/15/2025	—	—
Jarrod Longcor	11/30/2023(1)	166,700	333,300	$ 2.65	11/30/2033		
	1/17/2023(1)	184,010	103,990	$ 1.68	1/17/2033	—	—
	1/25/2022(1)	46,180	1,320	$ 5.50	1/25/2032	—	—
	3/4/2021	45,000	—	$ 17.40	3/4/2031	—	—
	2/3/2020	4,000	—	$ 27.10	2/3/2030	—	—
	1/17/2019	3,000	—	$ 19.90	1/17/2029	—	—
	10/12/2018	6,300	—	$ 26.10	10/12/2028	—	—
	9/18/2017	250	—	$ 183.00	9/18/2027	—	—
	7/15/2016	750	—	$ 293.00	7/15/2026	—	—
Chad J. Kolean	11/30/2023(1)	96,686	193,314	$ 2.65	11/30/2033		
	1/17/2023(1)	132,896	75,104	$ 1.68	1/17/2033	—	—
	2/22/2022(2)	10,000	5,000	$ 4.90	2/21/2032	—	—

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

(2) These options are scheduled to vest annually in increments of one-third over three years from the date of grant.

Pursuant to the terms of the option award agreements, options granted pursuant to the Amended and Restated 2015 Stock Incentive Plan and the 2021 Plan become fully vested upon a termination event within one year following a change in control, as defined in such plans. A termination event is defined as either termination of employment other than for cause or constructive termination resulting from a significant reduction in either the nature or scope of duties and responsibilities, a reduction in compensation or a required relocation.

Policies and Practices Regarding Long-Term Incentive Awards

As described above, in November 2023, the Compensation Committee approved stock option awards to Messrs. Caruso, Longcor and Kolean with respect to 900,000 shares, 500,000 shares, and 290,000 shares, respectively, subject to stockholder approval of an amendment to the 2021 Plan at the 2024 Annual Meeting of Stockholders. Under ASC 718, these stock option awards are considered granted on June 14, 2024 because stockholder approval was received on such date. No other equity awards were granted to the NEOs in 2024. We attempt to make equity awards during periods when we do not have material non-public information ("MNPI") that could impact our stock price and we do not time the release of MNPI based on equity grant dates.

The following table presents information regarding stock options issued to our NEOs in 2024 during any period beginning four business days before the filing or furnishing of a periodic report or current report disclosing MNPI and ending one business day after the filing or furnishing of such report with the SEC.

Name	Grant Date(1)	Number of securities underlying the award	Exercise price of the award ($/share)	Grant date fair value of award	Percentage change in the closing market price of the securities underlying the award between the trading day ending immediately prior to the disclosure of material non-public information and the trading day beginning immediately following the disclosure of material non-public information
James V. Caruso	June 14, 2024	900,000	$ 2.65	$ 2,214,000	(13.7)%
Jarrod Longcor	June 14, 2024	500,000	$ 2.65	$ 1,230,000	(13.7)%
Chad J. Kolean	June 14, 2024	290,000	$ 2.65	$ 713,400	(13.7)%

(1) As noted above, these grants were approved by the Compensation Committee in November 2023, with the exercise price set at the time of approval. Because these grants were subject to stockholder approval at the Company's 2024 Annual Meeting of Stockholders, the grant date is June 14, 2024 under ASC 718. On June 14, 2024, the Company issued a Current Report on Form 8-K reporting the adoption of the amendment to the 2021 Plan as well as the voting results for the Company's 2024 Annual Meeting of Stockholders.

Risks Related to Compensation Policies and Practices

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

2024 Director Compensation

The following table sets forth certain information about the compensation of our non-employee directors who served during the year ended December 31, 2024:

Name	Year	Director Fees ($)[1]	Option Awards ($)[2]	Total ($)
Asher Chanan-Khan, M.B.B.S., M.D.	2024	$ 60,000	$ 148,200	$ 208,200
Frederick W. Driscoll	2024	60,000	148,200	208,200
Stefan D. Loren, Ph.D.	2024	60,000	148,200	208,200
John Neis	2024	60,000	148,200	208,200
Douglas J. Swirsky	2024	90,000	222,300	312,300

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

(2) Granted on December 15, 2023, subject to stockholder approval of an amendment to the 2021 Plan at the 2024 annual meeting of stockholders. Because stockholder approval was received in 2024, these stock option awards are considered granted in 2024 under ASC 718 and are reflected as 2024 compensation in the 2024 Director Compensation Table. These stock options have an exercise price of $2.58 per share and fully vest on the first anniversary of the grant date, subject to continued service through applicable vesting date. The reported amounts represent the aggregate grant date fair value computed in accordance with ASC 718. All assumptions made regarding the valuation of equity awards can be referenced in Note 7 in the Notes to Restated Consolidated Financial Statements included in this prospectus.

During 2024, we paid each of our non-employee directors a quarterly cash fee of $15,000 ($22,500 for Mr. Swirsky). In addition, in December 2023, we granted to each non-employee director stock options to purchase 60,000 shares (90,000 shares for Mr. Swirsky), which were subject to the approval of an amendment to the 2021 Plan at the 2024 annual meeting of stockholders. Mr. Swirsky receives additional cash remuneration and option awards for his service as Chairman of the Board of the Company. We reimbursed directors for reasonable out-of-pocket expenses incurred in attending Board and committee meetings and undertaking certain matters on our behalf. Directors who are our employees do not receive additional fees for their service as directors.

The aggregate number of option awards outstanding as of December 31, 2024, for each non-employee director was as follows:

Name	Stock Options Outstanding
Asher Chanan-Khan, M.B.B.S., M.D.	100,600
Frederick W. Driscoll	107,650
Stefan D. Loren, Ph.D.	107,885
John Neis	107,885
Douglas J. Swirsky	161,925

CERTAIN RELATIONSHIPS AND RELATED-PERSON TRANSACTIONS

We do not have a written policy for the review, approval or ratification of transactions with related parties or conflicted transactions. When such transactions arise, they are referred to the Audit Committee for consideration or referred to the Board of Directors for consideration. Since January 1, 2022, we have not entered into or participated in any transactions in which the amount involved in the transaction exceeds or will exceed $120,000 and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or any immediate family member of, or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest, other than as described below.

Private Offering

On September 5, 2023, the Company entered into a securities purchase agreement with certain accredited investors, including ADAR1 Partners, LP, certain entities associated with AIGH Capital Management LLC, Laurence W. Lytton, certain entities associated with Nantahala Capital Management, LLC and certain entities associated with Rosalind Advisors, Inc., pursuant to which the Company agreed to issue and sell, in a private placement, (i) 1,225 shares of Series E-1 Convertible Voting Preferred Stock, par value $0.0001 per share (the "Series E-1 Preferred Stock"), (ii) Tranche A Warrants (the "Tranche A Warrants") to acquire shares of Series E-3 Convertible Voting Preferred Stock and (iii) Tranche B Warrants (the "Tranche B Warrants," together with the Tranche A Warrants, the "Warrants") to acquire shares of Series E-4 Convertible Voting Preferred Stock, par value $0.00001 per share (the "Series E-4 Preferred Stock" and together with the Series E-3 Preferred Stock, the "Warrant Shares") for an aggregate offering price of $24.5 million. ADAR1 Partners, LP, AIGH Capital Management LLC, Laurence W. Lytton, Nantahala Capital Management, LLC and Rosalind Advisors, Inc. are beneficial owners of more than 5% of our outstanding capital stock.

The securities issued and sold to ADAR1 Partners, LP consisted of (i) 162.5 shares of Series E-1 Preferred Stock (convertible to 1,785,714 shares of Common Stock), (ii) Tranche A Warrants to purchase 292.5 shares of Series E-3 Preferred Stock (convertible to 1,836,734 shares of Common Stock) and (iii) Tranche B Warrants to purchase 227.5 shares of Series E-4 Preferred Stock (convertible to 952,380 shares of Common Stock) for an aggregate offering price of $3.25 million (excluding any additional payments in connection with the exercise of the Tranche A Warrants or Tranche B Warrants).

The securities issued and sold to the entities associated with AIGH Capital Management LLC consisted of (i) 175 shares of Series E-1 Preferred Stock (convertible to 1,923,076 shares of Common Stock), (ii) Tranche A Warrants to purchase 315 shares of Series E-3 Preferred Stock (convertible to 1,978,021 shares of Common Stock) and (iii) Tranche B Warrants to purchase 245 shares of Series E-4 Preferred Stock (convertible to 1,025,641 shares of Common Stock) for an aggregate offering price of $3.5 million (excluding any additional payments in connection with the exercise of the Tranche A Warrants or Tranche B Warrants).

The securities issued and sold to Laurence W. Lytton consisted of (i) 160 shares of Series E-1 Preferred Stock (convertible to 1,758,241 shares of Common Stock), (ii) Tranche A Warrants to purchase 288 shares of Series E-3 Preferred Stock (convertible to 1,808,477 shares of Common Stock) and (iii) Tranche B Warrants to purchase 224 shares of Series E-4 Preferred Stock (convertible to 937,728 shares of Common Stock) for an aggregate offering price of $3.2 million (excluding any additional payments in connection with the exercise of the Tranche A Warrants or Tranche B Warrants).

The securities issued and sold to the entities associated with Nantahala Capital Management, LLC consisted of (i) 150 shares of Series E-1 Preferred Stock (convertible to 1,648,349 shares of Common Stock), (ii) Tranche A Warrants to purchase 270 shares of Series E-3 Preferred Stock (convertible to 1,695,446 shares of Common Stock) and (iii) Tranche B Warrants to purchase 210 shares of Series E-4 Preferred Stock (convertible to 879,119 shares of Common Stock) for an aggregate offering price of $3 million (excluding any additional payments in connection with the exercise of the Tranche A Warrants or Tranche B Warrants).

The securities issued and sold to the entities associated with Rosalind Advisors, Inc. consisted of (i) 350 shares of Series E-1 Preferred Stock (convertible to 3,846,153 shares of Common Stock), (ii) Tranche A Warrants to purchase 630 shares of Series E-3 Preferred Stock (convertible to 3,956,043 shares of Common Stock) and (iii) Tranche B Warrants to purchase 490 shares of Series E-4 Preferred Stock (convertible to 2,051,282 shares of Common Stock) for an aggregate offering price of $7 million (excluding any additional payments in connection with the exercise of the Tranche A Warrants or Tranche B Warrants).

In January 2024, the Company announced that all of the Tranche A Warrants were exercised in full.

On July 21, 2024, the Company entered into warrant exercise inducement offer letters (the "Inducement Letters") with certain accredited investors, including ADAR1 Partners, LP, certain entities associated with AIGH Capital Management LLC, Laurence W. Lytton, certain entities associated with Nantahala Capital Management, LLC, certain entities associated with Kingsbrook Partners LP, Triple Gate Partners, LP, Bigger Capital Fund, LP, District 2 Capital Fund, LP, Healthcare Opportunities Master Fund, LP, The Hewlett Fund, LP and certain entities associated with Rosalind Advisors, Inc., who are holders of the Tranche B Warrants, which were originally issued on September 8, 2023, pursuant to which such holders agreed to exercise for cash their Tranche B Warrants to purchase an amount of shares of the Series E-4 Preferred Stock which is convertible to 6,739,918 shares of the Company's common stock, in the aggregate, at a reduced, as-converted common stock exercised price of $2.52 per share, in exchange for the Company's agreement to issue new warrants: (i) the Tranche A inducement warrants are immediately exercisable at an exercise price of $2.52 per share and will expire the earlier of (a) ten trading days following the date of the Company's public announcement of written notification from the Food and Drug Administration (FDA) that the FDA has assigned a Prescription Drug User Fee Act goal date for review of iopofosine I 131 and (b) July 20, 2029; (ii) the Tranche B inducement warrants are immediately exercisable at an exercise price of $4.00 per share and will expire the earlier of (a) ten trading days following the date of the Company's public announcement of its receipt of written approval from the FDA of its New Drug Application for iopofosine I 131 and (b) July 20, 2029; and (iii) the Tranche C inducement warrants are immediately exercisable at an exercise price of $5.50 per share and will expire the earlier of (a) ten trading days following the date of the Company's public announcement that it has recorded quarterly gross revenues from sales of iopofosine I 131 in the United States in excess of $10 million and (b) July 20, 2029 (collectively, the "Inducement Warrants"). The Company received aggregate gross proceeds of approximately $19.4 million from the exercise of the Tranche B Warrants by such holders and the sale of the Inducement Warrants.

The Company agreed to file a registration statement covering the resale of the shares of common stock issuable upon exercise of the Inducement Warrants within 30 days of the date of the Inducement Letters. The Company also agreed with one of the investors, Rosalind Advisors, Inc., not to effect or agree to effect certain subsequent equity issuances until 60 days from the effectiveness of such registration statement, unless waived by Rosalind Advisors, Inc.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

As of January 27, 2025, there were 46,079,876 shares of our common stock outstanding, 111.11 shares of non-voting Series D Preferred Stock outstanding, and 35.60 shares of Series E Preferred Stock outstanding. The following table provides information regarding beneficial ownership of our common stock as of such date by:

- each person known by us to be the beneficial owner of more than 5% of our common stock;
- each of our directors;
- each executive officer named in the summary compensation table; and
- all of our current directors and executive officers as a group.

The persons named in this table have sole voting and investment power with respect to the shares listed, except as otherwise indicated. In these cases, the information with respect to voting and investment power has been provided to us by the security holder. The identification of natural persons having voting or investment power over securities held by a beneficial owner listed in the table below does not constitute an admission of beneficial ownership of any such natural person. Shares included in the "Right to Acquire" column consist of shares that may be purchased through the exercise of options or warrants that are exercisable within 60 days of January 27, 2025.

Unless otherwise indicated, the business address of each person listed in the table below is c/o Cellectar Biosciences, Inc., 100 Campus Drive, Florham Park, New Jersey 07932.

	Common Stock			
Name and Address of Beneficial Owner	Outstanding	Right to Acquire	Total	Percentage
Entities affiliated with Rosalind Advisors, Inc.[1]	—	7,472,745	7,472,745	9.99[1]%
Laurence W. Lytton[2]	503,296	3,452,174	3,955,470	7.99 %
ADAR1 Partners, LP[3]	545,708	2,716,062	3,261,770	6.68 %
Entities affiliated with Nantahala Capital Management, LLC[4][5][6]	—	2,507,125	2,507,125	5.16[4][5][6]%
James V. Caruso[7]	49,218	966,411	1,015,629	2.16 %
Jarrod Longcor[8]	53,141	456,190	509,331	1.09 %
Chad J. Kolean[9]	42,578	239,582	282,160	*
Frederick W. Driscoll	1,941	107,650	109,591	*
Asher Chanan-Khan, M.B.B.S., M.D.	—	100,600	100,600	*
Stefan D. Loren, Ph.D.	—	107,885	107,885	*
John Neis[10]	6,260	107,885	114,145	*
Douglas Swirsky	2,500	161,925	164,425	*
All directors and officers as a group (8 persons)	155,638	2,248,128	2,403,766	5.15 %

* Less than 1%

(1) Consists of (i) warrants to acquire 1,622,762 shares of Common Stock, (ii) 2,051,281 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (iii) 2,500,001 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iv) 1,298,701 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Each of Rosalind Advisors, Inc., Steven Salamon, and Gilad Aharon have shared voting and dispositive power with respect to these shares. The address for Rosalind Advisors, Inc., Rosalind Opportunities Fund I L.P., Mr. Salamon and Mr. Aharon is 15 Wellesley Street West, Suite 326, Toronto, Ontario, M4Y 0G7 Canada. The address for Rosalind Master Fund, L.P. is P.O. Box 309, Ugland House, Grand Cayman KY1-1104, Cayman Islands. The address of each of Investor Company ITF Rosalind Opportunities Fund I L.P and Investor Company ITF Rosalind Master Fund L.P. is c/o TD Waterhouse, 77 Bloor Street West, 3rd Floor, Toronto, ON M5S 1M2 Canada. Entities associated with Rosalind are subject to an ownership limitation of 9.99% of common stock.

(2) Consists of (i) 503,296 shares of Common Stock, (ii) warrants to acquire 777,897 shares of Common Stock, (iii) 937,728 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (iv) 1,142,857 shares of Common Stock issuable upon

exercise of Tranche B Inducement Warrants and (v) 593,692 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. The address of the stockholder is 467 Central Park West, New York, NY 10025.

(3) Consists of (i) 545,708 shares of Common Stock, (ii) 952,380 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (iii) 1,160,714 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iv) 602,968 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. The selling stockholder's address is 3503 Wild Cherry Drive, Building 9, Austin, TX 78738.

(4) Nantahala Capital Partners Limited Partnership holdings consist of (i) 152,145 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (ii) 185,426 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iii) 96,325 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Nantahala Capital Management, LLC is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of the selling stockholder as a General Partner, Investment Manager, or Sub-Advisor and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or the selling stockholder that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other purpose. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The business address for Nantahala Capital Partners Limited Partnership is 130 Main St., 2nd Floor, New Canaan, CT 06840.

(5) NCP RFM LP holdings consist of (i) 174,417 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (ii) 212,570 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iii) 110,426 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Nantahala Capital Management, LLC is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of the selling stockholder as a General Partner, Investment Manager, or Sub-Advisor and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or the selling stockholder that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other purpose. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The business address for NCP RFM LP is 130 Main St., 2nd Floor, New Canaan, CT 06840.

(6) Blackwell Partners LLC – Series A holdings consist of (i) 552,556 shares of Common Stock issuable upon exercise of Tranche A Inducement Warrants, (ii) 673,428 shares of Common Stock issuable upon exercise of Tranche B Inducement Warrants and (iii) 349,832 shares of Common Stock issuable upon exercise of Tranche C Inducement Warrants. Nantahala Capital Management, LLC is a Registered Investment Adviser and has been delegated the legal power to vote and/or direct the disposition of such securities on behalf of the selling stockholder as a General Partner, Investment Manager, or Sub-Advisor and would be considered the beneficial owner of such securities. The above shall not be deemed to be an admission by the record owners or the selling stockholder that they are themselves beneficial owners of these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other purpose. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The business address for Blackwell Partners LLC – Series A is 280 South Mangum Street, Suite 210, Durham, NC 27701.

(7) Shares in the "Right to Acquire" column consists of (i) 1,087 shares of common stock issuable upon the exercise of warrants held by Mr. Caruso and (ii) common stock issuable currently or within 60 days of January 27, 2025 upon exercise of options to purchase 965,324 shares of common stock issued to Mr. Caruso.

(8) Shares in the "Right to Acquire" column consists of (i) 3,260 shares of common stock issuable upon the exercise of warrants held by Mr. Longcor and (ii) common stock issuable currently or within 60 days of January 27, 2025 upon exercise of options to purchase 452,930 shares of common stock issued to Mr. Longcor.

(9) Shares in the "Right to Acquire" column consists of common stock issuable currently or within 60 days of January 27, 2025 upon exercise of options to purchase 239,582 shares of common stock issued to Mr. Kolean.

