2025 Annual Report

Dear Stockholders,

2025 was a pivotal year for Actuate Therapeutics as we advanced our clinical programs and continued building a foundation for long-term value creation. At the center of that progress is elraglusib, a novel small molecule with a differentiated, multi-layered mechanism of action.

In metastatic pancreatic ductal adenocarcinoma (mPDAC), one of the most aggressive and difficult-to-treat cancers, we achieved what we believe is a meaningful clinical breakthrough. Our randomized Phase 2 trial met its primary endpoint, demonstrating a statistically significant improvement in overall survival when elraglusib was added to the standard of care gemcitabine/nab-paclitaxel. The combination reduced the risk of death by 38%, increased the median overall survival to 10.1 months versus 7.2 months, and importantly demonstrated durable survival. We saw 12-month survival rates double and 24-month survival increase fivefold. In a disease where historical survival is often less than one year, these results truly matter.

What excites us most is not just the magnitude of benefit but the pattern - increased durability, patients living longer than expected, and signals, both genomic and immunologic, that suggest elraglusib is not simply adding incremental benefit but may be reshaping the tumor environment and enhancing anti-tumor response. With that, we increasingly believe elraglusib has the potential to serve as a backbone therapy in pancreatic cancer, capable of combining across multiple treatment regimens.

Our strategy has always extended beyond a single indication. Elraglusib, originally developed as a GSK-3 inhibitor, modulates key tumor survival and resistance pathways. This positions it differently from therapies that focus solely on driver mutations – it allows us to potentially enhance the effectiveness of existing treatments across multiple cancers. In 2025 and recently, we expanded this vision by:

- Advancing combination strategies, including ongoing and planned studies with chemotherapy, immunotherapy, and RAS / RAF pathway-inhibitors;
- Updating our clinical data package to support planned regulatory submissions with the FDA and EMA in 2026; and
- Continuing to build clinical and scientific evidence supporting elraglusib's role across additional tumor types.

We are particularly encouraged by early signals of efficacy in pediatric cancers, where unmet need is especially high. In a Phase 1 study in heavily pretreated patients, we observed clinical responses and disease control, including complete responses in Ewing sarcoma and neuroblastoma patients. These data, along with Rare Pediatric Disease Designations from the FDA, support advancing elraglusib in these indications in 2026.

We are also expanding potential use of elraglusib with an oral tablet formulation, with a planned Phase 1/2 program in advanced cancers. This approach enables broader use and builds on early encouraging activity in refractory metastatic melanoma, including a durable complete response lasting more than six years using elraglusib as a monotherapy. Importantly, the oral formulation has the potential to expand patient access, improve convenience, and ultimately drive better outcomes, while also enabling more flexible and efficient development across multiple indications. We believe that the new oral formulation will play an important role in extending elraglusib across additional indications and treatment settings.

As we enter 2026, our priorities are clear:

- Request meetings with the FDA to gain regulatory clarity on the design of a future clinical trial required to support potential product registration in the U.S., and with the EMA to discuss regulatory and clinical trial requirements for potential conditional approval in Europe for the treatment of first-line mPDAC;
- Advance development of elraglusib in pediatric cancers and other high-need indications;
- Initiate the oral tablet program;
- Expand combination strategies across tumor types, including combinations with RAS / RAF pathway-inhibitors; and
- Continue to strengthen our balance sheet with additional capital with which to fund our goals.

The data we generated to date reinforce our belief that elraglusib has the potential to become a foundational therapy across multiple oncology settings. We are energized by the data, the opportunities ahead, and the potential to deliver meaningful impact for patients.

Thank you for your continued support.

Yours sincerely,

Daniel M. Schmitt, President & Chief Executive Officer
Actuate Therapeutics, Inc.