(10) Consists of shares of common stock held by Advantage Capital Wisconsin Partners I, Limited Partnership. Venture Investors LLC is the submanager and special limited partner of Advantage Capital Wisconsin Partners I, Limited Partnership. The investment decisions of Venture Investors LLC are made collectively by five managers, including Mr. Neis. Each such manager and Mr. Neis disclaim such beneficial ownership except to the extent of his pecuniary interest therein. The address of Mr. Neis is c/o Venture Investors LLC, 505 South Rosa Road, #201, Madison, Wisconsin 53719. Shares in the "Right to Acquire" column consists of common stock issuable currently or within 60 days of January 27, 2025 upon exercise of options to purchase 107,885 shares of common stock issued to Mr. Neis.

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 January 27, 2025, there were 100 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 Charter and By-Law Provisions

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

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

Amendments to By-laws. Our 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 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.

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

Notice Periods for Stockholder Meetings. Our by-laws provide that for business to be brought by a stockholder before an annual meeting of stockholders, the stockholder must give written notice to the corporation not 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 or the Chair of such meeting may postpone, reschedule or cancel any annual meeting of stockholders previously scheduled by the Board 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, the president or by our Board. These provisions could have the effect of delaying until the next stockholders' meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions may also discourage another person or entity from making a tender offer for our common stock, because that person or entity, even if it acquired a majority of our outstanding voting securities, would be able to take action as a stockholder only at a duly called stockholders' meeting, and not by written consent. Our certificate of incorporation requires the affirmative vote of the holders of at least 75% of our shares of capital stock issued and outstanding and entitled to vote to amend or repeal the provisions relating to prohibition on action by written consent and the calling of a special meeting of stockholders.

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

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

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

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

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

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

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

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

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

Transfer Agent and Registrar

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

Exchange Listing

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

Inducement Warrants

The Inducement Warrants overlying shares offered for resale under this prospectus were issued in three different tranches: the Tranche A Inducement Warrants, the Tranche B Inducement Warrants and the Tranche C Inducement Warrants.

The Tranche A Inducement Warrants are immediately exercisable at an exercise price of $2.52 per share and will expire the earlier of (i) ten (10) Trading Days following the date of the Company's public announcement of written notification from the Food and Drug Administration (FDA) that the FDA has assigned a Prescription Drug User Fee Act goal date for review of iopofosine I 131 and (ii) July 20, 2029. The Tranche A Inducement Warrants are exercisable for up to 6,739,918 shares of our common stock, subject to adjustments as described below.

The Tranche B Inducement Warrants are immediately exercisable at an exercise price of $4.00 per share and will expire the earlier of (i) ten (10) Trading Days following the date of the Company's public announcement of its receipt of written approval from the FDA of its New Drug Application for iopofosine I 131 and (ii) July 20, 2029. The Tranche B Inducement Warrants are exercisable for up to 8,214,278 shares of our common stock, subject to adjustments as described below.

The Tranche C Inducement Warrants are immediately exercisable at an exercise price of $5.50 per share and will expire the earlier of (i) ten (10) Trading Days following the date of the Company's public announcement that it has recorded quarterly gross revenues from sales of iopofosine I 131 in the United States in excess of $10 million and (ii) July 20, 2029. The Tranche C Inducement Warrants are exercisable for up to 4,267,152 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, 2023 and 2022, and for each of the two years in the period ended December 31, 2023, included 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 included 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.

All documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of the offering will be deemed to be incorporated by reference into this prospectus.

You should rely only on the information contained in this prospectus, as updated and supplemented by any prospectus supplement, or that information to which this prospectus or any prospectus supplement has referred you by reference. We have not authorized anyone to provide you with any additional information.

Any statement contained in a document incorporated or deemed to be incorporated by reference herein will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein modifies or supersedes such statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

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

INDEX TO FINANCIAL STATEMENTS FOR CELLECTAR BIOSCIENCES, INC.

FINANCIAL INFORMATION
Unaudited Consolidated Financial Statements

CELLECTAR BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 34,263,371	$ 9,564,988
Prepaid expenses and other current assets	1,635,818	888,225
Total current assets	35,899,189	10,453,213
Property, plant & equipment, net	910,131	1,090,304
Operating lease right-of-use asset	454,166	502,283
Other long-term assets	29,780	29,780
TOTAL ASSETS	$ 37,293,266	$ 12,075,580
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 8,304,311	$ 9,178,645
Warrant liability	11,929,242	16,120,898
Lease liability, current	80,821	58,979
Total current liabilities	20,314,374	25,358,522
Long-term lease liability, net of current portion	431,929	494,003
TOTAL LIABILITIES	20,746,303	25,852,525
COMMITMENTS AND CONTINGENCIES (Note 7)		
MEZZANINE EQUITY:		
Series D preferred stock, 111.11 shares authorized, issued and outstanding as of September 30, 2024 and December 31, 2023	1,382,023	1,382,023
STOCKHOLDERS' EQUITY (DEFICIT):		
Series E-2 preferred stock, 1,225.00 shares authorized; 149.60 and 319.76 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	2,188,434	4,677,632
Series E-3 preferred stock, 2,205.00 shares authorized; 202.50 and 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	4,369,317	—
Series E-4 preferred stock, 1,715.00 shares authorized; 714.00 and 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	7,057,793	—
Common stock, $0.00001 par value; 170,000,000 shares authorized; 40,566,534 and 20,744,110 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	406	207
Additional paid-in capital	246,536,080	182,924,210
Accumulated deficit	(244,987,090)	(202,761,017)
Total stockholders' equity (deficit)	15,164,940	(15,158,968)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 37,293,266	$ 12,075,580

The accompanying notes are an integral part of these condensed consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
OPERATING EXPENSES:				
Research and development	$ 5,493,496	$ 7,034,656	$ 19,927,019	$ 19,528,898
General and administrative	7,834,181	2,378,804	19,105,853	6,883,866
Total operating expenses	13,327,677	9,413,460	39,032,872	26,412,764
LOSS FROM OPERATIONS	(13,327,677)	(9,413,460)	(39,032,872)	(26,412,764)
OTHER INCOME (EXPENSE):				
Warrant issuance expense	(7,743,284)	(470,000)	(7,743,284)	(470,000)
Gain (loss) on valuation of warrants	6,088,355	(7,688,028)	3,583,440	(8,254,649)
Interest income	317,887	51,110	966,643	247,925
Total other expense	(1,337,042)	(8,106,918)	(3,193,201)	(8,476,724)
NET LOSS	$ (14,664,719)	$ (17,520,378)	(42,226,073)	$ (34,889,488)
NET LOSS PER SHARE — BASIC	$ (0.37)	$ (1.55)	(1.21)	$ (3.09)
NET LOSS PER SHARE — DILUTED	$ (0.40)	$ (1.55)	(1.39)	$ (3.09)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC	39,335,924	11,308,738	34,850,441	11,277,231
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — DILUTED	39,794,220	11,308,738	35,545,500	11,277,231

The accompanying notes are an integral part of these condensed consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)

	Series D Preferred Stock		Preferred Stock		Common Stock		Additional	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	Shares	Par Amount	Paid-In Capital	Deficit	Equity
Balance at December 31, 2022	111.11	$ 1,382,023	—	$ —	9,385,272	$ 94	$ 168,143,557	$ (159,990,407)	$ 8,153,244
Conversion of pre-funded warrants into common stock	—	—	—	—	355,235	3	—	—	3
Stock-based compensation	—	—	—	—	—	—	408,206	—	408,206
Net loss	—	—	—	—	—	—	—	(7,190,470)	(7,190,470)
Balance at March 31, 2023	111.11	1,382,023	—	—	9,740,507	97	168,551,763	(167,180,877)	1,370,983
Stock-based compensation	—	—	—	—	—	—	419,757	—	419,757
Net loss	—	—	—	—	—	—	—	(10,178,640)	(10,178,640)
Balance at June 30, 2023	111.11	1,382,023	—	—	9,740,507	97	168,971,520	(177,359,517)	(8,387,900)
Issuance of Series E-1 preferred stock, net of issuance costs (Note 6)	1,225.00	17,820,000	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	497,878	—	497,878
Exercise of warrants into common stock	—	—	—	—	177,877	2	649,248	—	649,250
Reclassification of pre-funded warrants to liability	—	—	—	—	—	—	(3,239,112)	—	(3,239,112)
Net loss	—	—	—	—	—	—	—	(17,520,378)	(17,520,378)
Balance at September 30, 2023	1,336.11	$ 19,202,023	—	$ —	9,918,384	$ 99	$ 166,879,534	$ (194,879,895)	$ (28,000,262)
Balance at December 31, 2023	111.11	$ 1,382,023	319.76	$ 4,677,632	20,744,110	$ 207	$ 182,924,210	$ (202,761,017)	$ (15,158,968)
Stock-based compensation	—	—	—	—	—	—	454,363	—	454,363
Conversion of pre-funded warrants into common shares	—	—	—	—	1,079,132	11	3,972,529	—	3,972,540
Exercise of warrants for preferred stock, net of issuance costs (Note 2)	—	—	2,205.00	47,577,000	—	—	—	—	47,577,000
Conversion of Series E-3 preferred stock into common stock	—	—	(1,575.00)	(33,983,571)	9,890,099	100	33,983,471	—	—
Exercise of warrants for common stock	—	—	—	—	547,177	5	2,298,138	—	2,298,143
Conversion of Series E-2 preferred stock into common stock	—	—	(82.26)	(1,203,346)	903,956	9	1,203,337	—	—
Retired shares	—	—	—	—	(8)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(26,641,983)	(26,641,983)
Balance at March 31, 2024	111.11	1,382,023	867.50	17,067,715	33,164,466	332	224,836,048	(229,403,000)	12,501,095
Stock-based compensation	—	—	—	—	—	—	799,249	—	799,249
Conversion of Series E-3 preferred stock into common stock	—	—	(427.50)	(9,224,112)	2,684,458	26	9,224,086	—	—
Net loss	—	—	—	—	—	—	—	(919,371)	(919,371)
Balance at June 30, 2024	111.11	$ 1,382,023	440.00	$ 7,843,603	35,848,924	$ 358	$ 234,859,383	$ (230,322,371)	$ 12,380,973
Stock-based compensation							1,534,054	—	1,534,054
Issuance of E-4 preferred stock net of issuance costs	—	—	1,610.00	15,914,632	—	—	—	—	15,914,632
Conversion of Series E-2 preferred stock into common stock	—	—	(87.90)	(1,285,851)	965,934	10	1,285,841	—	—
Conversion of Series E-4 preferred stock into common stock	—	—	(896.00)	(8,856,840)	3,750,909	38	8,856,802	—	—
Stock option exercise into common stock	—	—	—	—	767	—	—	—	—
Net loss	—	—	—	—	—	—	—	(14,664,719)	(14,664,719)
Balance at September 30, 2024	111.11	$ 1,382,023	1,066.10	$ 13,615,544	40,566,534	$ 406	$ 246,536,080	$ (244,987,090)	$ 15,164,940

The accompanying notes are an integral part of these condensed consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Nine Months Ended September 30,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (42,226,073)	$ (34,889,488)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	223,082	122,415
Stock-based compensation expense	2,787,666	1,325,841
Warrant issuance expense	7,743,284	470,000
Change in operating lease right-of-use asset	48,117	42,768
Change in fair value of warrants	(3,583,440)	8,254,649
Changes in:		
Prepaid expenses and other current assets	(747,593)	(408,790)
Lease liability	(40,232)	(34,815)
Accounts payable and accrued liabilities	(874,334)	2,336,146
Cash used in operating activities	(36,669,523)	(22,781,274)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant & equipment	(42,909)	(597,282)
Cash used in investing activities	(42,909)	(597,282)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of preferred stock and warrants, net of issuance costs	—	22,150,000
Proceeds from exercise of warrants, net of issuance costs	61,410,815	348,641
Cash provided by financing activities	61,410,815	22,498,641
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	24,698,383	(879,915)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	9,564,988	19,866,358
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 34,263,371	$ 18,986,443
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Settlement of warrants to equity	$ 7,410,000	$ —
Conversion of preferred stock to common stock	$ 54,553,720	$ —

The accompanying notes are an integral part of these condensed consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. NATURE OF BUSINESS AND ORGANIZATION

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

Going Concern — As an emerging growth company, the Company has, by design, incurred significant recurring losses and used net cash in its operations since its inception as it devotes substantially all of its efforts towards researching, developing and seeking approval for its product candidates to be commercialized in the marketplace. As a result of these efforts, the Company had an accumulated deficit of approximately $244,987,000 as of September 30, 2024, and incurred a net loss of approximately $42,226,000 during the nine months ended September 30, 2024. The Company expects it will continue to generate significant losses and use net cash for the foreseeable future, until such time that one or more of its product candidates are approved and successfully commercialized in the marketplace. While management believes one or more of the Company's product candidates will be approved and successfully commercialized in the marketplace, no assurance can be provided any products will be approved or commercialized in a profitable manner.

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

As of the date the accompanying consolidated financial statements were issued (the "issuance date"), the Company's available liquidity to fund the Company's operations over the next twelve months beyond the issuance date was limited to approximately $28.6 million of unrestricted cash and cash equivalents. Absent further action taken by management to increase its liquidity, the Company may be unable to fund its operations under normal course beyond the second quarter of 2025. To improve the Company's liquidity, management plans to secure additional outside capital via the sale of equity and/or debt securities or execute a strategic transaction. Management also plans to preserve liquidity, as needed, by implementing temporary cost saving measures. While management believes their plans will be successful, no assurance can be provided such plans will be effectively implemented over the next twelve months beyond the issuance date. In the event management's plans are not effectively implemented, the Company will be required to seek other alternatives which may include, among others, the sale of the Company or its assets, discontinuance of certain operations, a wind-down of operations and/or filing for bankruptcy protection.

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

The condensed consolidated financial statements have been prepared by Cellectar Biosciences, Inc. in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. Management believes the disclosures made in this document are adequate with respect to interim reporting requirements.

The accompanying Condensed Consolidated Balance Sheet as of December 31, 2023, has been derived from the Company's audited financial statements. The accompanying Condensed Consolidated Balance Sheet as of September 30, 2024, and the Condensed Consolidated Statements of Operations, Cash Flows, and the Consolidated Statements of Stockholders' Equity for the nine months ended September 30, 2024 and 2023, and the related interim information contained within the Notes to the Condensed Consolidated Financial Statements, have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and with the instructions, rules and regulations of the Securities and Exchange Commission (SEC) for interim financial information. Accordingly, they do not include all the information and the notes required by U.S. GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all adjustments which are of a nature necessary for the fair presentation of the Company's consolidated financial position as of September 30, 2024, and consolidated results of its operations, cash flows, and stockholders' equity for the nine months ended September 30, 2024 and 2023. The results for the nine months ended September 30, 2024, are not necessarily indicative of future results.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes thereto included in the Company's Form 10-K/A for the fiscal year ended December 31, 2023, which was filed with the SEC on October 29, 2024.

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

Use of Estimates — The preparation of the accompanying consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Significant estimates include the assumptions used in the accrual for potential liabilities, the valuation of the warrant liability, the valuation of debt and equity instruments, the valuation of stock options issued for services, and deferred tax valuation allowances. Actual results could differ from those estimates.

Property, Plant & Equipment — Property, plant & equipment are stated at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets (3 to 10 years). Leasehold improvements are depreciated over 64 months (their estimated useful life), which represents the full term of the lease at the time the leasehold improvements were capitalized. The Company's only long-lived assets are property, plant & equipment and right-of-use (ROU) assets. Periodically, and at a minimum annually, the Company evaluates long-lived assets for potential impairment. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. Such analyses necessarily involve judgement. The Company did not experience any events or changes in circumstances that indicate the carrying amount of the assets may not be recoverable as of September 30, 2024. There were no fixed asset impairment charges recorded during the nine months ended September 30, 2024 or 2023.

Right-of-Use (ROU) Asset and Lease Liabilities -The Company accounts for all material leases in accordance with FASB Accounting Standards Codification (ASC) Topic 842, Leases. ROU Assets are amortized over their estimated useful life, which represents the full term of the lease. See Note 8.

Stock-Based Compensation — The Company uses the Black-Scholes option-pricing model to calculate the grant-date fair value of stock option awards. The resulting compensation expense, net of forfeitures for awards that are not performance-based, is recognized on a straight-line basis over the service period of the award, which in the three and nine months ended September 30, 2024 and 2023, ranged from twelve months to three years.

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

Income Taxes — Income taxes are accounted for using the liability method of accounting. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement basis and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more-likely-than-not that some portion of the deferred tax assets will not be realized. Management has provided a full valuation allowance against the Company's gross deferred tax asset. Tax positions taken or expected to be taken in the course of preparing tax returns are required to be evaluated to determine whether the tax positions are more-likely-than-not to be sustained by the applicable tax authority. Tax positions deemed not to meet a more-likely-than-not threshold would be recorded as tax expense in the current year. There are no uncertain tax positions that require accrual to or disclosure in the financial statements as of September 30, 2024 and December 31, 2023.

Fair Value of Financial Instruments — The guidance under ASC Topic 825, Financial Instruments, requires disclosure of the fair value of certain financial instruments. Financial instruments in the accompanying financial statements consist of cash equivalents, prepaid expenses and other assets, accounts payable and accrued liabilities, and long-term obligations. The carrying amount of cash equivalents, prepaid expenses, other current assets and accounts payable approximate their fair value as a result of their short-term nature. (See Notes 2 and 3)

Warrants — The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity and ASC 815, Derivatives and Hedging. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require net cash settlement in a fundamental transaction outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding (see Note 2). If the warrants are liability-classified, valuation changes, as well as the cost to issue the warrants, are included in Other Income (Expense) in the financial statements (see Note 3). If these instruments are initially classified as either liabilities or equity and a subsequent assessment determines that the classification has changed, the Company reflects that change in the financial statements.

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

Concentration of Credit Risk — Financial instruments that subject the Company to credit risk consist of cash and cash equivalents on deposit with financial institutions. The Company's excess cash as of September 30, 2024 and December 31, 2023 is on deposit in interest-bearing accounts with well-established financial institutions. At times, such amounts may exceed the FDIC insurance limits. As of September 30, 2024, and December 31, 2023, uninsured cash balances totaled approximately $33,814,000 and $9,123,000, respectively.

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

During the nine months ended September 30, 2024 and 2023, the Company received approximately $602,000 and $1,314,000 in NCI grant funding under the grants described above, respectively, all of which was reported as a reduction of research and development expenses.

Recently Adopted Accounting Pronouncements Not Yet Adopted — In December 2023, the FASB issued Accounting Standards Update (ASU) No. 2023-09, Income Taxes (Topic 740)—Improvements to Income Tax Disclosures, which is intended to enhance the transparency and decision usefulness of income tax disclosures. Public business entities are required to adopt this standard for annual fiscal periods beginning after December 15, 2024, and early adoption is permitted. The Company is evaluating the impact the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280). The amendments in this update expand segment disclosure requirements, including new segment disclosure requirements for entities with a single reportable segment among other disclosure requirements. This update is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact that the adoption of ASU 2023 - 07 will have on its condensed consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. The amendments in ASU 2024-03 address investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating this guidance to determine the impact it may have on its condensed consolidated financial statements.

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

Restatement of Previously Issued Consolidated Financial Statements — During the third quarter of 2024 the Company determined that it was necessary to re-evaluate its accounting treatment for certain previously issued warrants and preferred stock. Additionally, the Company identified certain operating costs previously presented as research and development expenses which are more appropriately classified as general and administrative. In accordance with Staff Accounting Bulletins No. 99 (SAB No. 99) Topic 1.M, “Materiality” and SAB No. 99 Topic 1.N “Considering the Effects of Misstatements when Quantifying Misstatements in the Current Year Financial Statements,” the Company assessed the materiality of these errors to its previously issued consolidated financial statements. Based upon the Company’s evaluation of both quantitative and qualitative factors, the Company concluded the errors were material to the Company’s previously issued consolidated financial statements for the fiscal years ended December 31, 2023 and 2022, as well as those for the first quarter of 2024. Accordingly, this Form 10-Q presents the Company’s Restated Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2023 as reflected in the Company’s Form 10-K/A for the year ended December 31, 2023.

2. STOCKHOLDERS’ EQUITY

July 2024 Warrant Inducement

On July 21, 2024, the Company, entered into a warrant exercise inducement (the “Inducement”) with certain holders of its September 2023 Tranche B warrants, pursuant to which the holders agreed to exercise the warrants to purchase 1,610 shares of the Company’s Series E-4 Convertible Voting Preferred Stock, par value $0.00001 per share (the “Series E-4 preferred stock”) which is convertible to 6,739,918 shares of the Company’s common stock in the aggregate, at a reduced, as-converted common stock price of $2.52 per share, in exchange for the Company’s issuance of new warrants (the “Inducement Warrants”), with varying termination dates and exercise prices. The Company received gross proceeds of $19.4 million and net proceeds of $17.5 million.

The Inducement Warrants have the following terms:

- The 2024 Tranche A warrants have an exercise price of $2.52 and expire at the earlier of (i) ten (10) trading days following the date of the Company’s public announcement that the FDA has assigned a Prescription Drug User Fee Act goal date for review of iopofosine I 131, and (ii) July 21, 2029.

- The 2024 Tranche B warrants have an exercise price of $4.00 and expire at the earlier of (i) ten (10) trading days following the date of the Company's public announcement of its receipt of written approval from the FDA of its New Drug Application for iopofosine I 131, and (ii) July 21, 2029.

- The 2024 Tranche C warrants have an exercise price of $5.50 and expire at the earlier of (i) ten (10) trading days following the date of the Company's public announcement that it has recorded quarterly gross revenues from sales of iopofosine I 131 in the United States in excess of $10 million and (ii) July 21, 2029.

Due to a cash settlement feature that requires cash settlement in event of a fundamental transaction that is outside the Company's control resulting in a form of settlement inconsistent with that which would be received by other security holders, the warrants do not qualify under the equity classification guidance. As a result, and in accordance with the guidance in ASC 815, the warrants issued in July 2024 are deemed to be liabilities. All such liabilities are required to be presented at fair value, with changes reflected in financial results for the period. See Note 3 for the related valuation.

In accordance with the guidance above, the Company recorded the Inducement Warrants and preferred stock at their respective fair values. Utilizing valuation techniques described in Note 3 below, the Company computed the fair value of the Inducement Warrants as $12.0 million and recorded the preferred stock at approximately $15.9 million, which represented its fair value of $17.0 million less allocated issuance costs. The value of the preferred stock and Inducement Warrants sold exceeded the proceeds received by the Company and the fair value of the Tranche B warrants that were exercised in the transaction, which was approximately $2.6 million at the time of exercise. The value in excess of the net proceeds and the fair value of the Tranche B warrants of approximately $7.7 million is reflected in Other Expense.

Subsequent to the issuance of the Series E-4 preferred stock and prior to September 30, 2024, investors who held 896.00 shares of Series E-4 preferred stock converted them into 3,750,909 shares of common stock. There remain 714.00 shares of Series E-4 preferred stock outstanding as of September 30, 2024.

September 2023 Private Placement

On September 8, 2023, in a private placement with certain institutional investors, the Company issued 1,225 shares of Series E-1 preferred stock, along with Tranche A warrants to purchase 2,205 shares of Series E-3 preferred stock and Tranche B warrants to purchase 1,715 shares of Series E-4 preferred stock. Shares of Series E preferred stock were issued at a fixed price of $20,000 per share, resulting in gross proceeds of $24.5 million and net proceeds of approximately $22.2 million after placement agent fees and other customary expenses.

The conversion prices for the preferred stock are as follows: for the Series E-1 or E-2 preferred stock, $1.82 per share of common stock, or a total of 13,461,538 shares of common stock; for the Series E-3 preferred stock, $3.185 per share of common stock, or a total of 13,846,154 shares of common stock; and for the Series E-4 preferred stock, $4.7775 per share of common stock, or a total of 7,179,487 shares of common stock, in each case subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization. The warrants were exercisable as follows:

- Tranche A warrants, for an aggregate exercise price of $44.1 million, exercisable for Series E-3 preferred stock until the earlier of September 6, 2026, or 10 trading days after the Company's announcement of positive topline data from the Waldenstrom's macroglobulinemia CLOVER WaM pivotal trial; and,

- Tranche B warrants, for an aggregate exercise price of $34.3 million, exercisable for Series E-4 preferred stock until the earlier of September 6, 2028, or 10 days following the Company's public announcement of its receipt of written approval from the FDA of its New Drug Application for iopofosine I 131.

As of December 31, 2023, the Tranche A and Tranche B warrants did not qualify as derivatives; however, they did not meet the requirements necessary to be considered indexable in the Company's stock. As a result, and in accordance with the guidance in FASB ASC 815, the warrants were deemed to be liabilities. As of September 30, 2024, the Tranche B warrants do not qualify as derivatives and meet the requirements necessary to be considered indexable in the Company's stock. However, due to a cash settlement feature that requires cash settlement in event of a fundamental transaction that is outside the Company's control resulting in a form of settlement inconsistent with that which would be received by other security holders, the warrants do not qualify under the equity classification guidance. As a result, and in accordance with the guidance in ASC 815, the Tranche B warrants continue to be deemed

liabilities. All such liabilities are required to be presented at fair value, with changes reflected in financial results for the period. As discussed above, the majority of the Tranche B warrants were exercised in July 2024. See Note 3 for the related valuation.

When issued, the Series E-1 preferred stock had a redemption feature; therefore, it was classified as mezzanine equity as of September 30, 2023. The Series E-1 preferred stock also had a liquidation preference, which was calculated as an amount per share equal to the greater of (i) two times (2X) the Original Per Share Price, together with any declared, unpaid dividends, or (ii) such amount per share as would have been payable had all shares of Series E-1 preferred stock been converted into Common Stock immediately prior to such Liquidation. While the Series E-1 preferred was outstanding, this resulted in both the Tranche A and Tranche B warrants being considered puttable by virtue of the liquidation preference impacting the disposition of these warrants in the event of a liquidation. In accordance with the guidance in ASC 480, a puttable warrant is deemed to be a liability. These features only applied to the Series E-1 preferred stock when it was outstanding; upon stockholder approval of the transaction, which was obtained by the Company at a special meeting of stockholders held on October 25, 2023, the Series E-1 preferred stock immediately converted into either Series E-2 preferred stock and/or common stock, dependent upon the beneficial ownership position of the holder.

The net proceeds from the September 2023 Private Placement were allocated first to the fair value of the Tranche A and Tranche B warrants, which had a fair value upon issuance of $4,800,000, with the remainder, or $17,820,000, allocated to the Series E-1 preferred stock. Upon stockholder approval of the transaction, the entire amount that had been assigned to mezzanine equity was reclassified to Series E-2 preferred stock and is a component of permanent equity, as is reflected in the financial statements. As a result of the stockholder approval, Series E-1 preferred stock was fully extinguished in accordance with the terms of the financing. The outstanding shares of Series E preferred stock were classified as permanent equity upon issuance.

Series E preferred stock is convertible to common stock at the request of the holder, subject to the holder not exceeding certain beneficial ownership percentages as stipulated in the financing agreement. Subsequent to the issuance of the Series E-2 preferred stock and prior to December 31, 2023, preferred holders converted 905.24 shares of preferred stock into 9,947,684 shares of common stock at the stated rate of $1.82 per common share, resulting in 319.76 shares of Series E-2 preferred stock outstanding as of December 31, 2023.

During the nine months ended September 30, 2024, 170.16 shares of Series E-2 preferred stock were converted into 1,869,890 shares of common stock. There remain 149.60 shares of Series E-2 preferred stock outstanding as of September 30, 2024.

In January 2024, the Company released topline data from its pivotal, Phase 2b CLOVER WaM trial. In accordance with the terms of the Tranche A warrant, the warants' expiration accelerated to 10 trading days after the topline data release. Warrant holders exercised the Tranche A warrants in their entirety, resulting in the Company issuing 2,205.00 shares of Series E-3 preferred stock, which are convertible to common stock at the stated rate of $3.185 per share, and receiving gross proceeds of $44.1 million and net proceeds of $42.8 million (see Note 3).

During the nine months ended September 30, 2024, investors who held 2,002.50 shares of Series E-3 preferred stock converted them into 12,574,557 shares of common stock. There remain 202.50 shares of Series E-3 preferred stock outstanding as of September 30, 2024.

October 2022 Public Offering and Private Placement

On October 25, 2022, the Company completed a registered direct offering of 3,275,153 shares of the Company's common stock at $2.085 per share and warrants to purchase up to an aggregate of 3,275,153 shares of common stock in a concurrent private placement priced at-the-market under Nasdaq rules. In a separate concurrent private placement transaction, the Company offered and sold pre-funded warrants to purchase an aggregate of 1,875,945 shares of common stock and warrants to purchase an aggregate of 1,875,945 shares of common stock. The warrants are immediately exercisable at an exercise price of $1.96 per share and will expire on the fifth anniversary of the closing date. Each pre-funded warrant had a purchase price of $2.08499, is immediately exercisable at an exercise price of $0.00001 per share and will not expire until exercised in full. The registered direct offering and private placements resulted in total gross proceeds of approximately $10.7 million with net proceeds to the Company of approximately $9.6 million after deducting estimated offering expenses.

During the nine months ended September 30, 2024, 1,079,132 pre-funded warrants were converted into 1,079,132 shares of common stock, and 547,177 warrants issued in October 2022 were exercised for net proceeds of approximately $1.1 million. There were no such conversions or exercises in the nine months ended September 30, 2023.

Warrants

The following table summarizes information with regard to outstanding warrants to purchase stock as of September 30, 2024:

Offering	Number of Common Shares Issuable Upon Exercise of Outstanding Warrants	Exercise Price	Expiration Date
2024 Tranche A Warrants	6,739,918	$ 2.52	July 21, 2029
2024 Tranche B Warrants	8,214,278	$ 4.00	July 21, 2029
2024 Tranche C Warrants	4,267,152	$ 5.50	July 21, 2029
2023 Tranche B Preferred Warrants	439,560	$ 4.7775	September 8, 2028
2022 Common Warrants	4,201,044	$ 1.96	October 25, 2027
June 2020 Series H Common Warrants	720,796	$ 12.075	June 5, 2025
October 2017 Series D Common Warrants	31,085	$ 178.00	October 14, 2024
Total	24,613,833		

All warrants in the table above are liability-classified.

3. FAIR VALUE

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

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

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. The carrying value of cash and cash equivalents approximates fair value as maturities are less than three months. The carrying amounts reported for other current financial assets and liabilities approximate fair value because of their short-term nature. As of September 30, 2024, the Company does not have any Level 1 or Level 2 liabilities.

July 2024 Warrants

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

The 2024 Warrants are classified within the Level 3 hierarchy because of the nature of these inputs and the valuation technique utilized, and had a fair value of $12,000,000 and $6,900,000 as of July 21, 2024, the date of issuance, and September 30, 2024, respectively, which is included in the warrant liability caption on the accompanying balance sheets.

The following table summarizes the modified option-pricing assumptions used on September 30, 2024 and December 31, 2023:

	July 21, 2024	September 30, 2024
Volatility	75.9-82.0 %	80.6-83.0 %
Risk-free interest rate	4.10-4.20 %	3.50-3.60 %
Expected life (years)	0.7-5.0	0.5-4.8
Dividend	0 %	0 %

September 2023 Warrants

As part of the September 2023 financing (see Note 2) the Company issued Tranche A and Tranche B warrants (the 2023 Warrants) to purchase shares of preferred stock which, on an as-converted basis, represented an aggregate of 21,025,641 shares of common stock. The fair value of the Tranche A and B warrants was determined using a probability-weighted expected return method (PWERM) with a scenario-based Monte Carlo simulation and Black-Scholes model. The PWERM is a scenario-based methodology that estimates the fair value of the Company's different classes of equity based upon an analysis of future values for the Company, assuming various outcomes. Under both models, assumptions and estimates are used to value the preferred stock warrants. The Company assesses these assumptions and estimates on a quarterly basis as additional information that impacts the assumptions is obtained. The quantitative elements associated with the inputs impacting the fair value measurement of the 2023 Warrants include the value per share of the underlying common stock, the timing, form and overall value of the expected exits for the stockholders, the risk-free interest rate, the expected dividend yield and the expected volatility of the Company's shares. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared cash dividends. Expected volatility was determined based upon the historical volatility of the Company's common stock.

As previously described, all of the Tranche A warrants were exercised in January 2024. Additionally, in July 2024, the holders of the Tranche B warrants exercised all but 105.00 of the Tranche B warrants outstanding. As a result, those warrants were marked-to-market on July 21, 2024, the date of the exercise and subsequent settlement.

The 2023 Warrants are classified within the Level 3 hierarchy because of the nature of these inputs and the valuation technique utilized, and had a fair value of $30,000 and $4,200,000 as of September 30, 2024 and December 31, 2023, respectively, which is included in the warrant liability caption on the accompanying balance sheets.

The following table summarizes the modified option-pricing assumptions used on September 30, 2024 and December 31, 2023:

	September 30, 2024	December 31, 2023
Volatility	81.0-85.0 %	82.0-83.0 %
Risk-free interest rate	4.41 %	3.80-5.40 %
Expected life (years)	0.8-4.2	0.3-4.7
Dividend	0 %	0 %

At the time the Tranche A warrants were exercised, their fair value, calculated as the difference between the common stock conversion rate in the Series E-3 preferred stock and the trading price of the stock when the warrants were exercised, was determined to be $4,800,000. Due to the settlement of the Tranche A warrants relieving the Company of any further related obligation, the liability was reclassified to equity in accordance with ASC 815. The Tranche B warrants continue to be classified as a liability due to a cash settlement feature in the agreement.

October 2022 Warrants

In October 2022 the Company issued a total of 5,151,098 common warrants that are immediately exercisable with a five-year life and a strike price of $1.96 for shares of common stock (the 2022 Common Warrants), and 1,875,941 pre-funded warrants (the 2022 Pre-Funded Warrants) to acquire shares of common stock (see Note 6). The 2022 Pre-Funded Warrants are exercisable by the holder upon payment of the par value of the common stock and are classified as Level 2 liabilities as their value is equal to the Company's common stock value less the par value.

The fair value of the 2022 Common Warrants was determined by utilizing a Black-Scholes option-pricing model. The quantitative elements associated with the inputs impacting the fair value measurement of the 2022 Common Warrants include the value per share of the underlying common stock, the risk-free interest rate, the expected dividend yield and the expected volatility of the Company's shares. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared cash dividends. Expected volatility was determined based upon the historical volatility of the Company's common stock. These warrants are classified within the Level 3 hierarchy because of the nature of these inputs and the valuation technique utilized. The following table summarizes the assumptions used at each financial reporting date:

	September 30, 2024	December 31, 2023
Volatility	78.3 %	81.1 %
Risk-free interest rate	3.58 %	3.84 %
Expected life (years)	3.1	3.8
Dividend	0 %	0 %

The following table summarizes the changes in the fair market value of the warrants which are classified within the Level 3 fair value hierarchy.

	Level 3
Fair value of Level 3 liabilities as of December 31, 2023	$ 13,131,691
Change in warrant fair value	(4,566,773)
Issuance of July 2024 Inducement Warrants	12,000,000
Settlement of 2023 Tranche A Warrants to equity	(4,800,000)
Settlement of 2023 Tranche B Warrants to equity	(2,610,000)
Exercise of October 2022 Warrants	(1,225,676)
June 30, 2024, fair value of Level 3 liabilities	$ 11,929,242

4. STOCK-BASED COMPENSATION

Accounting for Stock-Based Compensation

2021 Stock Incentive Plans

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

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

At the annual meeting of stockholders held on June 14, 2024, the Company's stockholders approved an increase in the number of shares of common stock available for issuance under the 2021 Stock Incentive Plan by 7,000,000 to 9,368,900.

The following table summarizes amounts charged to expense for stock-based compensation related to employee and director stock option grants:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Employee and director stock option grants:				
Research and development	$ 309,933	$ 89,172	$ 453,158	$ 227,896
General and administrative	1,224,121	408,706	2,334,508	1,097,945
Total stock-based compensation	$ 1,534,054	$ 497,878	$ 2,787,666	$ 1,325,841

In December 2023, the Company granted 2,776,000 contingent, non-statutory stock option awards at an exercise price of $2.65 per share to employees and directors, and in March 2024 the Company granted 200,000 contingent, non-statutory stock option awards at an exercise price of $3.63 and $3.35 per share to our employees. Each of these grants was contingent on approval of an increase in the shares available in the 2021 Stock Incentive Plan that was approved by the stockholders at the annual meeting of stockholders held on June 14, 2024. In accordance with the removal of the contingency, the Company began recognizing the expense for these awards in June 2024.

Assumptions Used in Determining Fair Value

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

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

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

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

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

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

Exercise prices for all grants made during the nine months ended September 30, 2024 and September 30, 2023, were equal to the market value of the Company's common stock on the date of grant.

5. INCOME TAXES

The Company accounts for income taxes in accordance with the liability method of accounting. Deferred tax assets or liabilities are computed based on the difference between the financial statement and income tax basis of assets and liabilities, and net operating loss carryforwards ("NOLs"), using the enacted tax rates. Deferred income tax expense or benefit is based on changes in the asset or liability from period to period. The Company did not record a provision or benefit for federal, state or foreign income taxes for the nine months ended September 30, 2024 or 2023 because the Company has experienced losses on a tax basis since inception. Management has provided a full allowance against the value of its gross deferred tax assets in light of the continuing losses and uncertainty associated with the utilization of the NOLs in the future.