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM _____ TO _____ _**

Commission File Number: 001-42139

ACTUATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-3044785**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1751 River Run, Suite 400, Fort Worth, Texas	**76107**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (817) 887-8455

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.000001 per share	ACTU	The Nasdaq Stock Market LLC

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

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

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

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

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

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

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

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

Aggregate market value of registrant's common stock held by non-affiliates of the registrant on June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing price of the registrant's common stock on such date as reported by Nasdaq Global Market, was approximately $42.1 million. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of registrant's common stock outstanding as of March 25, 2026 was 23,709,943.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days after the end of the fiscal year ended December 31, 2025. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Table of Contents

PART I

PART II

PART III

PART IV

Unless the context requires otherwise, references in this Annual Report on Form 10-K to "Actuate," the "Company," "we," "us," and "our" refer to Actuate Therapeutics, Inc.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Report" or "Annual Report") contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") about us and our industry. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "ongoing," "plan," "potential," "predict," "project," "should," "target," "will," "would," or the negative of these terms or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements involve estimates, assumptions and uncertainties which could cause actual results to differ materially from those expressed in them. The forward-looking statements in this Report include, but are not limited to, statements concerning the following:

- our expectations for the results of our ongoing Phase 2 clinical trial of elraglusib for the treatment of mPDAC;
- our plans to meet with the U.S. Food and Drug Administration (the "FDA") or European Medicines Agency ("EMA") in the first half of 2026 to discuss the design and execution of a Phase 3 global registration study of elraglusib for the treatment of mPDAC;
- our expectations for the results of our pre-clinical studies and clinical trials;
- our ability to enroll additional patients or establish or advance plans for further development, including through conversations with the FDA or EMA;
- our ability to successfully manage our relationships with our licensors and third-party service providers;
- our ability to maintain, protect and further develop our intellectual property rights;
- our ability to fund our current operations with our cash on hand as of the date of this Report and our ability to raise additional capital as and when needed;
- our future financial and operating results;
- our intentions, expectations and beliefs regarding anticipated growth, market penetration and trends in our business; and
- the timing and success of our plan of commercialization.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those summarized under the heading "Risk Factor Summary" and discussed further under the heading "Risk Factors" in this Report.

You should assume that the information appearing in this Report is accurate as of its date only. 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. 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. All written or oral forward-looking statements attributable to us or any person acting on our behalf made after the date of this Report are expressly qualified in their entirety by the risk factors and cautionary statements contained in this Report. Unless legally required, we do not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date of this Report or to reflect the occurrence of unanticipated events.

In addition, statements that "we believe" and similarly qualified statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Report, and

while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon them.

The discussion of the Company's financial condition and results of operations should be read in conjunction with the Company's consolidated financial statements and the related notes thereto included in this Report.

RISK FACTOR SUMMARY

The following is a summary of the key risks and uncertainties that make an investment in our securities speculative and risky. The summary below does not contain all of the information that may be important to you, and you should read this summary together with the more detailed description of the risks set forth under "Item 1A. Risk Factors" of this Annual Report.

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant operating losses for the foreseeable future. We may never generate revenue or achieve profitability, and if we do achieve profitability, it may not be sustained.
- We will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or our operations.
- Raising additional capital or acquiring or licensing assets by issuing equity or debt securities may cause dilution to our stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

Risks Related to the Development and Commercialization of Our Product Candidates

- We currently depend entirely on the success of elraglusib, which is our only product candidate. If we are unable to advance elraglusib in clinical development, obtain regulatory approval and ultimately commercialize elraglusib in a timely manner, our business will be materially harmed.
- We do not have and may never have any approved products on the market. Our business is highly dependent upon receiving approvals from various governmental agencies and will be severely harmed if we are not granted approval to manufacture and sell our product candidates.
- Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Elraglusib or any future product candidates may not achieve favorable results or receive regulatory approval on a timely basis, if at all.
- Our product development efforts are at an early stage. We have not yet undertaken any marketing efforts, and there can be no assurance that future anticipated market testing and analyses will validate our marketing strategy. We may need to modify the products, or we may not be successful in either developing or marketing those products.
- The successful commercialization of elraglusib or any future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