The Company also accounts for the uncertainty in income taxes related to the recognition and measurement of a tax position taken or expected to be taken in an income tax return. The Company follows the applicable accounting guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition related to the uncertainty in income tax positions. No uncertain tax positions have been identified.

6. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock and pre-funded warrants outstanding during the period. The pre-funded warrants are considered common shares outstanding for the purposes of the basic net loss per share calculation due to the nominal cash consideration and lack of other contingencies for issuance of the underlying common shares. Diluted net loss attributable to common stockholders per share is computed by dividing net loss attributable to common stockholders, as adjusted, by the sum of the weighted average number of shares of common stock and the dilutive potential common stock equivalents then outstanding. Potential common stock equivalents consist of stock options, warrants, and convertible preferred shares. In accordance with ASC Topic 260, Earnings per Share, diluted earnings per share are the amount of earnings for the period available to each share of common stock outstanding during the reporting period and to each share that would have been outstanding assuming the issuance of common shares for all dilutive potential common shares outstanding during the reporting period. In the quarter ended September 30, 2024, the common warrants issued in October 2022 were dilutive. In all other periods presented, all outstanding warrants were antidilutive.

Periods ended September 30, 2024	**Three Months**	**Nine Months**
Net loss	$ (14,664,719)	$ (42,226,073)
Dilutive effect of warrant liability	(1,428,355)	(7,283,786)
Net loss allocated to common shares	$ (16,093,074)	$ (49,509,859)
Weighted average common shares outstanding - basic	39,335,924	34,850,441
Dilutive effect of warrant liability	458,296	695,060
Weighted average common shares outstanding - diluted	39,794,220	35,545,500
Net loss per share - diluted	$ (0.40)	$ (1.39)

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

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2024	**2023**	**2024**	**2023**
Warrants	20,412,789	27,148,243	20,412,789	27,148,243
Preferred shares on an as-converted-into-common-stock basis	6,015,662	111,111	6,015,662	111,111
Stock options	5,359,624	2,280,756	5,359,624	2,280,756
Total potentially dilutive shares	31,788,075	29,540,110	31,788,075	29,540,110

7. COMMITMENTS AND CONTINGENCIES

Legal

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

8. LEASES

Operating Lease Liability

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

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

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

Discount Rate

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

Maturity Analysis of Short-Term and Operating Leases

The following table approximates the dollar maturity of the Company's undiscounted payments for its short-term leases and operating lease liabilities as of September 30, 2024:

Years ending September 30,		
Remaining period of 2024	$	36,000
2025		146,000
2026		150,000
2027		153,000
2028		155,000
Thereafter		53,000
Total undiscounted lease payments		693,000
Less: Imputed interest		(180,000)
Present value of lease liabilities	$	513,000

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cellectar Biosciences, Inc. and subsidiaries (the "Company") as of December 31, 2023 and December 31, 2022, the related consolidated statements of operations, statements of convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and December 31, 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Restatement of the 2023 and 2022 Financial Statements

As discussed in Notes 2 and 14 to the financial statements, the accompanying 2023 and 2022 financial statements have been restated to correct misstatements.

Going Concern

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

Basis for Opinion

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

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

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

Critical Audit Matter

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

Initial Accounting for the September 2023 Private Placement — Refer to Note 6 to the Financial Statements

Critical Audit Matter Description

In September 2023, in a private placement with certain institutional investors, the Company issued 1,225 shares of Series E-1 preferred stock, along with Tranche A warrants to purchase 2,205 shares of Series E-3 preferred stock and Tranche B warrants to purchase 1,715 shares of Series E-4 preferred stock. Shares of Series E preferred stock were issued at a fixed price of $20,000 per share, resulting in gross proceeds of $24.5 million and net proceeds of approximately $22.2 million, of which $4,800,000 million was allocated to the warrants.

The warrants were deemed to be liabilities and are adjusted to fair value each reporting period. When issued, the Series E-1 preferred stock had a redemption feature; therefore, it was classified as mezzanine equity as of September 30, 2023. Upon stockholder approval of the transaction, the entire amount that had been assigned to mezzanine equity was reclassified to Series E-2 preferred stock and is a component of permanent equity, as is reflected in the financial statements. As a result of the stockholder approval, Series E-1 preferred stock was fully extinguished in accordance with the terms of the financing.

We identified the assessment of the initial accounting for the September 2023 Private Placement as a critical audit matter because of the complexity in applying the accounting framework and the significant judgments made by management in the determination of the classification of the preferred stock and the classification and valuation of the Tranche A and B warrants. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of management's classification, as well as the valuation of the warrants.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the classification of the preferred stock and the warrants and the valuation of the warrants included the following, among others:

- We read the agreements associated with the September 2023 Private Placement and tested the accuracy and completeness of the significant terms identified by management for purposes determining the appropriate accounting treatment, including the classification of the preferred stock and the Tranche A and B warrants, and the valuation of the warrants.
- With the assistance of professionals in our firm having expertise in the accounting treatment for financial instruments, we evaluated the Company's conclusions regarding the accounting treatment applied to preferred stock and Tranche A and B warrants.
- With the assistance of our fair value specialists, we evaluated management's valuation of the Tranche A and B warrants by:
    - Evaluating management's use of the Monte Carlo simulation methodology
    - Testing the significant valuation assumptions, including the expected volatility, the expected life and dividend yield.
    - Independently calculating a fair value estimate for the Tranche A and B warrants and comparing our estimates to management's estimates.

Initial Accounting for the October 2022 Public Offering and Private Placement — Refer to Note 6 to the financial statements

Critical Audit Matter Description

In October 2022, the Company completed a registered direct offering of 3,275,153 shares of its common stock and warrants to purchase up to an aggregate of 3,275,153 shares of its common stock in a concurrent private placement. In a separate concurrent private placement transaction, the Company issued pre-funded warrants to purchase an aggregate of 1,875,945 shares of its common stock and warrants to purchase an aggregate of 1,875,945 shares of its common stock. Upon issuance, the warrants were classified as a liability and are adjusted to fair value at each subsequent reporting date. The pre-funded warrants were initially classified as equity.

We identified the assessment of the initial accounting for certain aspects of the October 2022 public offering and private placement as a critical audit matter because of the complexity in applying the accounting framework and the significant judgments made by management in the determination of the classification of the warrants and pre-funded warrants. This required a high degree of auditor

judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of management's classification of such warrants and pre-funded warrants.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the classification of the warrants and pre-funded warrants included the following, among others:

- We read the agreements associated with the October 2022 Public Offering and Private Placement and tested the accuracy and completeness of the significant terms identified by management for purposes determining the appropriate accounting treatment, including the classification of the warrants and pre-funded warrants.
- With the assistance of professionals in our firm having expertise in the accounting treatment for financial instruments, we evaluated the Company's conclusions regarding the accounting treatment applied to the warrants and prefunded warrants.

/s/ Deloitte & Touche LLP

Morristown, New Jersey
October 29, 2024

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

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED BALANCE SHEETS

	December 31, 2023 Restated	December 31, 2022 Restated
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 9,564,988	$ 19,866,358
Prepaid expenses and other current assets	888,225	663,243
Total current assets	10,453,213	20,529,601
Property, plant & equipment, net	1,090,304	418,641
Operating lease right-of-use asset	502,283	560,334
Other long-term assets	29,780	81,214
TOTAL ASSETS	$ 12,075,580	$ 21,589,790
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 9,178,645	$ 5,478,443
Warrant liability	16,120,898	5,972,252
Lease liability, current	58,979	50,847
Total current liabilities	25,358,522	11,501,542
Lease liability, net of current portion	494,003	552,981
TOTAL LIABILITIES	25,852,525	12,054,523
COMMITMENTS AND CONTINGENCIES (Note 10)		
MEZZANINE EQUITY:		
Series D convertible preferred stock, 111.11 shares authorized; 111.11 shares issued and outstanding as of December 31, 2023 and 2022	1,382,023	1,382,023
STOCKHOLDERS' (DEFICIT) EQUITY:		
Series E-2 preferred stock, 1,225.00 shares authorized; 319.76 and 0.00 shares issued and outstanding as of December 31, 2023 and 2022, respectively	4,677,632	—
Common stock, $0.00001 par value; 170,000,000 shares authorized; 20,744,110 and 9,385,272 shares issued and outstanding as of December 31, 2023 and 2022, respectively	207	94
Additional paid-in capital	182,924,210	168,143,557
Accumulated deficit	(202,761,017)	(159,990,407)
Total stockholders' (deficit) equity	(15,158,968)	8,153,244
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	$ 12,075,580	$ 21,589,790

See accompanying notes to the consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2023 Restated	2022 Restated
OPERATING EXPENSES:		
Research and development	$ 27,266,276	$ 18,265,711
General and administrative	11,694,367	10,548,062
Total operating expenses	38,960,643	28,813,773
LOSS FROM OPERATIONS	(38,960,643)	(28,813,773)
OTHER INCOME (EXPENSE):		
Warrant issuance expense	(470,000)	(6,824,605)
(Loss) gain on valuation of warrants	(3,787,114)	3,633,241
Interest income	387,147	152,519
Total other income (expense), net	(3,869,967)	(3,038,845)
LOSS BEFORE INCOME TAXES	(42,830,610)	(31,852,618)
INCOME TAX BENEFIT	(60,000)	(60,000)
NET LOSS	$ (42,770,610)	$ (31,792,618)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (3.50)	$ (4.51)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	12,221,571	7,055,665

See accompanying notes to the consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

	Series D Preferred Stock		Preferred Stock		Common Stock				Total Stockholders'
	Shares Restated	Amount Restated	Shares Restated	Amount Restated	Shares Restated	Par Amount Restated	Additional Paid-In Capital Restated	Accumulated Deficit Restated	Equity (Deficit) Restated
Balance at December 31, 2021	111.11	$1,382,023	—	$ —	6,110,125	$ 61	$ 157,260,859	$(128,197,789)	$ 29,063,131
Issuance of common stock and pre-funded warrants, net of issuance costs	—	—	—	—	3,275,153	33	9,429,734	—	9,429,767
Stock-based compensation	—	—	—	—	—	—	1,452,964	—	1,452,964
Retired shares	—	—	—	—	(6)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(31,792,618)	(31,792,618)
Balance at December 31, 2022	111.11	1,382,023	—	—	9,385,272	94	168,143,557	(159,990,407)	8,153,244
Stock-based compensation (Note 7)	—	—	—	—	—	—	2,410,288	—	2,410,288
Exercise of warrants into common stock	—	—	—	—	1,197,622	12	2,467,210	—	2,467,222
Issuance of Series E-2 preferred stock, net of issuance costs (Note 6)	—	—	1,225.00	17,820,000	—	—	—	—	17,820,000
Conversion of preferred stock to common stock	—	—	(905.24)	(13,142,368)	9,947,684	99	13,142,269	—	—
Reclassification of pre-funded warrants to liability	—	—	—	—	—	—	(3,239,112)	—	(3,239,112)
Stock awards (Note 7)	—	—	—	—	213,532	2	(2)	—	—
Net loss	—	—	—	—	—	—	—	(42,770,610)	(42,770,610)
Balance at December 31, 2023	111.11	$1,382,023	319.76	$ 4,677,632	20,744,110	$ 207	$ 182,924,210	$(202,761,017)	$ (15,158,968)

See accompanying notes to the consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2023 Restated	2022 Restated
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (42,770,610)	$ (31,792,618)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	192,375	148,435
Stock-based compensation	2,410,288	1,452,964
Loss on disposal of asset	—	3,386
Costs to issue warrants	470,000	6,824,605
Change in fair value of warrants	3,787,114	(3,633,241)
Change in operating lease right-of-use asset	58,051	90,432
Changes in:		
Prepaid expenses and other assets	(173,548)	204,242
Accounts payable and accrued liabilities	3,700,202	1,623,529
Lease liability	(50,846)	(144,035)
Cash used in operating activities	(32,376,974)	(25,222,301)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant & equipment	(864,038)	(225,971)
Cash used in investing activities	(864,038)	(225,971)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of stock and warrants, net of issuance costs	22,150,000	9,610,655
Proceeds from exercise of warrants	789,642	—
Cash provided by financing activities	22,939,642	9,610,655
DECREASE IN CASH AND CASH EQUIVALENTS	(10,301,370)	(15,837,617)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	19,866,358	35,703,975
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 9,564,988	$ 19,866,358
SUPPLEMENTAL DISCLOSURE OF NON-CASH INFORMATION		
Conversion of preferred stock to common stock	$ 13,242,368	$ —
Conversion of pre-funded warrants to liability	$ 3,239,112	$ —

See accompanying notes to the consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.

NOTES TO RESTATED CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS AND ORGANIZATION

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

Going Concern — As an emerging growth company, the Company has, by design, incurred significant recurring losses and used net cash in its operations since its inception as it devotes substantially all of its efforts towards researching, developing and seeking approval for its product candidates to be commercialized in the marketplace. As a result of these efforts, the Company had an accumulated deficit of approximately $202,761,000 as of December 31, 2023, and incurred a net loss of approximately $42,770,000 during the year ended December 31, 2023. The Company expects it will continue to generate significant losses and use net cash for the foreseeable future, until such time that one or more of its product candidates are approved and successfully commercialized in the marketplace. While management believes one or more of the Company's product candidates will be approved and successfully commercialized in the marketplace, no assurance can be provided any products will be approved or commercialized in a profitable manner.

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

As of the date the accompanying consolidated financial statements were issued (the "issuance date"), the Company's available liquidity to fund the Company's operations over the next twelve months beyond the issuance date was limited to approximately $34.3 million of unrestricted cash and cash equivalents. Absent further action taken by management to increase its liquidity the Company may be unable to fund its operations under normal course beyond the second quarter of 2025. To improve the Company's liquidity, management plans to secure additional outside capital via the sale of equity and/or debt securities or execute a strategic transaction. Management also plans to preserve liquidity, as needed, by implementing temporary cost saving measures. While management believes their plans will be successful, no assurance can be provided such plans will be effectively implemented over the next twelve months beyond the issuance date. In the event management's plans are not effectively implemented, the Company will be required to seek other alternatives which may include, among others, the sale of assets, discontinuance of certain operations, a wind-down of operations and return of capital to stockholders, and/or filing for bankruptcy protection.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

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

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

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

Property, Plant & Equipment — Property, plant & equipment are stated at cost. Depreciation on property and equipment is provided using the straight-line method over the estimated useful lives of the assets (3 to 10 years). Leasehold improvements are depreciated over 64 months (their estimated useful life), which represented the full term of the lease at the time the leasehold improvements were capitalized. Our only long-lived assets are property, equipment and Right-of-Use (ROU) assets. The Company periodically, and at a minimum annually, evaluates long-lived assets for potential impairment. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset. Such analyses necessarily involve judgement. The Company did not experience any events or changes in circumstances that indicate the carrying amount of the assets may not be recoverable as of December 31, 2023. There were no impairment charges recorded during the years ended December 31, 2023 or 2022.

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

Stock-Based Compensation — The Company uses the Black-Scholes option-pricing model to calculate the grant-date fair value of stock option awards. The resulting compensation expense, net of forfeitures, for awards that are not performance-based, is recognized on a straight-line basis over the service period of the award, which for 2023 and 2022 ranged from twelve months to three years.

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

Income Taxes — Income taxes are accounted for using the liability method of accounting. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement basis and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more-likely-than-not that some portion of the deferred tax assets will not be realized. Management has provided a full valuation allowance against the Company's net deferred tax asset. Tax positions taken or expected to be taken in the course of preparing tax returns are required to be evaluated to determine whether the tax positions are more-likely-than-not to be sustained by the applicable tax authority. Tax positions deemed to not meet a more-likely-than-not threshold would be recorded as tax expense in the current year. There were no uncertain tax positions that require accrual to or disclosure in the consolidated financial statements as of December 31, 2023 and 2022.

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

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

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

Concentration of Credit Risk — Financial instruments that subject the Company to credit risk consist of cash and cash equivalents on deposit with financial institutions. The Company's excess cash as of December 31, 2023 and 2022 is on deposit in interest-bearing accounts with well-established financial institutions. At times, such amounts may exceed the Federal Deposit Insurance Corporation (FDIC) insurance limits. As of December 31, 2023, uninsured cash balances totaled approximately $9,123,000.

Prior Presentation — Certain prior year captions and amounts have been relabeled or combined to conform with the current presentation.

Recently Adopted Accounting Pronouncements — For the fiscal year beginning January 1, 2022, management adopted ASU 2021-10, Government Assistance (Topic 832), which aims to provide increased transparency by requiring business entities to disclose information about certain type of government assistance they receive in the notes to the financial statements. Reimbursements of eligible expenditures pursuant to government assistance programs are recorded as reductions of operating costs when it is probable that the Company will comply with the conditions attached to the grant arrangement and the grant proceeds will be received. The determination of the amount of the claim, and accordingly the receivable amount, requires management to make calculations based on its interpretation of eligible expenditures in accordance with the terms of the programs. The reimbursement claims submitted by the Company are subject to review by the relevant government agencies. The Company currently has a cancer treatment research award through the National Cancer Institute (NCI) totaling approximately $2.0 million over a period of approximately three years. In September 2022, the Company was awarded $1.98 million in additional grant funding to expand our ongoing Phase 1 study of iopofosine I 131 in children and adolescents with inoperable relapsed or refractory high-grade gliomas (HGGs). The grant was awarded by the NCI based upon the initial signals of efficacy in the Phase 1 study, which is an international, open-label, dose escalation, safety study. The funding allows for an expansion from Part 1a into the Part 1b portion of our ongoing Phase 1 pediatric study.

During the twelve months ended December 31, 2023, the Company received approximately $1,759,000 in NCI grant funding under the grants described above, all of which was reported as a reduction of research and development (R&D) expenses. During the twelve months ended December 31, 2022, the Company received approximately $697,000 in NCI grant funding under the grants described above, all of which was reported as a reduction of research and development (R&D) expenses.

Recently Issued Accounting Pronouncements Not Yet Adopted — In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures (ASU 2023-07), which is intended to enable investors to better understand an entity's overall performance and assist in assessing potential future cash flows. Public business entities are required to adopt this standard for annual fiscal periods beginning after December 15, 2023, and early adoption is permitted. The Company is evaluating the impact the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740)—Improvements to Income Tax Disclosures (ASU 2023-09), which is intended to enhance the transparency and decision usefulness of income tax disclosures. Public business entities are required to adopt this standard for annual fiscal periods beginning after December 31, 2024, and early adoption is permitted. The Company is evaluating the impact the adoption of this guidance will have on its consolidated financial statements and related disclosures.