Risks Related to Our Reliance on Third Parties

- The termination of third-party licenses could adversely affect our rights to important technologies.
- Our current drug substance (“DS”) manufacturer of elraglusib is in China, and it is unknown how current or future geopolitical relationships with China may affect our ability to obtain DS, increase our costs, delay clinical trials and potential regulatory approval, and adversely impact our financial condition.
- We depend on a third-party manufacturer for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. We obtain our supplies on a purchase order basis and do not have any long-term supply agreements in place. If we are unable to source these supplies on a timely basis, or establish longer-term contracts with suppliers, we will not be able to complete our clinical trials or studies on time and the development of our product candidates may be delayed.
- Data provided by collaborators and other parties upon which we rely have not been independently verified and could turn out to be inaccurate, misleading, or incomplete.

Risks Related to Our Intellectual Property

- We may not be able to enforce our intellectual property rights throughout the world.
- If we and our third-party licensors do not obtain and preserve protection for key intellectual property rights, our competitors may be able to take advantage of our (and our licensors') development efforts.
- Intellectual property disputes could require us to spend time and money to address such disputes and could limit our intellectual property rights.
- Patent terms may be inadequate to protect the competitive position of elraglusib or any future product candidates for an adequate amount of time.
- We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.
- Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse impact on the success of our business.
- Intellectual property rights of third parties could adversely affect our ability to commercialize our current or future technologies or drug candidates, and we might be required to litigate or obtain licenses from third parties to develop or market our current or future technologies or drug candidates, which may not be available on commercially reasonable terms, or at all.
- We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Risks Related to Our Business Operations and Industry

- We may be subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability or otherwise adversely affect our business.
- The U.S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.
- Our information technology systems, or those of any of our service providers, may fail or suffer security incidents and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.
- Disruptions at the U.S. Food and Drug Administration (the "FDA") and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.
- Effective collaboration with the FDA's Center for Drug Evaluation and Research ("CDER") for the approval of drug candidates is a highly demanding process which can result in increased time and expense to gain approvals.

Risks Related to our Common Stock

- Concentration of ownership by our principal stockholders limits the ability of others to influence the outcome of director elections and other transactions requiring stockholder approval, creates the potential for conflicts of interest, may negatively impact our stock price and may deter or prevent efforts by others to acquire us, preventing our stockholders from realizing a control premium.
- There was no public market for our common stock prior to the IPO in August 2024. An active, liquid and orderly market for our common stock may not be sustained, or we may in the future fail to satisfy the continued listing requirements of Nasdaq, and you may not be able to resell your shares at or above your purchase price or at all.
- The trading price of the shares of our common stock could be highly volatile regardless of our operating performance, and purchasers of our common stock could incur substantial losses.

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PART I

Item 1. Business.

Overview

Class-Leading GSK-3β Inhibitor

We are a clinical stage biopharmaceutical company focused on developing therapies for the treatment of high impact, difficult to treat cancers through the inhibition of glycogen synthase kinase-3 ("GSK-3"). We are developing elraglusib, an ATP-competitive small molecule that is designed to enter cancer cells and block the function of the enzyme glycogen synthase kinase-3 beta ("GSK-3β"), a master regulator of complex biological signaling cascades, including those mediated by oncogenes, that lead to tumor cell survival, growth, migration, and invasion. We believe that the blockade of GSK-3β signaling ultimately results in the death of the cancer cells and the regulation of anti-tumor immunity. There are no approved high-affinity inhibitors of GSK-3β and we believe elraglusib is one of the most advanced GSK-3β inhibitors in clinical development. Elraglusib was originally known as 9-ING-41 but was granted the elraglusib International Nonproprietary Names ("INN") and United States Adopted Names ("USAN") generic name in 2021.

Exclusive Rights

We have exclusively licensed elraglusib, a proprietary and patent protected GSK-3 inhibitor developed in a collaboration between The Board of Trustees of the University of Illinois-Chicago ("UIC") and Northwestern University ("NU").

Broad Therapeutic Potential

We believe elraglusib represents a "pipeline in a molecule" with a broad opportunity for us to potentially initiate and advance multiple drug development programs around our lead asset based on its multimodal mechanisms of action, data emerging from completed or ongoing clinical trials and non-clinical biological, cellular, and animal data. Animal tumor model data, clinical trial data and AI-based computational approaches have identified a number of areas of unmet clinical need in cancer treatment where elraglusib may play an interventional role, including pancreatic, metastatic melanoma, lung, colon, breast, renal, and ovarian cancer, leukemias and lymphomas, as well as some pediatric cancers including Ewing sarcoma, neuroblastoma and pediatric leukemias.

Figure 1 shows the broad therapeutic potential of elraglusib where evidence of preclinical and clinical activity has been observed.

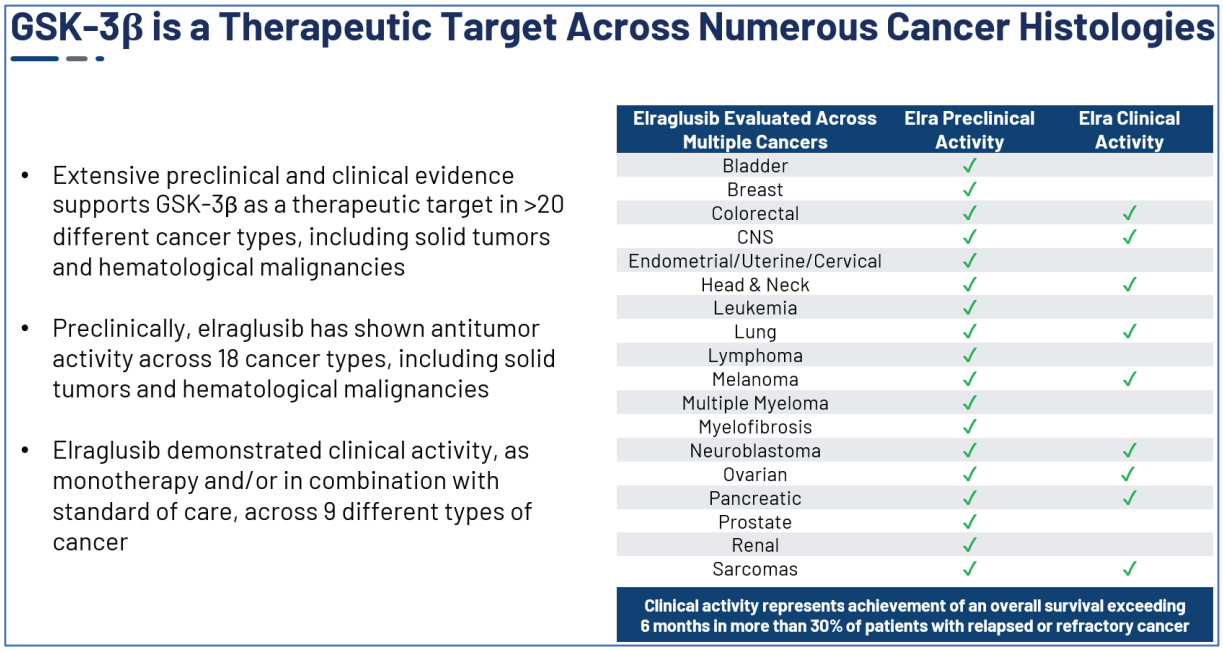

Figure 1: GSK-3β inhibitors and elraglusib's potential to treat numerous cancer histologies.

Significant Clinical Experience and Promising Phase 2 Data in mPDAC

To date, we have treated over 500 patients with elraglusib as an IV injection ("Elraglusib Injection") in Phase 1 and Phase 2 studies.