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

Restatement of Previously Issued Consolidated Financial Statements — During the third quarter of 2024, and prior to the filing of the Company's Form 10-Q for the quarter ended June 30, 2024, the Company determined that it was necessary to re-evaluate the Company's accounting treatment for certain previously issued warrants and preferred stock. Additionally, the Company identified certain operating costs previously as research and development expenses which should have been classified as general and administrative expenses. In accordance with Staff Accounting Bulletins No. 99 (SAB No. 99) Topic 1.M, "Materiality" and SAB No. 99 Topic 1.N "Considering the Effects of Misstatements when Quantifying Misstatements in the Current Year Financial Statements," the Company assessed the materiality of these errors to its previously issued consolidated financial statements. Based upon the Company's evaluation of both quantitative and qualitative factors, the Company concluded the errors were material to the Company's previously issued consolidated financial statements for the fiscal years ended December 31, 2023 and 2022. Accordingly, this Form 10-K/A presents the Company's Restated Consolidated Financial Statements for the fiscal years ended December 31, 2023 and 2022. Additionally, the Company has restated its previously filed unaudited interim condensed consolidated financial statements for the periods ending March 31, 2023, June 30, 2023, September 30, 2023, March 31, 2022, June 30, 2022, and September 30, 2022, contained in its Quarterly Reports on Form 10-Q. See Notes 14 and 15 for further information.

3. FAIR VALUE

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

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

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

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period, pursuant to the policy described in Note 2. This determination requires significant judgments be made. The following table summarizes the conclusions reached as of December 31, 2023 and 2022 for financial instruments measured at fair value on a recurring basis

	Balance	Level 1	Level 2	Level 3
December 31, 2023				
Cash and cash equivalents	$ 9,564,988	$ 9,564,988	$ —	$ —
Total assets	$ 9,564,988	$ 9,564,988	$ —	$ —
Warrant liability	$ 16,120,898	$ —	$ 2,989,207	$ 13,131,691
Total liabilities	$ 16,120,898	$ —	$ 2,989,207	$ 13,131,691
December 31, 2022				
Cash and cash equivalents	$ 19,866,358	$ 19,866,358	$ —	$ —
Total assets	$ 19,866,358	$ 19,866,358	$ —	$ —
Warrant liability	$ 5,972,252	$ —	$ —	$ 5,972,252
Total liabilities	$ 5,972,252	$ —	$ —	$ 5,972,252

In September 2023 the Company issued warrants to purchase shares of preferred stock which, on an as-converted basis, represent an aggregate of 21,025,641 shares of common stock (the September 2023 Warrants) (see Note 6). The fair value of the September 2023 Warrants was determined using a probability-weighted expected return method (PWERM) with a scenario-based Monte Carlo simulation and Black-Scholes model. The PWERM is a scenario-based methodology that estimates the fair value of the Company's different classes of equity based upon an analysis of future values for the Company, assuming various outcomes. Under both models, assumptions and estimates are used to value the preferred stock warrants. The Company assesses these assumptions and estimates on a quarterly basis as additional information that impacts the assumptions is obtained. The quantitative elements associated with the inputs impacting the fair value measurement of the September 2023 Warrants include the value per share of the underlying common stock, the timing, form and overall value of the expected exits for the stockholders, the risk-free interest rate, the expected dividend yield and the expected volatility of the Company's shares. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared cash dividends. Expected volatility was determined based upon the historical volatility of the Company's common stock. These warrants are classified within the Level 3 hierarchy because of the nature of these inputs and the valuation technique utilized. The September 2023 Warrants had a fair value of $4,200,000, which is included in the warrant liability caption on the accompanying balance sheet as of December 31, 2023.

The following table summarizes the modified option-pricing assumptions used on September 8, 2023, which was the date of issuance, and December 31, 2023:

	September 8	December 31
Volatility	83.0-84.0 %	82.0-83.0 %
Risk-free interest rate	4.39-5.53 %	3.80-5.40 %
Expected life (years)	0.4-5.0	0.3-4.7
Dividend	0 %	0 %

In October 2022 the Company issued a total of 5,151,098 common warrants that are immediately exercisable with a five-year life and a strike price of $1.96 for shares of common stock (the 2022 Common Warrants), and 1,875,941 pre-funded warrants (the 2022 Pre-Funded Warrants) to acquire shares of common stock (see Note 6). The 2022 Pre-Funded Warrants are exercisable by the holder upon payment of the par value of the common stock and are classified as Level 2 liabilities as their value is equal to the Company's common stock value less the par value.

The fair value of the 2022 Common Warrants was determined by utilizing a Black-Scholes option-pricing model. The quantitative elements associated with the inputs impacting the fair value measurement of the 2022 Common Warrants include the value per share of the underlying common stock, the risk-free interest rate, the expected dividend yield and the expected volatility of the Company's

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

	October 20, 2022	December 31, 2022	December 31, 2023
Volatility	84.5 %	86.5 %	81.1 %
Risk-free interest rate	4.45 %	3.99 %	3.84 %
Expected life (years)	5.0	4.8	3.8
Dividend	0 %	0 %	0 %

The following table summarizes the changes in the fair market value of the warrants which are classified within the Level 3 fair value hierarchy, inclusive of all Preferred and Common Warrants, excluding the Pre-Funded Common Warrants:

	Level 3
Fair value of Level 3 liabilities as of January 1, 2022	$ 2,600,000
Issuance of 2022 Common Warrants	7,005,493
Change in fair value	(3,633,241)
December 31, 2022, fair value of Level 3 liabilities	$ 5,972,252
Issuance of September 2023 Warrants	$ 4,800,000
Exercise of 2022 Common Warrants	(732,612)
Change in fair value	3,092,051
December 31, 2023, fair value of Level 3 liabilities	$ 13,131,691

4. PROPERTY, PLANT & EQUIPMENT

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

	2023	2022
Office and laboratory equipment	$ 1,661,316	$ 797,278
Computer software	4,000	4,000
Leasehold improvements	309,897	309,897
Total fixed assets	1,975,213	1,111,175
Less– accumulated depreciation and amortization	(884,909)	(692,534)
Property, plant & equipment, net	$ 1,090,304	$ 418,641

For the years ended December 31, 2023 and 2022, the Company recorded approximately $192,000 and $148,000 of depreciation and amortization expense, respectively.

5. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

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

	2023	2022
Incentive compensation	$ 2,069,000	$ 916,000
Accounts payable	5,620,000	2,558,000
Clinical project costs	1,252,000	1,637,000
Professional fees	153,000	359,000
Other	85,000	8,000
	$ 9,179,000	$ 5,478,000

6. STOCKHOLDERS' EQUITY

September 2023 Private Placement

On September 8, 2023, in a private placement with certain institutional investors, the Company issued 1,225 shares of Series E-1 preferred stock, along with Tranche A warrants to purchase 2,205 shares of Series E-3 preferred stock and Tranche B warrants to purchase 1,715 shares of Series E-4 preferred stock. Shares of Series E preferred stock were issued at a fixed price of $20,000 per share, resulting in gross proceeds of $24.5 million and net proceeds of approximately $22.2 million after placement agent fees and other customary expenses. The conversion prices for the preferred stock are as follows: for the Series E-1 or E-2 preferred stock, $1.82 per share of common stock, or a total of 13,461,538 shares of common stock; for the Series E-3 preferred stock, $3.185 per share of common stock, or a total of 13,846,154 shares of common stock; and for the Series E-4 preferred stock, $4.7775 per share of common stock, or a total of 7,179,487 shares of common stock, in each case subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization. The warrants are exercisable as follows:

- Tranche A warrants, for an aggregate exercise price of $44.1 million, exercisable for Series E-3 preferred stock until the earlier of September 6, 2026, or 10 trading days after the Company's announcement of positive topline data from the Waldenstrom's macroglobulinemia CLOVER WaM pivotal trial; and,

- Tranche B warrants, for an aggregate exercise price of $34.3 million, exercisable for Series E-4 preferred stock until the earlier of September 6, 2028, or 10 days following the Company's public announcement of its receipt of written approval from the FDA of its New Drug Application for iopofosine I 131.

The Tranche A and Tranche B warrants do not qualify as derivatives; however, they do not meet the requirements necessary to be considered indexed to the Company's stock. As a result, and in accordance with the guidance in FASB ASC 815, the warrants continue to be deemed liabilities. All such liabilities are required to be presented at fair value, with changes reflected in financial results for the period.

When issued, the Series E-1 preferred stock had a redemption feature; therefore, it was classified as mezzanine equity as of September 30, 2023. The Series E-1 preferred stock also had a liquidation preference, which was calculated as an amount per share equal to the greater of (i) two times (2X) the Original Per Share Price, together with any declared, unpaid dividends, or (ii) such amount per share as would have been payable had all shares of Series E-1 preferred stock been converted into Common Stock immediately prior to such Liquidation. These features only applied to the Series E-1 preferred stock when it was outstanding; upon stockholder approval of the transaction, which was obtained by the Company at a special meeting of stockholders held on October 25, 2023, the Series E-1 preferred stock immediately converted into either Series E-2 preferred stock and/or common stock, dependent upon the beneficial ownership position of the holder.

The net proceeds from the September 2023 Private Placement were allocated first to the fair value of the Tranche A and Tranche B warrants, which had a fair value upon issuance of $4,800,000, with the remainder, or $17,820,000, allocated to the Series E-1 preferred stock. Upon stockholder approval of the transaction, the entire amount that had been assigned to mezzanine equity was reclassified to Series E-2 preferred stock and is a component of permanent equity, as is reflected in the financial statements. As a result of the stockholder approval, Series E-1 preferred stock was fully extinguished in accordance with the terms of the financing.

Series E preferred stock is convertible to common stock at the request of the holder, subject to the holder not exceeding certain beneficial ownership percentages as stipulated in the financing agreement, and votes on an as-converted to common basis. Subsequent to the issuance of the Series E-2 preferred stock and prior to December 31, 2023, preferred holders converted 905.24 shares of Series E-2 preferred stock into 9,947,684 shares of common stock at the stated rate of $1.82 per common share.

October 2022 Public Offering and Private Placement

On October 25, 2022, the Company completed a registered direct offering of 3,275,153 shares of the Company's common stock at $2.085 per share and common warrants to purchase up to an aggregate of 3,275,153 shares of common stock in a concurrent private placement priced at-the-market under Nasdaq rules. In a separate concurrent private placement transaction, the Company offered and sold pre-funded warrants to purchase an aggregate of 1,875,945 shares of common stock and common warrants to purchase an aggregate of 1,875,945 shares of common stock. The common warrants sold in the registered direct offering and those sold in the private placement have identical terms. These common warrants are immediately exercisable at an exercise price of $1.96 per share and will expire on the fifth anniversary of the closing date. Each 2022 Pre-Funded Warrant had a purchase price of $2.08499, is immediately exercisable at an exercise price of $0.00001 per share and will not expire until exercised in full. The registered direct offering and private placements resulted in total gross proceeds of approximately $10.7 million, with net proceeds to the Company of approximately $9.6 million after deducting estimated offering expenses. During the twelve months ended December 31, 2023, 355,235 pre-funded warrants were converted into 355,235 shares of common stock. During the twelve months ended December 31, 2023, 177,877 common warrants were exercised for proceeds of $348,638. There were no common warrants exercised during the twelve months ended December 31, 2022.

Upon issuance, the 2022 Common Warrants were classified as a liability and were marked to market at each reporting date. The 2022 Pre-Funded Warrants were initially classified as equity, until the issuance of the Series E preferred stock in September 2023, at which point the 2022 Pre-Funded Warrants were reclassified to liability.

In accordance with the concept of FASB ASC 820 regarding the October 2022 public offering, the Company allocated the value of the proceeds to the common stock, common warrants, and pre-funded warrants utilizing a fair value basis. Using the closing trading price for Cellectar stock on October 20, 2022, and a Black-Scholes valuation for the warrants, the Company computed the fair value of the warrants. To the extent that the value of the warrants, pre-funded warrants and common stock sold exceeded the proceeds, the Company records a charge to the statement of operations. The Company allocated approximately $7.0 million to the 2022 Common Warrants, $3.7 million to the 2022 Pre-Funded warrants and $6.4 million to the common stock, with the value in excess of the proceeds received of approximately $6.3 million reflected in Other Expense.

December 2020 Public Offering and Private Placement

On December 23, 2020, the Company issued and sold 1,814,813 shares of common stock, par value $0.00001 per share, at a public offering price of $13.50 per share of common stock, prior to deducting underwriting discounts and commissions and estimated offering expenses.

In a concurrent private placement, the Company issued and sold 1,518.5180 shares of Series D convertible preferred stock. These preferred shares are convertible into a number of shares of common stock equal to $13,500 divided by $13.50 (or 1,000 shares of common stock for each share of Series D preferred stock) and were issued at a price of $13,500 per share of Series D preferred stock. The preferred shares were only convertible into common stock upon receipt of stockholder approval of the issuance of the underlying shares of common stock as required by Nasdaq Marketplace Rule 5635(d) at a special stockholder meeting to be called for that purpose. At a special meeting of stockholders held on February 25, 2021, the stockholders approved, in accordance with Nasdaq Listing Rule 5635(d), the issuance of shares of the Company's common stock upon the conversion of the Series D preferred stock.

2022 Reverse Stock Split

At the annual stockholders' meeting held on June 24, 2022, the Company's stockholders approved an amendment to the Company's certificate of incorporation to effect a reverse split of the Company's common stock at a ratio between 1-for-5 to 1-for-10 in order to satisfy requirements for continued listing of the Company's common stock on Nasdaq. The board of directors authorized the 1-for-10 ratio of the reverse split on June 27, 2022, and effective at the close of business on July 21, 2022, the Company's certificate of incorporation was amended to effect a 1-for-10 reverse split of the Company's common stock (the "Reverse Stock

Split"). The accompanying consolidated financial statements and notes to consolidated financial statements give retroactive effect to the Reverse Stock Split for all periods presented.

Authorized Share Increase

At a special meeting of stockholders held on October 25, 2023, the Company's stockholders approved an amendment of the Company's Second Amended and Restated Certificate of Incorporation, as amended, to increase the authorized common stock from 160,000,000 shares to 170,000,000 shares.

Warrants

The following table summarizes the outstanding warrants to purchase stock as of December 31, 2023:

Offering	Number of Shares Issuable Upon Exercise of Outstanding Warrants	Exercise Price	Expiration Date
2023 Tranche A Preferred Warrants	13,846,154	$ 3.185	September 8, 2026 (1)
2023 Tranche B Preferred Warrants	7,179,487	$ 4.7775	September 8, 2028 (1)
2022 Common Warrants	4,748,221	$ 1.96	October 25, 2027 (2)
2022 Pre-Funded Common Warrants	1,079,136	$ 0.00001	N/A (2)
June 2020 Series H Common Warrants	720,796	$ 12.075	June 5, 2025
May 2019 Series F Common Warrants	195,700	$ 24.00	May 20, 2024
May 2019 Series G Common Warrants	201,800	$ 24.00	May 20, 2024
October 2017 Series D Common Warrants	31,085	$ 178.00	October 14, 2024
Total	28,002,379		

(1) These warrants are described further under the caption "September 2023 Private Placement" above.

(2) These warrants are described further under the caption "October 2022 Public Offering and Private Placement" above.

The 2022 Pre-Funded Warrants are classified as mezzanine equity. All other warrants in the table above are liability-classified.

7. STOCK-BASED COMPENSATION

Accounting for Stock-Based Compensation

2021 Stock Incentive Plan

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

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

At the annual meeting of stockholders held on June 23, 2023, the Company's stockholders approved an increase in the number of shares of common stock available for issuance under our 2021 Stock Incentive Plan by 1,100,000 to 2,368,000.

During the twelve months ended December 31, 2023 and 2022, stock options granted were 1,617,000 and 440,250, respectively. The following table summarizes amounts charged to expense for stock-based compensation related to employee and director stock option grants:

	Twelve Months Ended December 31,	
	2023	2022
Employee and director stock option and stock grants:		
Research and development	$ 505,155	$ 165,461
General and administrative	1,905,133	1,287,502
Total stock-based compensation	$ 2,410,288	$ 1,452,964

In January 2023, the Company granted 609,000 non-statutory stock option awards at an average exercise price of $1.68 per share to employees. These grants were contingent upon the approval of the increase in the number of shares available for issuance under the 2021 Plan that was approved by the stockholders at the Annual Meeting of Stockholders held on June 23, 2023. In accordance with the removal of the contingency, the Company began recognizing the expense for these awards beginning in June 2023.

In December 2023, the Company granted 2,776,000 contingent, non-statutory stock option awards at an exercise price of $2.63 per share to our employees and our directors. Each of these grants is contingent on approval of an increase in the shares available in the 2021 Stock Incentive Plan that is to be voted on by the stockholders at the annual meeting of stockholders expected to be held in June 2024. Until such time that the contingent non-statutory stock option awards are approved by stockholders, no expense will be recognized by the Company.

In December 2023, the Company awarded $434,132 in cash and 213,532 shares of stock, valued at $565,868, to certain employees as a result of the attainment of milestones established and approved by a committee of the Board of Directors. Due to the contingent nature of those awards, which were fully vested upon milestone attainment, the expense was recognized by the Company upon grant.

Assumptions Used in Determining Fair Value

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

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

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

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

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

Dividends. The Company has not historically issued dividends.

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

	Year Ended December 31,	
	2023	2022
Volatility	82.02-83.28 %	82.47-100 %
Risk-free interest rate	3.59-4.68 %	1.65-3.96 %
Expected term (years)	6.0	6.0
Dividend	0 %	0 %

Exercise prices for all grants made during the twelve months ended December 31, 2023 and 2022 were equal to the market value of the Company's common stock on the date of grant.

Stock Option Activity

A summary of stock option activity is as follows:

	Number of Shares Issuable Upon Exercise of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term in Years	Aggregate Intrinsic Value
Outstanding as of December 31, 2021	423,820	$ 22.70		
Granted	440,250	$ 4.51		
Expired	(6)	$ 15,000.00		
Forfeited	(117,807)	$ 12.02		
Outstanding as of December 31, 2022	746,257	$ 13.48	8.58	$ —
Granted	1,617,000	$ 1.78		
Expired	(8)	$ 8,325		
Forfeited	(11,346)	$ 1.92		
Outstanding as of December 31, 2023	2,351,903	$ 5.46	8.64	$ 1,682,667
Exercisable as of December 31, 2023	514,171	$ 15.68		$ 30,817
Unvested as of December 31, 2023	1,837,732	$ 2.58		$ 1,652,350

The aggregate intrinsic value of options outstanding is calculated based on the positive difference between the estimated per-share fair value of common stock at the end of the respective period and the exercise price of the underlying options. Shares of common stock issued upon the exercise of options are from authorized but unissued shares. At December 31, 2023, we had 116,579 shares available for grant under the 2021 Option Plan.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2023 and 2022 was $1.35 and $3.52, respectively. The total fair value of shares vested during the years ended December 31, 2023 and 2022 was $1,670,964 and $1,340,967, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2023 was $11.13 and $1.81, respectively. The weighted-average grant-date fair value of vested and unvested options outstanding at December 31, 2022 was $19.92 and $5.25, respectively.

The weighted average grant date fair value of options forfeited during the years ended December 31, 2023 and 2022 was $1.41 and $7.33, respectively. The number of options vested during the years ended December 31, 2023 and December 31, 2022 was 308,136 and 135,976, respectively. The number of options unvested at December 31, 2023 and December 31, 2022, was 1,837,732 and 540,223, respectively.