Our most advanced clinical indication is first-line metastatic pancreatic ductal adenocarcinoma ("mPDAC"). Our Phase 2 study in mPDAC, known as Actuate-1801 Part 3B study, is a randomized, controlled Phase 2 trial that enrolled 286 patients with no prior systemic treatment for metastatic disease. The primary endpoint for this study was median overall survival ("mOS"), with overall survival ("OS") summarized throughout the study by estimates of 1-year survival. Updated data results presented at the American Society of Clinical Oncology ("ASCO") Genitourinary Cancers Symposium ("ASCO GI") in January 2026 utilizing a data cutoff as of November 22, 2025 showed that the trial met its primary endpoint, demonstrating a statistically significant improvement in mOS with elraglusib plus gemcitabine/nab-paclitaxel ("GnP") versus GnP alone.

Data presented at ASCO GI included:

- Statistically significant benefit in mOS in the elraglusib/GnP arm vs GnP control arm (mOS 10.1 months vs. 7.2 months, p=0.02, HR=0.62);
- Near doubling of the 12-month survival rate, from 22.3% in the GnP arm to 44.4% in the elraglusib/GnP arm; and
- Almost fivefold increase in 24-month survival rate, from 2.6% in the GnP control arm to 12.9% in the elraglusib/GnP arm, emphasizing the potential for long-term clinical benefit.

Elraglusib Injection Shows Promise in the Treatment of Pediatric Cancers

In addition to mPDAC, Elraglusib Injection is also being evaluated in pediatric cancer patients with recurrent/refractory solid cancers. This study, Actuate-1902, is a Phase 1/2 study that evaluated escalating doses of elraglusib as a single agent as well as in combination with irinotecan or cyclophosphamide/topotecan in the Phase 1 portion of the trial. Patients in this Actuate-1902 study also experienced a number of objective responses

in the combination chemotherapy arms, and based on this data, we identified Ewing sarcoma and neuroblastoma as new indications for further development of Elraglusib Injection, further expanding the potential of elraglusib.

Elraglusib Oral Dose Tablet Allows Us to Expand into New Indications

We have developed several oral dosage forms of elraglusib, which we believe will allow us to expand the number of cancer indications that we are able to target and allow us to further explore more convenient dose delivery options for patients. A clinical candidate tablet, the Elraglusib Oral Tablet, has been selected for further development and, subject to future funding, we are planning a Phase 1 study to identify the maximum tolerated dose and recommended Phase 2 dose ("RP2D") for Elraglusib Oral Tablet in adult patients with advanced, refractory cancers. Once we have determined a RP2D, several Phase 2 studies have been identified for further clinical development of Elraglusib Oral Tablet, subject to additional funding, based on data from previous studies, including but not limited to, refractory, metastatic melanoma and refractory, metastatic colorectal cancer, and non-small cell lung cancer.

Pancreatic Cancer Represents a High Unmet Need with Limited Treatment Options for Patients

According to the American Cancer Society, the annual incidence of pancreatic cancer is expected to exceed 67,000 patients in the United States in 2026. Pancreatic ductal adenocarcinoma ("PDAC") is considered one of the most aggressive malignancies, with approximately 90% of patients presenting with advanced disease. Despite advances in the treatment therapies over the last 30 years, the 5-year survival rate for Stage IV disease is less than 5%. The standard of care for first-line treatment of mPDAC generally includes one of the following two chemotherapy regimens:

- FOLFIRINOX: A combination of 5-fluorouracil, irinotecan, and oxaliplatin, which has been established as the new standard of care for advanced or mPDAC. It achieved a mOS of 11.1 months in the ACCORD/PRODIGE Phase 3 trial.
- GnP: This regimen achieved a mOS of 8.5 months with GnP compared to 6.7 months with gemcitabine alone in the MPACT Phase 3 trial.

A recent review of clinical trials in *Future Oncology*[1] showed that the mOS in patients with mPDAC treated with GnP ranged from approximately 3.6 to 9.8 months with an unweighted mOS of 6.9 months. Therefore, we believe the ability to extend survival by even a few months would be considered meaningful in this patient population.

Our Strategy and Strengths

We believe that we have several strengths that support our vision of developing therapies for the treatment of high impact, difficult to treat cancers through the inhibition of GSK-3β, including:

- Advancing a potentially class-leading GSK-3β inhibitor, elraglusib with a novel, multimodal mechanisms of action ("MOA") profile, in multiple advanced trials for the treatment of cancer.
- Broad potential with clinical responses (complete responses and partial responses) and extended disease control observed across multiple cancer histologies.
    - Extended survival and increased responses observed in mPDAC, relapsed/refractory Ewing sarcoma, and neuroblastoma.
    - Preliminary evidence of clinical benefit has also been observed in patients with metastatic melanoma and relapsed/refractory colorectal and lung cancer.
- Elraglusib Oral Tablet developed and ready for Phase 1/2 study in advanced cancer patients.
- Broad composition of matter intellectual property protection and development incentives.

[1] Cockrum P, Dennen S, Brown A, Briggs J, Paluri R. Real-world clinical outcomes and economic burden of metastatic pancreatic ductal adenocarcinoma: a systematic review. Future Oncol. 2025; 21: 241-260. doi: 10.1080/14796694.2024.2435253. Epub 2024 Dec 8.

- Orphan Drug Designations for pancreatic and other cancer types; Fast Track Designation for pancreatic cancer.

Our strategy is to develop elraglusib for multiple advanced cancer indications with high unmet medical need and significant commercial potential, initially in patients with metastatic pancreatic cancer, pediatric cancers, and metastatic melanoma, subject to available financing and/or funding from potential strategic collaborations. We believe that our two product candidates, Elraglusib Injection and Elraglusib Oral Tablet, will provide us with two different dosage forms of drug product with different attributes that will allow us to tailor each dosage form to a specific cancer type to potentially improve outcomes and compliance. Key elements of our strategy to accomplish this objective include:

- ***Build a Sustainable Oncology Company.*** Our vision is to build a leading oncology company with a sustainable pipeline of target indications revolving around a patented, active product candidate, elraglusib, that can be delivered in different ways to potentially treat a wide variety of cancers. To accomplish this, we are focused on rapid advancement of our currently active clinical trials while curating and preparing additional indications for future expansion of elraglusib development. This effort is led by Daniel Schmitt, our president, chief executive officer and founder, and Dr. Andrew Mazar, our scientific co-founder and chief operating officer. Together, they bring more than 60 years of combined experience in biotechnology management and healthcare investing. Mr. Schmitt has led and contributed to the successful development and launch of multiple pharmaceutical and health technology products and executed licensing, acquisition, and development transactions totaling over approximately $1.0 billion in milestone value. Dr. Mazar has founded seven start-ups and is the co-founder, former chief scientific officer and director of Monopar Therapeutics, Inc. (Nasdaq: MNPR) as well as the former chief scientific officer of Attenuon, LLC. Dr. Mazar has shepherded eleven drugs from discovery stage through Phase 2 and Phase 3 trials.

- ***Advance Our Lead Product Candidate, Elraglusib, Through Clinical Trials.*** We have generated clinical data from over 500 patients who have been treated with elraglusib to date. Under the innovative seamless study design of our Actuate-1801 Master Protocol, we have reported promising top-line data from our Phase 2 trial testing Elraglusib Injection in combination with GnP in mPDAC. We are also considering advancing the development of elraglusib in pediatric cancers, including Ewing sarcoma and neuroblastoma, based on promising data from the Phase 1 portion of the Actuate-1902 study, pending additional internal or external funding support. We also intend to explore strategically identified investigator-initiated trials ("IITs") that may identify additional indications and standard of care products to combine with elraglusib in indications that go beyond those already identified, which would allow us to further leverage our pipeline in a molecule. By collaborating with our network of oncology Key Opinion Leaders ("KOLs"), we anticipate partnering to access non-dilutive funding for our IITs, to the extent available.