As of December 31, 2023, there was approximately $2,205,192 of total unrecognized compensation cost related to unvested stock-based compensation arrangements. Of this total amount, the Company expects to recognize approximately $1,330,233, $775,193, and $99,766 during 2024, 2025 and 2026, respectively. The Company's expense estimates are based upon the expectation that all unvested options will vest in the future.

8. INCOME TAXES

	2023	2022
Tax provision (benefit)		
Current		
Federal	$ —	$ —
State	(60,000)	(60,000)
Total current	(60,000)	(60,000)
Deferred		
Federal	(12,233,641)	(7,800,350)
State	(2,764,638)	(2,633,146)
Total deferred	(14,998,279)	(10,433,496)
Change in valuation allowance	14,998,279	10,433,496
Total	$ (60,000)	$ (60,000)

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

	2023	2022
Deferred tax assets		
Federal net operating loss	$ 39,914,591	$ 35,958,687
Federal research and development tax credit carryforwards	15,868,907	11,484,209
State net operating losses and tax credit carryforwards	7,626,490	6,186,679
Capitalized research and development expenses	20,203,493	15,820,893
Stock-based compensation expense	3,710,609	3,186,702
Other	754,180	443,693
Total deferred tax assets	88,078,270	73,080,863
Deferred tax liabilities		
Depreciable assets	(156,626)	(157,498)
Total deferred tax liabilities	(156,626)	(157,498)
Net deferred tax assets	87,921,644	72,923,365
Less- valuation allowance	(87,921,644)	(72,923,365)
Total deferred tax assets	$ —	$ —

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

	Year ended December 31,	
	2023	2022
Income tax benefit using U.S. federal statutory rate	21.00 %	21.00 %
State income taxes	6.92 %	8.42 %
Permanent nondeductible items	(0.28)%	(0.01)%
Federal tax credits	9.95 %	5.92 %
Change in valuation allowance	(35.48)%	(32.76)%
Warrant cost	(2.11)%	(2.10)%
Other	0.14 %	(0.29)%
Total	0.14 %	0.18 %

As of December 31, 2023, the Company had federal net operating loss (NOL) carryforwards of approximately $110,069,000 generated as of December 31, 2017, and NOL carryforwards of approximately $80,001,000 after December 31, 2017. Federal NOLs generated as of December 31, 2017, will expire in 2023 through 2037, while NOLs generated during 2018 and later will be carried forward indefinitely until utilized. As of December 31, 2023, the Company had state NOL carryforwards of approximately $97,080,000. State NOL carryforwards will expire in 2029 through 2043.

As of December 31, 2023, the Company had federal research and development (R&D) and orphan drug credit carryforwards of approximately $15,869,000 which will expire in 2024 through 2042. As of December 31, 2023, the Company also had state credit carryforwards of approximately $1,045,000 which will expire in 2025 through 2038.

The Company had federal NOLs and R&D credit carryforwards of $502,000 and $13,000, respectively, that expired in 2023.

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

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

The Company did not have unrecognized tax benefits or accrued interest and penalties at any time during the years ended December 31, 2023 or 2022, and does not anticipate having unrecognized tax benefits over the next twelve months. The Company is subject to audit by the Internal Revenue Service and state taxing authorities for tax periods commencing January 1, 2018, as a result of its NOLs. However, any adjustment related to these periods would be limited to the amount of the NOL generated in the year(s) under examination.

9. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock and pre-funded warrants outstanding during the period. The pre-funded warrants are considered common shares outstanding for the purposes of the basic net loss per share calculation because of the nominal cash consideration and lack of other contingencies for issuance of the underlying common shares. Diluted net loss attributable to common stockholders per share is computed by dividing net loss attributable to common stockholders, as adjusted, by the sum of the weighted average number of shares of common stock and the dilutive potential common stock equivalents then outstanding. Potential common stock equivalents consist

of stock options, warrants, and convertible preferred shares. Since there is a net loss attributable to common stockholders for the years ended December 31, 2023 and 2022, the inclusion of common stock equivalents in the computation for those periods would be antidilutive. Accordingly, basic and diluted net loss per share is the same for all periods presented.

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

	Year Ended December 31,	
	2023	2022
Warrants	26,923,243	6,714,479
Stock options	2,351,903	746,257
Convertible preferred shares	3,624,957	111,111
Total potentially dilutive shares	32,900,103	7,571,847

10. COMMITMENTS AND CONTINGENCIES

Legal

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

11. LEASES

Operating Lease Liability

In June 2018, the Company executed an agreement for office space in the Borough of Florham Park, Morris County, New Jersey to be used as its headquarters (HQ Lease). The HQ Lease commenced upon completion of certain improvements in October 2018 and terminates in February 2024 with an option to extend the term of the lease for one additional 60-month period.

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

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

Discount Rate

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

Maturity Analysis of Short-Term and Operating Leases

The following table approximates the dollar maturity of the Company's undiscounted payments for its short-term leases and operating lease liabilities as of December 31, 2023:

Years ending December 31,		
2024	$	132,000
2025		146,000
2026		150,000
2027		153,000
2028		155,000
Thereafter		53,000
Total undiscounted lease payments		789,000
Less: Imputed interest		(236,000)
Present value of lease liabilities	$	553,000

12. EMPLOYEE RETIREMENT PLAN

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

13. SUBSEQUENT EVENTS

In January 2024, the Company released topline data from its pivotal, Phase 2b CLOVER WaM trial. In accordance with the terms of the September 2023 financing, the Tranche A warrant expiration accelerated to 10 trading days after the topline data release. Warrant holders exercised the Tranche A warrants in their entirety, resulting in the Company issuing 2,205 shares of Series E-3 preferred stock, which are convertible to common stock at the stated rate of $3.185 per share, and receiving gross proceeds of $44.1 million and net proceeds of $42.8 million.

During January and February 2024, 547,177 warrants issued in October 2022 were exercised for net proceeds of approximately $1.1 million.

On July 21, 2024, the Company, entered into a warrant exercise inducement with certain holders of its 2023 Tranche B warrants. The warrant holders agreed to exercise their existing warrants to purchase an amount of shares of the Company's Series E - 4 Preferred Stock, which is convertible to 6,739,918 shares of the Company's common stock in the aggregate, at a reduced, as - converted common stock exercise price of $2.52 per share, in exchange for the Company's agreement to issue new warrants with varying termination dates and exercise prices. The Company received gross proceeds of $19.4 million and net proceeds of $17.5 million.

14. RESTATEMENT OF PREVIOUSLY ISSUED FINANCIAL STATEMENTS

As described in Note 2 and detailed below, in July 2024 the Company determined that it was necessary to re-evaluate its accounting treatment for certain previously issued warrants and preferred stock. The Company identified five areas where the historical accounting treatment applied to previously issued warrants and preferred stock required modification:

1. Contractual terms contained within the agreements governing the warrants issued to its investors in prior periods required further evaluation under Topic 815. After consultation with external advisors and completing an extensive review process, management concluded that the classification of certain previously issued warrants as equity was not consistent with Topic 815 and has restated them as liabilities. This also results in the requirement to account for the change in the fair value of the liability classified warrants through the Consolidated Statements of Operations at each reporting date they remain outstanding. Additionally, upon the issuance of the 2022 common warrants, pre-funded warrants and common stock, the Company determined the fair value of each security issued and booked a charge for the amount that the fair value exceeded the proceeds received (see Note 6).

2. Upon the issuance of the Series E Preferred Stock in September 2023, the contractual language required the 2022 Pre-Funded Warrants be reclassified from equity to liability.

3. The Series D Preferred Stock issued in 2020 was determined to be temporary, or mezzanine equity upon issuance and was so recorded.

4. The accounting treatment for the Tranche A and B warrants issued as part of the September 2023 financing (See Note 6) continues to be appropriate; however, as part of the work performed for the restatement, the warrant valuation was adjusted to correct prior errors in the valuation.

5. Certain operating costs previously recorded as research and development expenses were corrected to general and administrative expenses.

The impact on the consolidated financial statements is as follows (lettered for reference to the financial statement adjustments):

A. All the outstanding common warrants were corrected from permanent equity to Warrant Liability, and the Series D Preferred Stock was corrected from permanent equity to Mezzanine Equity as of December 31, 2021.

B. The proceeds from the October 2022 financing were adjusted as described in Note 6. Additionally, the cost of the 2022 financing allocated to the issuance of the 2022 Warrants, which was $463,000, was removed from Additional Paid-In Capital and charged to Other Expense.

C. After the issuance of the Series E Preferred in September 2023, the 2022 Pre-Funded Warrants were corrected from Additional Paid-In Capital to Warrant Liability.

D. At each reporting period the warrants accounted for as liabilities were marked to market with the adjustment reflected in Other Income (Expense).

E. Certain operating costs previously recorded as research and development expenses were corrected to general and administrative expenses.

F. Adjusted the balance sheet as of December 31, 2021 by reducing additional paid-in capital and increasing accumulated deficit by $25,300,000 which was the change from the initial fair value amount of the warrants issued in 2017, 2018 and 2020 through December 31, 2021.

Below are the Company's restated consolidated balance sheets as of December 31, 2023 and 2022, and the restated consolidated statements of operations, statements of convertible preferred stock and stockholders' equity (deficit), and statements of cash flows, with adjustments, for the years ended December 31, 2023 and 2022.

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED BALANCE SHEETS

	December 31, 2023			
	As Previously Reported	Restatement Adjustments	Reference	As Restated
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	$ 9,564,988	$ —		$ 9,564,988
Prepaid expenses and other current assets	888,225	—		888,225
Total current assets	10,453,213	—		10,453,213
Property, plant & equipment, net	1,090,304	—		1,090,304
Operating lease right-of-use asset	502,283	—		502,283
Other long-term assets	29,780	—		29,780
TOTAL ASSETS	$ 12,075,580	$ —		$ 12,075,580
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accrued liabilities	$ 9,178,645	$ —		$ 9,178,645
Warrant liability	3,700,000	12,420,898	A, C	16,120,898
Lease liability, current	58,979	—		58,979
Total current liabilities	12,937,624	12,420,898		25,358,522
Lease liability, net of current portion	494,003	—		494,003
TOTAL LIABILITIES	13,431,627	12,420,898		25,852,525
COMMITMENTS AND CONTINGENCIES (Note 10)				
MEZZANINE EQUITY:				
Series D preferred stock, 111.11 shares authorized, issued and outstanding as of December 31, 2023	—	1,382,023	A	1,382,023
STOCKHOLDERS' (DEFICIT) EQUITY:				
Series D convertible preferred stock, 111.11 shares authorized, issued and outstanding as of December 31, 2023	1,382,023	(1,382,023)	A	—
Series E-2 preferred stock, 1,225.00 shares authorized; 319.76 shares issued and outstanding as of December 31, 2023	4,677,632	—		4,677,632
Common stock, $0.00001 par value; 170,000,000 shares authorized; 20,744,110 shares issued and outstanding as of December 31 2023	207	—		207
Additional paid-in capital	210,066,630	(27,142,420)	A, B, C, F	182,924,210
Accumulated deficit	(217,482,539)	14,721,522	B, D, F	(202,761,017)
Total stockholders' (deficit) equity	(1,356,047)	(13,802,921)		(15,158,968)
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	$ 12,075,580	$ —		$ 12,075,580

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED BALANCE SHEETS

	December 31, 2022			
	As Previously Reported	Restatement Adjustments	Reference	As Restated
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	$ 19,866,358	$ —		$ 19,866,358
Prepaid expenses and other current assets	663,243	—		663,243
Total current assets	20,529,601	—		20,529,601
Property, plant & equipment, net	418,641	—		418,641
Operating lease right-of-use asset	560,334	—		560,334
Other long-term assets	81,214	—		81,214
TOTAL ASSETS	$ 21,589,790	$ —		$ 21,589,790
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accrued liabilities	$ 5,478,443	$ —		$ 5,478,443
Warrant liability	—	5,972,252	A	5,972,252
Lease liability, current	50,847	—		50,847
Total current liabilities	5,529,290	5,972,252		11,501,542
Lease liability, net of current portion	552,981	—		552,981
TOTAL LIABILITIES	6,082,271	5,972,252		12,054,523
COMMITMENTS AND CONTINGENCIES (Note 10)				
MEZZANINE EQUITY:				
Series D convertible preferred stock, 111.11 shares authorized, issued and outstanding as of December 31, 2023	—	1,382,023	A	1,382,023
STOCKHOLDERS' (DEFICIT) EQUITY:				
Series D preferred stock, 111.11 shares authorized, issued and outstanding as of December 31, 2022	1,382,023	(1,382,023)	A	—
Common stock, $0.00001 par value; 170,000,000 shares authorized; 9,385,272 shares issued and outstanding as of December 31 2022	94	—		94
Additional paid-in capital	193,624,445	(25,480,888)	A, B, F	168,143,557
Accumulated deficit	(179,499,043)	19,508,636	B, D, F	(159,990,407)
Total stockholders' (deficit) equity	15,507,519	(7,354,275)		8,153,244
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	$ 21,589,790	$ —		$ 21,589,790

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31, 2023			
	As Previously Reported	Adjustments	Reference	As Restated
OPERATING EXPENSES:				
Research and development	$ 28,211,460	$ (945,184)	E	$ 27,266,276
General and administrative	10,749,183	945,184	E	11,694,367
Total operating expenses	38,960,643	—		38,960,643
LOSS FROM OPERATIONS	(38,960,643)	—		(38,960,643)
OTHER INCOME (EXPENSE):				
Warrant issuance expense	(470,000)	—		(470,000)
Gain (loss) on valuation of warrants	1,000,000	(4,787,114)	D	(3,787,114)
Interest income	387,147	—		387,147
Total other income (expense), net	917,147	(4,787,114)		(3,869,967)
LOSS BEFORE INCOME TAXES	(38,043,496)	(4,787,114)		(42,830,610)
INCOME TAX BENEFIT	(60,000)	—		(60,000)
NET LOSS	$ (37,983,496)	$ (4,787,114)		$ (42,770,610)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (3.11)	$ (0.39)		$ (3.50)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	12,221,571	—		12,221,571

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31, 2022			
	As Previously Reported	Adjustments	Reference	As Restated
OPERATING EXPENSES:				
Research and development	$ 19,219,603	$ (953,892)	E	$ 18,265,711
General and administrative	9,594,170	953,892	E	10,548,062
Total operating expenses	28,813,773	—		28,813,773
LOSS FROM OPERATIONS	(28,813,773)	—		(28,813,773)
OTHER INCOME (EXPENSE):				
Warrant issuance expense	—	(6,824,605)	B, D	(6,824,605)
Gain (loss) on valuation of warrants	—	3,633,241	D	3,633,241
Interest income	152,519	—		152,519
Total other income (expense), net	152,519	(3,191,364)		(3,038,845)
LOSS BEFORE INCOME TAXES	(28,661,254)	(3,191,364)		(31,852,618)
INCOME TAX BENEFIT	(60,000)	—		(60,000)
NET LOSS	$ (28,601,254)	$ (3,191,364)		$ (31,792,618)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (4.05)	$ (0.45)		$ (4.51)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	7,055,665	—		7,055,665

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY

	Series D Preferred Stock		Preferred Stock		Common Stock				Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Par Amount	Additional Paid-In Capital	Accumulated Deficit	
Previously Reported									
Balance at December 31, 2021	—	$ —	111.11	$ 1,382,023	6,110,125	$ 61	$ 182,560,859	$ (150,897,789)	$ 33,045,154
Issuance of common stock, pre-funded warrants and warrants, net of issuance costs	—	—	—	—	3,275,153	33	9,610,622	—	9,610,655
Stock-based compensation	—	—	—	—	—	—	1,452,964	—	1,452,964
Retired shares	—	—	—	—	(6)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(28,601,254)	(28,601,254)
Balance at December 31, 2022	—	—	111.11	1,382,023	9,385,272	94	193,624,445	(179,499,043)	15,507,519
Stock-based compensation	—	—	—	—	—	—	2,410,288	—	2,410,288
Exercise of warrants into common stock	—	—	—	—	1,197,622	12	789,630	—	789,642
Issuance of preferred stock, net of issuance costs (Note 6)	—	—	1,225.00	17,920,000	—	—	—	—	17,920,000
Conversion of preferred stock to common stock	—	—	(905.24)	(13,242,368)	9,947,684	99	13,242,269	—	—
Stock awards (Note 7)	—	—	—	—	213,532	2	(2)	—	—
Net loss	—	—	—	—	—	—	—	(37,983,496)	(37,983,496)
Balance at December 31, 2023	—	$ —	430.87	$ 6,059,655	20,744,110	$ 207	$ 210,066,630	$ (217,482,539)	$ (1,356,047)
Adjustments									
Balance at December 31, 2021 (A, F)	111.11	$ 1,382,023	(111.11)	$ (1,382,023)	—	$ —	$ (25,300,000)	$ 22,700,000	$ (3,982,023)
Reclassification of warrants to liability (A)	—	—	—	—	—	—	(7,005,493)	—	(7,005,493)
Warrant-related issuance expense (B)	—	—	—	—	—	—	6,824,605	—	6,824,605
Net loss (B, D)	—	—	—	—	—	—	—	(3,191,364)	(3,191,364)
Balance at December 31, 2022	111.11	1,382,023	(111.11)	(1,382,023)	—	—	(25,480,888)	19,508,636	(7,354,275)
Exercise of warrants into common stock (A)	—	—	—	—	—	—	1,677,580	—	1,677,580
Reclassification of warrants to liability (C)	—	—	—	—	—	—	(3,239,112)	—	(3,239,112)
Issuance of Series E-2 preferred stock, net of issuance costs (Note 6) (D)	—	—	—	(100,000)	—	—	—	—	(100,000)
Conversion of preferred stock to common stock (D)	—	—	—	100,000	—	—	(100,000)	—	—
Net loss (D)	—	—	—	—	—	—	—	(4,787,114)	(4,787,114)
Balance at December 31, 2023	111.11	$ 1,382,023	(111.11)	$ (1,382,023)	—	$ —	$ (27,142,420)	$ 14,721,522	$ (13,802,921)
As Restated									
Balance at December 31, 2021	111.11	$ 1,382,023	—	$ —	6,110,125	$ 61	$ 157,260,859	$ (128,197,789)	$ 29,063,131
Issuance of common stock and pre-funded warrants net of issuance costs	—	—	—	—	3,275,153	33	9,429,734	—	9,429,767
Stock-based compensation	—	—	—	—	—	—	1,452,964	—	1,452,964
Retired shares	—	—	—	—	(6)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(31,792,618)	(31,792,618)
Balance at December 31, 2022	111.11	1,382,023	—	—	9,385,272	94	168,143,557	(159,990,407)	8,153,244
Stock-based compensation (Note 7)	—	—	—	—	—	—	2,410,288	—	2,410,288
Exercise of warrants into common stock	—	—	—	—	1,197,622	12	2,467,210	—	2,467,222
Issuance of Series E-2 preferred stock, net of issuance costs (Note 6)	—	—	1,225.00	17,820,000	—	—	—	—	17,820,000
Conversion of preferred stock to common stock	—	—	(905.24)	(13,142,368)	9,947,684	99	13,142,269	—	—
Reclassification of pre-funded warrants to liability liability	—	—	—	—	—	—	(3,239,112)	—	(3,239,112)
Stock awards (Note 7)	—	—	—	—	213,532	2	(2)	—	—
Net loss	—	—	—	—	—	—	—	(42,770,610)	(42,770,610)
Balance at December 31, 2023	111.11	$ 1,382,023	319.76	$ 4,677,632	20,744,110	$ 207	$ 182,924,210	$ (202,761,017)	$ (15,158,968)