- ***Obtain Regulatory Development Incentives to Accelerate the Path to Potential Approval of Elraglusib.*** One of our strategic objectives is to obtain development incentives in the United States and in other countries that we believe may accelerate our path to drug approval: Orphan Drug Designation ("ODD"), Fast Track Designation ("FTD") and Breakthrough Therapy Designation ("BTD") in the United States; Orphan and priority medicines ("PRIME") designations in the EU; and Orphan designations in Japan and Australia. There is no guarantee that any such designation, if received, will lead to a faster development, regulatory review or approval process; or increase the likelihood that a product candidate will receive FDA approval.

- ***Explore Strategic Partnerships That Can Accelerate and Maximize the Potential of GSK-3 Inhibitors.*** We will evaluate potential strategic partnering opportunities with pharmaceutical companies which could further help us to accelerate development of elraglusib by providing expertise, guidance, and funding to expand the pipeline into different tumors and other disease areas that could benefit from GSK-3 inhibitor therapy. We may also broaden the reach of our platform by selectively in-licensing technologies or novel product candidates, pending the availability of the necessary funding. In addition, we will consider

potentially out-licensing certain geographic rights to elraglusib or other product candidates in our target indications or for indications and industries that we are not currently pursuing ourselves.

- ***Leverage Our Academic and Research Partnerships.*** We are actively engaging with regulators, KOLs, advocates and other stakeholders early and throughout the development process in each cancer indication being considered for development to enhance the probability of technical success. We currently have clinical partnerships with investigators conducting IITs where we provide elraglusib drug product and input into study design while retaining the rights to any preexisting intellectual property and the right for exclusively licensing any joint inventions resulting from the studies. We also have a research and development collaboration with Lantern Pharma Inc. to leverage their artificial intelligence platform to further understand the effects of elraglusib and identify patient subtypes that are particularly susceptible to GSK-3 inhibition. We expect to continue to leverage these partnerships and establish others to hone and expand our research and development efforts.

Our Solution

Elraglusib represents a broad opportunity for us to potentially initiate and advance multiple drug development programs around our lead asset based on data emerging from completed or ongoing Phase 1/2 trials. Our lead program is developing Elraglusib Injection for the first-line treatment of mPDAC. Despite advances in the treatment therapies over the last 30 years, the 5-year survival rate for Stage IV mPDAC remains at less than 5%, representing one of the lowest of any cancer type.

Our Advancing Pipeline

Our initial focus is on the development of GSK-3 inhibitors for the treatment of cancers with ineffective treatment options and poor overall survival. Given our ability to formulate elraglusib in both the Elraglusib Injection and Elraglusib Oral Tablet forms, and given the potential to administer this molecule as an IV or oral formulation depending on the cancer type and existing standard of care, we believe that elraglusib represents a pipeline in a molecule that can be broadly developed if adequate funding is secured. We are focused on advancing trials in mPDAC, Ewing sarcoma, and neuroblastoma with Elraglusib Injection while also advancing the Elraglusib Oral Tablet in a Phase I trial in advanced solid tumors. Our ability to advance our ongoing and planned clinical trials listed in Figure 2 will depend on whether we can raise sufficient capital to support those trials, including potential support from strategic collaborations.