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2023			
	As Previously Reported	Adjustments	Reference	As Restated
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (37,983,496)	$ (4,787,114)	D	$ (42,770,610)
Adjustments to reconcile net loss to cash used in operating activities:				
Depreciation and amortization	192,375	—		192,375
Stock-based compensation	2,410,288	—		2,410,288
Loss on disposal of asset	—	—		—
Costs to issue warrants	470,000	—		470,000
Change in fair value of warrants	(1,000,000)	4,787,114	D	3,787,114
Change in operating lease right-of-use asset	58,051	—		58,051
Changes in:				
Prepaid expenses and other assets	(173,548)	—		(173,548)
Accounts payable and accrued liabilities	3,700,202	—		3,700,202
Lease liability	(50,846)	—		(50,846)
Cash used in operating activities	(32,376,974)	—		(32,376,974)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property, plant & equipment	(864,038)	—		(864,038)
Cash used in investing activities	(864,038)	—		(864,038)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from issuance of preferred stock and warrants, net of issuance costs	22,150,000	—		22,150,000
Proceeds from exercise of warrants	789,642	—		789,642
Cash provided by financing activities	22,939,642	—		22,939,642
DECREASE IN CASH AND CASH EQUIVALENTS	(10,301,370)	—		(10,301,370)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	19,866,358	—		19,866,358
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 9,564,988	$ —		$ 9,564,988
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION				
Conversion of preferred stock to common stock	$ 13,242,368	$ —		$ 13,242,368
Conversion of mezzanine equity to permanent equity (Note 6)	$ 17,920,000	$ (100,000)		$ 17,820,000
Conversion of pre-funded warrants to liability	$ —	$ 3,239,112		$ 3,239,112

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2022			
	As Previously Reported	Adjustments	Reference	As Restated
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (28,601,254)	$ (3,191,364)	B, D	$ (31,792,618)
Adjustments to reconcile net loss to cash used in operating activities:				
Depreciation and amortization	148,435	—		148,435
Stock-based compensation	1,452,964	—		1,452,964
Loss on disposal of asset	3,386	—		3,386
Costs to issue warrants	—	6,824,605	B	6,824,605
Change in fair value of warrants	—	(3,633,241)	D	(3,633,241)
Change in operating lease right-of-use asset	90,432	—		90,432
Changes in:				
Prepaid expenses and other assets	204,242	—		204,242
Accounts payable and accrued liabilities	1,623,529	—		1,623,529
Lease liability	(144,035)	—		(144,035)
Cash used in operating activities	(25,222,301)	—		(25,222,301)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property, plant & equipment	(225,971)	—		(225,971)
Cash used in investing activities	(225,971)	—		(225,971)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from issuance of preferred stock and warrants, net of issuance costs	9,610,655	—		9,610,655
Cash provided by financing activities	9,610,655	—		9,610,655
DECREASE IN CASH AND CASH EQUIVALENTS	(15,837,617)	—		(15,837,617)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	35,703,975	—		35,703,975
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 19,866,358	$ —		$ 19,866,358

15. RESTATEMENT OF PREVIOUSLY ISSUED QUARTERLY FINANCIAL STATEMENTS (Unaudited)

As described previously, when the Company determined that it was necessary to re-evaluate its accounting treatment for previously issued warrants and preferred stock and restate previously filed financial statements, the previously reported quarterly financial statements also required restatement. The statements below present the unaudited restated condensed consolidated balance sheets and the restated condensed consolidated statements of operations, convertible preferred stock and stockholders' equity, and cash flows, with adjustments, for the quarters ended March 31, 2023, June 30, 2023, September 30, 2023, March 31, 2022, June 30, 2022, and September 30, 2022. The lettered references are consistent with those in Note 14.

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2023			
	As Previously Reported	Restatement Adjustments	Reference	As Restated
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	$ 12,682,691	$ —		$ 12,682,691
Prepaid expenses and other current assets	1,163,745	—		1,163,745
Total current assets	13,846,436	—		13,846,436
Property, plant & equipment, net	376,084	—		376,084
Operating lease right-of-use asset	546,505	—		546,505
Other long-term assets	69,431	—		69,431
TOTAL ASSETS	$ 14,838,456	$ —		$ 14,838,456
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accrued liabilities	$ 6,904,545	$ —		$ 6,904,545
Warrant liability	—	4,581,455	A	4,581,455
Lease liability, current	51,106	—		51,106
Total current liabilities	6,955,651	4,581,455		11,537,106
Lease liability, net of current portion	548,344	—		548,344
TOTAL LIABILITIES	7,503,995	4,581,455		12,085,450
COMMITMENTS AND CONTINGENCIES (Note 10)				
MEZZANINE EQUITY:				
Series D convertible preferred stock; 111.11 shares authorized, issued and outstanding as of March 31, 2023	—	1,382,023	A	1,382,023
STOCKHOLDERS' (DEFICIT) EQUITY:				
Series D convertible preferred stock, 111.11 shares authorized, issued and outstanding as of March 31, 2023	1,382,023	(1,382,023)	A	—
Common stock, $0.00001 par value; 170,000,000 shares authorized; 9,740,507 shares issued and outstanding as of March 31, 2023	97	—		97
Additional paid-in capital	194,032,651	(25,480,888)	A, B, F	168,551,763
Accumulated deficit	(188,080,310)	20,899,433	B, D, F	(167,180,877)
Total stockholders' equity	7,334,461	(5,963,478)		1,370,983
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	$ 14,838,456	$ —		$ 14,838,456

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2023			
	As Previously Reported	Restatement Adjustments	Reference	As Restated
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	$ 5,152,972	$ —		$ 5,152,972
Prepaid expenses and other current assets	456,679	—		456,679
Total current assets	5,609,651	—		5,609,651
Property, plant & equipment, net	337,434	—		337,434
Operating lease right-of-use asset	532,300	—		532,300
Other long-term assets	29,780	—		29,780
TOTAL ASSETS	$ 6,509,165	$ —		$ 6,509,165
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accrued liabilities	$ 6,391,673	$ —		$ 6,391,673
Warrant liability	—	6,538,873	A	6,538,873
Lease liability, current	53,640	—		53,640
Total current liabilities	6,445,313	6,538,873		12,984,186
Lease liability, net of current portion	530,856	—		530,856
TOTAL LIABILITIES	6,976,169	6,538,873		13,515,042
COMMITMENTS AND CONTINGENCIES (Note 10)				
MEZZANINE EQUITY:				
Series D convertible preferred stock; 111.11 shares authorized, issued and outstanding as of June 30, 2023	—	1,382,023	A	1,382,023
STOCKHOLDERS' (DEFICIT) EQUITY:				
Series D convertible preferred stock; 111.11 shares authorized, issued and outstanding as of June 30, 2023	1,382,023	(1,382,023)	A	—
Common stock, $0.00001 par value; 170,000,000 shares authorized; 9,740,507 shares issued and outstanding as of June 30 2023	97	—		97
Additional paid-in capital	194,452,408	(25,480,888)	A, B, F	168,971,520
Accumulated deficit	(196,301,532)	18,942,015	B, D, F	(177,359,517)
Total stockholders' (deficit) equity	(467,004)	(7,920,896)		(8,387,900)
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	$ 6,509,165	$ —		$ 6,509,165

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2023			
	As Previously Reported	Restatement Adjustments	Reference	As Restated
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	$ 18,986,443	$ —		$ 18,986,443
Prepaid expenses and other current assets	1,123,467	—		1,123,467
Total current assets	20,109,910	—		20,109,910
Property, plant & equipment, net	893,509	—		893,509
Operating lease right-of-use asset	517,566	—		517,566
Other long-term assets	29,780	—		29,780
TOTAL ASSETS	$ 21,550,765	$ —		$ 21,550,765
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accrued liabilities	$ 7,814,590	$ —		$ 7,814,590
Warrant liability	8,600,000	13,365,401	A, C	21,965,401
Lease liability, current	56,263	—		56,263
Total current liabilities	16,470,853	13,365,401		29,836,254
Lease liability, net of current portion	512,750	—		512,750
TOTAL LIABILITIES	16,983,603	13,365,401		30,349,004
COMMITMENTS AND CONTINGENCIES (Note 10)				
MEZZANINE EQUITY:				
Preferred stock, $0.00001 par value; Series E-1 preferred stock; 1,225 shares authorized, issued and outstanding as of September 30, 2023; Series D convertible preferred stock; 111.11 shares issued and outstanding as of September 30, 2023	17,920,000	1,282,023	A	19,202,023
STOCKHOLDERS' (DEFICIT) EQUITY:				
Series D convertible preferred stock; 111.11 shares authorized, issued and outstanding as of September 30, 2023	1,382,023	(1,382,023)	A	—
Common stock, $0.00001 par value; 170,000,000 shares authorized; 9,918,384 shares issued and outstanding as of September 30 2023	99	—		99
Additional paid-in capital	195,298,922	(28,419,388)	A, B, C, F	166,879,534
Accumulated deficit	(210,033,882)	15,153,987	B, D, F	(194,879,895)
Total stockholders' (deficit) equity	(13,352,838)	(14,647,424)		(28,000,262)
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	$ 21,550,765	$ —		$ 21,550,765

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31, 2023			
	As Previously Reported	Adjustments	Reference	As Restated
OPERATING EXPENSES:				
Research and development	$ 6,654,094	$ (294,838)	E	$ 6,359,256
General and administrative	2,051,207	294,838	E	2,346,045
Total operating expenses	8,705,301	—		8,705,301
LOSS FROM OPERATIONS	(8,705,301)	—		(8,705,301)
OTHER INCOME:				
Gain on valuation of warrants	—	1,390,797	D	1,390,797
Interest income	124,034	—		124,034
Total other income, net	124,034	1,390,797		1,514,831
NET LOSS	$ (8,581,267)	$ 1,390,797		$ (7,190,470)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (0.76)	$ 0.12		$ (0.64)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	11,261,217	—		11,261,217

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30, 2023			
	As Previously Reported	Adjustments	Reference	As Restated
OPERATING EXPENSES:				
Research and development	$ 6,308,430	$ (173,420)	E	$ 6,135,010
General and administrative	1,985,572	173,420	E	2,158,992
Total operating expenses	8,294,002	—		8,294,002
LOSS FROM OPERATIONS	(8,294,002)	—		(8,294,002)
OTHER INCOME (EXPENSE):				
Gain (loss) on valuation of warrants	—	(1,957,418)	D	(1,957,418)
Interest income	72,780	—		72,780
Total other income (expense), net	72,780	(1,957,418)		(1,884,638)
NET LOSS	$ (8,221,222)	$ (1,957,418)		$ (10,178,640)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (0.73)	$ (0.17)		$ (0.90)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	11,261,217	—		11,261,217

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENT OF OPERATIONS
(Unaudited)

	Six Months Ended June 30, 2023			
	As Previously Reported	Adjustments	Reference	As Restated
OPERATING EXPENSES:				
Research and development	$ 12,962,524	$ (468,258)	E	$ 12,494,266
General and administrative	4,036,779	468,258	E	4,505,037
Total operating expenses	16,999,303	—		16,999,303
LOSS FROM OPERATIONS	(16,999,303)	—		(16,999,303)
OTHER INCOME (EXPENSE):				
Loss on valuation of warrants	—	(566,621)	D	(566,621)
Interest income	196,814	—		196,814
Total other income (expense), net	196,814	(566,621)		(369,807)
NET LOSS	$ (16,802,489)	$ (566,621)		$ (17,369,110)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (1.49)	$ (0.05)		$ (1.54)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	11,261,217	—		11,261,217

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENT OF OPERATIONS
(Unaudited)

	Three Months Ended September 30, 2023			
	As Previously Reported	Adjustments	Reference	As Restated
OPERATING EXPENSES:				
Research and development	$ 7,312,504	$ (277,848)	E	$ 7,034,656
General and administrative	2,100,956	277,848	E	2,378,804
Total operating expenses	9,413,460	—		9,413,460
LOSS FROM OPERATIONS	(9,413,460)	—		(9,413,460)
OTHER INCOME (EXPENSE):				
Warrant issuance expense	(470,000)	—		(470,000)
Loss on valuation of warrants	(3,900,000)	(3,788,028)	D	(7,688,028)
Interest income	51,110	—		51,110
Total other income (expense), net	(4,318,890)	(3,788,028)		(8,106,918)
NET LOSS	$ (13,732,350)	$ (3,788,028)		$ (17,520,378)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (1.21)	$ (0.33)		$ (1.55)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	11,308,738	—		11,308,738

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENT OF OPERATIONS
(Unaudited)

	Nine Months Ended September 30, 2023			
	As Previously Reported	Adjustments	Reference	As Restated
OPERATING EXPENSES:				
Research and development	$ 20,275,004	$ (746,106)	E	$ 19,528,898
General and administrative	6,137,760	746,106	E	6,883,866
Total operating expenses	26,412,764	—		26,412,764
LOSS FROM OPERATIONS	(26,412,764)	—		(26,412,764)
OTHER INCOME (EXPENSE):				
Warrant issuance expense	(470,000)	—		(470,000)
Loss on valuation of warrants	(3,900,000)	(4,354,649)	D	(8,254,649)
Interest income	247,925	—		247,925
Total other income (expense), net	(4,122,075)	(4,354,649)		(8,476,724)
NET LOSS	$ (30,534,839)	$ (4,354,649)		$ (34,889,488)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (2.71)	$ (0.39)		$ (3.09)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	11,277,231	—		11,277,231

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY
(Unaudited)

	Series D and Series E-1 Preferred Stock		Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Shares	Par Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Previously Reported									
Balance at December 31, 2022	—	$ —	111.11	$ 1,382,023	9,385,272	$ 94	$ 193,624,445	$ (179,499,043)	$ 15,507,519
Conversion of pre-funded warrants into common shares	—	—	—	—	355,235	3	—	—	3
Stock-based compensation	—	—	—	—	—	—	408,206	—	408,206
Net loss (B, D)	—	—	—	—	—	—	—	(8,581,267)	(8,581,267)
Balance at March 31, 2023	—	—	111.11	1,382,023	9,740,507	97	194,032,651	(188,080,310)	7,334,461
Stock-based compensation	—	—	—	—	—	—	419,757	—	419,757
Net loss (D)	—	—	—	—	—	—	—	(8,221,222)	(8,221,222)
Balance at June 30, 2023	—	—	111.11	1,382,023	9,740,507	97	194,452,408	(196,301,532)	(467,004)
Issuance of Series E-1 preferred stock, net of issuance costs (Note 6)	1,225.00	17,920,000	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	497,878	—	497,878
Exercise of warrants into common shares	—	—	—	—	177,877	2	348,636	—	348,638
Net loss	—	—	—	—	—	—	—	(13,732,350)	(13,732,350)
Balance at September 30, 2023	1,225.00	$ 17,920,000	111.11	$ 1,382,023	9,918,384	$ 99	$ 195,298,922	$ (210,033,882)	$ (13,352,838)
Adjustments									
Balance at December 31, 2022 (A, F)	111.11	$ 1,382,023	(111.11)	$ (1,382,023)	—	$ —	$ (25,480,888)	$ 19,508,636	$ (7,354,275)
Net loss	—	—	—	—	—	—	—	1,390,797	1,390,797
Balance at March 31, 2023	111.11	1,382,023	(111.11)	(1,382,023)	—	—	(25,480,888)	20,899,433	(5,963,478)
Net loss	—	—	—	—	—	—	—	(1,957,418)	(1,957,418)
Balance at June 30, 2023	111.11	1,382,023	(111.11)	(1,382,023)	—	—	(25,480,888)	18,942,015	(7,920,896)
Issuance of Series E-1 preferred stock, net of issuance costs (Note 6) (D)	—	(100,000)	—	—	—	—	—	—	—
Reclassification of warrants to liability (C)	—	—	—	—	—	—	(3,239,112)	—	(3,239,112)
Exercise of warrants into common stock (A)	—	—	—	—	—	—	300,612	—	300,612
Net loss	—	—	—	—	—	—	—	(3,788,028)	(3,788,028)
Balance at September 30, 2023	111.11	$ 1,282,023	(111.11)	$ (1,382,023)	—	$ —	$ (28,419,388)	$ 15,153,987	$ (14,647,424)
As Restated									
Balance at December 31, 2022	111.11	$ 1,382,023	—	$ —	9,385,272	$ 94	$ 168,143,557	$ (159,990,407)	$ 8,153,244
Conversion of pre-funded warrants into common shares	—	—	—	—	355,235	3	—	—	3
Stock-based compensation	—	—	—	—	—	—	408,206	—	408,206
Net loss	—	—	—	—	—	—	—	(7,190,470)	(7,190,470)
Balance at March 31, 2023	111.11	1,382,023	—	—	9,740,507	97	168,551,763	(167,180,877)	1,370,983
Stock-based compensation	—	—	—	—	—	—	419,757	—	419,757
Net loss	—	—	—	—	—	—	—	(10,178,640)	(10,178,640)
Balance at June 30, 2023	111.11	1,382,023	—	—	9,740,507	97	168,971,520	(177,359,517)	(8,387,900)
Issuance of Series E-1 preferred stock, net of issuance costs (Note 6)	1,225.00	17,820,000	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	497,878	—	497,878
Exercise of warrants into common stock	—	—	—	—	177,877	2	649,248	—	649,250
Reclassification of pre-funded warrants to liability	—	—	—	—	—	—	(3,239,112)	—	(3,239,112)
Net loss	—	—	—	—	—	—	—	(17,520,378)	(17,520,378)
Balance at September 30, 2023	1,336.11	$ 19,202,023	—	$ —	9,918,384	$ 99	$ 166,879,534	$ (194,879,895)	$ (28,000,262)

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31, 2023			
	As Previously Reported	Adjustments	Reference	As Restated
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (8,581,267)	$ 1,390,797	D	$ (7,190,470)
Adjustments to reconcile net loss to cash used in operating activities:				
Depreciation and amortization	42,557	—		42,557
Stock-based compensation	408,206	—		408,206
Change in fair value of warrants	—	(1,390,797)	D	(1,390,797)
Change in operating lease right-of-use asset	13,829	—		13,829
Changes in:				
Prepaid expenses and other assets	(488,719)	—		(488,719)
Accounts payable and accrued liabilities	1,426,102	—		1,426,102
Lease liability	(4,378)	—		(4,378)
Cash used in operating activities	(7,183,670)	—		(7,183,670)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property, plant & equipment	—	—		—
Cash used in investing activities	—	—		—
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from exercise of pre-funded warrants	3	—		3
Cash provided by financing activities	3	—		3
DECREASE IN CASH AND CASH EQUIVALENTS	(7,183,667)	—		(7,183,667)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	19,866,358	—		19,866,358
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 12,682,691	$ —		$ 12,682,691

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30, 2023			
	As Previously Reported	Adjustments	Reference	As Restated
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (16,802,489)	$ (566,621)	D	$ (17,369,110)
Adjustments to reconcile net loss to cash used in operating activities:				
Depreciation and amortization	81,207	—		81,207
Stock-based compensation	827,963	—		827,963
Change in fair value of warrants	—	566,621	D	566,621
Change in operating lease right-of-use asset	28,034	—		28,034
Changes in:				
Prepaid expenses and other assets	257,998	—		257,998
Lease liability	(19,332)	—		(19,332)
Accounts payable and accrued liabilities	913,230	—		913,230
Cash used in operating activities	(14,713,389)	—		(14,713,389)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property, plant & equipment	—	—		—
Cash used in investing activities	—	—		—
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from exercise of pre-funded warrants	3	—		3
Cash provided by financing activities	3	—		3
DECREASE IN CASH AND CASH EQUIVALENTS	(14,713,386)	—		(14,713,386)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	19,866,358	—		19,866,358
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 5,152,972	$ —		$ 5,152,972

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30, 2023			
	As Previously Reported	Adjustments	Reference	As Restated
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (30,534,839)	$ (4,354,649)	D	$ (34,889,488)
Adjustments to reconcile net loss to cash used in operating activities:				
Depreciation and amortization	122,415	—		122,415
Stock-based compensation	1,325,841	—		1,325,841
Costs to issue warrants	470,000	—		470,000
Change in fair value of warrants	3,900,000	4,354,649	D	8,254,649
Change in operating lease right-of-use asset	42,768	—		42,768
Changes in:				
Prepaid expenses and other assets	(408,790)	—		(408,790)
Accounts payable and accrued liabilities	2,336,146	—		2,336,146
Lease liability	(34,815)	—		(34,815)
Cash used in operating activities	(22,781,274)	—		(22,781,274)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property, plant & equipment	(597,282)	—		(597,282)
Cash used in investing activities	(597,282)	—		(597,282)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from issuance of preferred stock and warrants, net of issuance costs	22,150,000	—		22,150,000
Proceeds from exercise of warrants	348,641	—		348,641
Cash provided by financing activities	22,498,641	—		22,498,641
DECREASE IN CASH AND CASH EQUIVALENTS	(879,915)	—		(879,915)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	19,866,358	—		19,866,358
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 18,986,443	$ —		$ 18,986,443

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2022			
	As Previously Reported	Restatement Adjustments	Reference	As Restated
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	$ 30,634,122	$ —		$ 30,634,122
Prepaid expenses and other current assets	760,420	—		760,420
Total current assets	31,394,542	—		31,394,542
Property, plant & equipment, net	331,144	—		331,144
Operating lease right-of-use asset	183,286	—		183,286
Other long-term assets	81,214	—		81,214
TOTAL ASSETS	$ 31,990,186	$ —		$ 31,990,186
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accrued liabilities	$ 4,511,716	$ —		$ 4,511,716
Warrant liability	—	2,700,000	A	2,700,000
Lease liability, current	139,594	—		139,594
Total current liabilities	4,651,310	2,700,000		7,351,310
Lease liability, net of current portion	129,714	—		129,714
TOTAL LIABILITIES	4,781,024	2,700,000		7,481,024
COMMITMENTS AND CONTINGENCIES (Note 10)				
MEZZANINE EQUITY:				
Series D convertible preferred stock; 111.11 shares authorized, issued and outstanding as of March 31, 2022	—	1,382,023	A	1,382,023
STOCKHOLDERS' EQUITY:				
Series D convertible preferred stock, 111.11 shares authorized, issued and outstanding as of March 31, 2022	1,382,023	(1,382,023)	A	—
Common stock, $0.00001 par value; 160,000,000 shares authorized; 6,110,124 shares issued and outstanding as of March 31, 2022	61	—		61
Additional paid-in capital	182,864,664	(25,300,000)	A, B, F	157,564,664
Accumulated deficit	(157,037,586)	22,600,000	D	(134,437,586)
Total stockholders' equity	27,209,162	(4,082,023)		23,127,139
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 31,990,186	$ —		$ 31,990,186

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2022			
	As Previously Reported	Restatement Adjustments	Reference	As Restated
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	$ 24,805,565	$ —		$ 24,805,565
Prepaid expenses and other current assets	479,668	—		479,668
Total current assets	25,285,233	—		25,285,233
Property, plant & equipment, net	364,838	—		364,838
Operating lease right-of-use asset	161,111	—		161,111
Other long-term assets	81,214	—		81,214
TOTAL ASSETS	$ 25,892,396	$ —		$ 25,892,396
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accrued liabilities	$ 5,462,267	$ —		$ 5,462,267
Warrant liability	—	900,000	A	900,000
Lease liability, current	143,843	—		143,843
Total current liabilities	5,606,110	900,000		6,506,110
Lease liability, net of current portion	92,214	—		92,214
TOTAL LIABILITIES	5,698,324	900,000		6,598,324
COMMITMENTS AND CONTINGENCIES (Note 10)				
MEZZANINE EQUITY:				
Series D convertible preferred stock; 111.11 shares authorized, issued and outstanding as of June 30, 2022	—	1,382,023	A	1,382,023
STOCKHOLDERS' EQUITY:				
Series D convertible preferred stock; 111.11 shares authorized, issued and outstanding as of June 30, 2022	1,382,023	(1,382,023)	A	—
Common stock, $0.00001 par value; 160,000,000 shares authorized; 6,110,122 shares issued and outstanding as of June 30 2022	61	—		61
Additional paid-in capital	183,284,617	(25,300,000)	A, B, F	157,984,617
Accumulated deficit	(164,472,629)	24,400,000	D	(140,072,629)
Total stockholders' equity	20,194,072	(2,282,023)		17,912,049
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 25,892,396	$ —		$ 25,892,396

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2022			
	As Previously Reported	Restatement Adjustments	Reference	As Restated
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	$ 17,785,322	$ —		$ 17,785,322
Prepaid expenses and other current assets	975,936	—		975,936
Total current assets	18,761,258	—		18,761,258
Property, plant & equipment, net	338,944	—		338,944
Operating lease right-of-use asset	138,097	—		138,097
Other long-term assets	81,214	—		81,214
TOTAL ASSETS	$ 19,319,513	$ —		$ 19,319,513
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accrued liabilities	$ 6,367,035	$ —		$ 6,367,035
Warrant liability	—	600,000	A, C	600,000
Lease liability, current	148,200	—		148,200
Total current liabilities	6,515,235	600,000		7,115,235
Lease liability, net of current portion	53,769	—		53,769
TOTAL LIABILITIES	6,569,004	600,000		7,169,004
COMMITMENTS AND CONTINGENCIES (Note 10)				
MEZZANINE EQUITY:				
Preferred stock, $0.00001 par value; Series D convertible preferred stock; 111.11 shares issued and outstanding as of September 30, 2022	—	1,382,023	A	1,382,023
STOCKHOLDERS' EQUITY:				
Series D convertible preferred stock; 111.11 shares authorized, issued and outstanding as of September 30, 2022	1,382,023	(1,382,023)	A	—
Common stock, $0.00001 par value; 160,000,000 shares authorized; 6,110,118 shares issued and outstanding as of September 30 2022	61	—		61
Additional paid-in capital	183,652,376	(25,300,000)	A, B, C, F	158,352,376
Accumulated deficit	(172,283,951)	24,700,000	D	(147,583,951)
Total stockholders' equity	12,750,509	(1,982,023)		10,768,486
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 19,319,513	$ —		$ 19,319,513

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31, 2022			
	As Previously Reported	Adjustments	Reference	As Restated
OPERATING EXPENSES:				
Research and development	$ 3,887,039	$ (183,208)	E	$ 3,703,831
General and administrative	2,253,188	183,208	E	2,436,396
Total operating expenses	6,140,227	—		6,140,227
LOSS FROM OPERATIONS	(6,140,227)	—		(6,140,227)
OTHER INCOME (EXPENSE):				
Loss on valuation of warrants	—	(100,000)	D	(100,000)
Interest income	430	—		430
Total other income (expense), net	430	(100,000)		(99,570)
NET LOSS	$ (6,139,797)	$ (100,000)		$ (6,239,797)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (1.00)	$ (0.02)		$ (1.02)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	6,110,126	—		6,110,126

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30, 2022			
	As Previously Reported	Adjustments	Reference	As Restated
OPERATING EXPENSES:				
Research and development	$ 4,498,657	$ (353,739)	E	$ 4,144,918
General and administrative	2,936,867	353,739	E	3,290,606
Total operating expenses	7,435,524	—		7,435,524
LOSS FROM OPERATIONS	(7,435,524)	—		(7,435,524)
OTHER INCOME:				
Gain on valuation of warrants	—	1,800,000	D	1,800,000
Interest income	481	—		481
Total other income, net	481	1,800,000		1,800,481
NET LOSS	$ (7,435,043)	$ 1,800,000		$ (5,635,043)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (1.22)	$ 0.29		$ (0.92)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	6,110,124	—		6,110,124

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENT OF OPERATIONS
(Unaudited)

	Six Months Ended June 30, 2022			
	As Previously Reported	Adjustments	Reference	As Restated
OPERATING EXPENSES:				
Research and development	$ 8,385,656	$ (536,947)	E	$ 7,848,709
General and administrative	5,190,095	536,947	E	5,727,042
Total operating expenses	13,575,751	—		13,575,751
LOSS FROM OPERATIONS	(13,575,751)	—		(13,575,751)
OTHER INCOME:				
Gain on valuation of warrants	—	1,700,000	D	1,700,000
Interest income	911	—		911
Total other income, net	911	1,700,000		1,700,911
NET LOSS	$ (13,574,840)	$ 1,700,000		$ (11,874,840)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (2.22)	$ 0.28		$ (1.94)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	6,110,125	—		6,110,125

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENT OF OPERATIONS
(Unaudited)

	Three Months Ended September 30, 2022			
	As Previously Reported	Adjustments	Reference	As Restated
OPERATING EXPENSES:				
Research and development	$ 5,380,190	$ (169,365)	E	$ 5,210,825
General and administrative	2,435,296	169,365	E	2,604,661
Total operating expenses	7,815,486	—		7,815,486
LOSS FROM OPERATIONS	(7,815,486)	—		(7,815,486)
OTHER INCOME:				
Gain on valuation of warrants	—	300,000	D	300,000
Interest income	4,164	—		4,164
Total other income, net	4,164	300,000		304,164
NET LOSS	$ (7,811,322)	$ 300,000		$ (7,511,322)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (1.28)	$ 0.05		$ (1.23)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	6,110,119	—		6,110,119

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENT OF OPERATIONS
(Unaudited)

	Nine Months Ended September 30, 2022			
	As Previously Reported	Adjustments	Reference	As Restated
OPERATING EXPENSES:				
Research and development	$ 13,765,846	$ (706,312)	E	$ 13,059,534
General and administrative	7,625,391	706,312	E	8,331,703
Total operating expenses	21,391,237	—		21,391,237
LOSS FROM OPERATIONS	(21,391,237)	—		(21,391,237)
OTHER INCOME:				
Gain on valuation of warrants	—	2,000,000	D	2,000,000
Interest income	5,075	—		5,075
Total other income, net	5,075	2,000,000		2,005,075
NET LOSS	$ (21,386,162)	$ 2,000,000		$ (19,386,162)
NET LOSS PER SHARE — BASIC AND DILUTED	$ (3.50)	$ 0.33		$ (3.17)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING — BASIC AND DILUTED	6,110,123	—		6,110,123

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY
(Unaudited)

	Series D Preferred Stock		Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Shares	Par Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Previously Reported									
Balance at December 31, 2021	—	$ —	111.11	$ 1,382,023	6,110,125	$ 61	$ 182,560,859	$ (150,897,789)	$ 33,045,154
Stock-based compensation	—	—	—	—	—	—	303,805	—	303,805
Retired shares	—	—	—	—	(1)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(6,139,797)	(6,139,797)
Balance at March 31, 2022	—	—	111.11	1,382,023	6,110,124	61	182,864,664	(157,037,586)	27,209,162
Stock-based compensation	—	—	—	—	—	—	419,953	—	419,953
Retired shares	—	—	—	—	(2)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(7,435,043)	(7,435,043)
Balance at June 30, 2022	—	—	111.11	1,382,023	6,110,122	61	183,284,617	(164,472,629)	20,194,072
Stock-based compensation	—	—	—	—	—	—	367,759	—	367,759
Retired shares	—	—	—	—	(4)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(7,811,322)	(7,811,322)
Balance at September 30, 2022	—	$ —	111.11	$ 1,382,023	6,110,118	$ 61	$ 183,652,376	$ (172,283,951)	$ 12,750,509
Adjustments									
Balance at December 31, 2021 (A, F)	111.11	$ 1,382,023	(111.11)	$ (1,382,023)	—	$ —	$ (25,300,000)	$ 22,700,000	$ (3,982,023)
Net loss	—	—	—	—	—	—	—	(100,000)	(100,000)
Balance at March 31, 2022	111.11	1,382,023	(111.11)	(1,382,023)	—	—	(25,300,000)	22,600,000	(4,082,023)
Net loss	—	—	—	—	—	—	—	1,800,000	1,800,000
Balance at June 30, 2022	111.11	1,382,023	(111.11)	(1,382,023)	—	—	(25,300,000)	24,400,000	(2,282,023)
Net loss	—	—	—	—	—	—	—	300,000	300,000
Balance at September 30, 2022	111.11	$ 1,382,023	(111.11)	$ (1,382,023)	—	$ —	$ (25,300,000)	$ 24,700,000	$ (1,982,023)
As Restated									
Balance at December 31, 2021	111.11	$ 1,382,023	—	$ —	6,110,125	$ 61	$ 157,260,859	$ (128,197,789)	$ 29,063,131
Stock-based compensation	—	—	—	—	—	—	303,805	—	303,805
Retired shares	—	—	—	—	(1)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(6,239,797)	(6,239,797)
Balance at March 31, 2022	111.11	1,382,023	—	—	6,110,124	61	157,564,664	(134,437,586)	23,127,139
Stock-based compensation	—	—	—	—	—	—	419,953	—	419,953
Retired shares	—	—	—	—	(2)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(5,635,043)	(5,635,043)
Balance at June 30, 2022	111.11	1,382,023	—	—	6,110,122	61	157,984,617	(140,072,629)	17,912,049
Stock-based compensation	—	—	—	—	—	—	367,759	—	367,759
Retired shares	—	—	—	—	(4)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(7,511,322)	(7,511,322)
Balance at September 30, 2022	111.11	$ 1,382,023	—	$ —	6,110,118	$ 61	$ 158,352,376	$ (147,583,951)	$ 10,768,486

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31, 2022			
	As Previously Reported	Adjustments	Reference	As Restated
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (6,139,797)	$ (100,000)	D	$ (6,239,797)
Adjustments to reconcile net loss to cash used in operating activities:				
Depreciation and amortization	43,417	—		43,417
Stock-based compensation	303,805	—		303,805
Change in fair value of warrants	—	100,000	D	100,000
Change in operating lease right-of-use asset	21,358	—		21,358
Changes in:				
Prepaid expenses and other assets	107,065	—		107,065
Accounts payable and accrued liabilities	656,802	—		656,802
Lease liability	(32,433)	—		(32,433)
Cash used in operating activities	(5,039,783)	—		(5,039,783)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property, plant & equipment	(30,070)	—		(30,070)
Cash used in investing activities	(30,070)	—		(30,070)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from exercise of warrants	—	—		—
Cash provided by financing activities	—	—		—
DECREASE IN CASH AND CASH EQUIVALENTS	(5,069,853)	—		(5,069,853)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	35,703,975	—		35,703,975
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 30,634,122	$ —		$ 30,634,122

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30, 2022			
	As Previously Reported	Adjustments	Reference	As Restated
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (13,574,840)	$ 1,700,000	D	$ (11,874,840)
Adjustments to reconcile net loss to cash used in operating activities:				
Depreciation and amortization	77,316	—		77,316
Stock-based compensation	723,758	—		723,758
Change in fair value of warrants	—	(1,700,000)	D	(1,700,000)
Change in operating lease right-of-use asset	43,533	—		43,533
Loss on disposal of property, plant & equipment	3,386			3,386
Changes in:				
Prepaid expenses and other assets	387,817	—		387,817
Lease liability	(65,684)	—		(65,684)
Accounts payable and accrued liabilities	1,607,353	—		1,607,353
Cash used in operating activities	(10,797,361)	—		(10,797,361)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property, plant & equipment	(101,049)	—		(101,049)
Cash used in investing activities	(101,049)	—		(101,049)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from exercise of pre-funded warrants	—	—		—
Cash provided by financing activities	—	—		—
DECREASE IN CASH AND CASH EQUIVALENTS	(10,898,410)	—		(10,898,410)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	35,703,975	—		35,703,975
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 24,805,565	$ —		$ 24,805,565

CELLECTAR BIOSCIENCES, INC.

RESTATED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30, 2022			
	As Previously Reported	Adjustments	Reference	As Restated
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (21,386,162)	$ 2,000,000	D	$ (19,386,162)
Adjustments to reconcile net loss to cash used in operating activities:				
Depreciation and amortization	110,276	—		110,276
Stock-based compensation	1,091,517	—		1,091,517
Change in fair value of warrants	—	(2,000,000)	D	(2,000,000)
Change in operating lease right-of-use asset	66,547	—		66,547
Loss on disposal of property, plant & equipment	3,386			3,386
Changes in:				
Prepaid expenses and other assets	(108,451)	—		(108,451)
Accounts payable and accrued liabilities	2,512,121	—		2,512,121
Lease liability	(99,772)	—		(99,772)
Cash used in operating activities	(17,810,538)	—		(17,810,538)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchases of property, plant & equipment	(108,115)	—		(108,115)
Cash used in investing activities	(108,115)	—		(108,115)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from issuance of preferred stock and warrants, net of issuance costs	—	—		—
Proceeds from exercise of warrants	—	—		—
Cash provided by financing activities	—	—		—
DECREASE IN CASH AND CASH EQUIVALENTS	(17,918,653)	—		(17,918,653)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	35,703,975	—		35,703,975
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 17,785,322	$ —		$ 17,785,322

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Up to 19,221,348 Shares of Common Stock Offered by the Selling Stockholders

PROSPECTUS

February 6, 2025

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