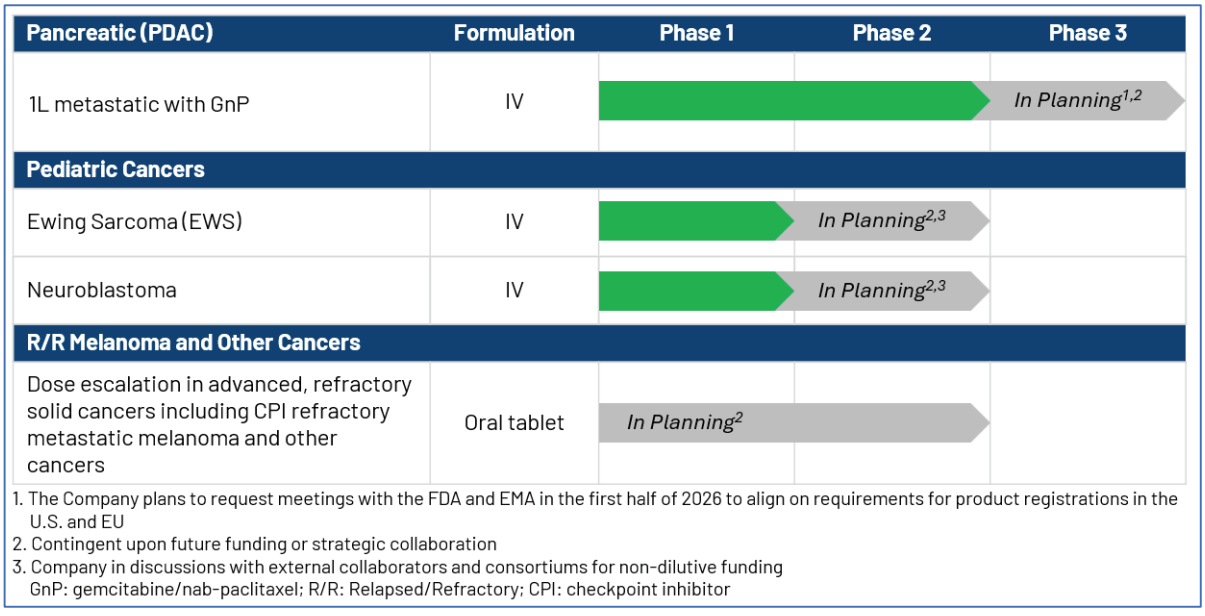

Figure 2: Ongoing and planned clinical trials.

Developing Elraglusib Injection for the Treatment of mPDAC

Our lead clinical program is focused on evaluating Elraglusib Injection for the treatment of first-line mPDAC. The Phase 2 trial is a randomized, controlled Phase 2 trial of elraglusib in combination with GnP versus GnP alone in first-line mPDAC. The trial enrolled 286 patients with mPDAC and no prior systemic treatment for metastatic disease. Patients were randomized 2:1 to the elraglusib/GnP combination arm or the GnP arm, respectively. This study included a run-in to explore two different dosing schedules of elraglusib/GnP (once weekly versus twice weekly) to evaluate the potential of moving to a more convenient, commercially viable elraglusib dosing schedule. The Phase 2 trial enrolled its first patient in October 2021 and the run-in part of the trial demonstrated that the weekly dosing of elraglusib was equivalent to twice weekly dosing of elraglusib with no meaningful clinical difference in safety or efficacy. After the dose run-in part of the trial, all patients that were randomized to the elraglusib/GnP arm received weekly elraglusib in addition to GnP. Last patient was enrolled in the first quarter of 2024.

Key inclusion criteria included patients that were 18 years or older with metastatic pancreatic adenocarcinoma and no prior therapy with measurable disease as defined by RECIST1.1.

The primary endpoint for this study was mOS, with OS summarized throughout the study by estimates of 1-year survival. Secondary endpoints were overall response rates ("ORR"), median progression-free survival ("mPFS"), disease control rate ("DCR") and adverse events.

Updated study results were presented at the ASCO GI conference in January 2026 utilizing a data cutoff of November 22, 2025. Log-rank analysis was used to determine statistical significance when comparing the two arms of the study. Data presented in the pre-specified safety population showed that the trial met its primary endpoint of improved mOS in patients in the elraglusib/GnP arm versus the GnP control arm. The analysis of updated data demonstrated treatment with elraglusib/GnP resulted in statistically significant increases in 1-year survival rate (p-value of 0.0004) and mOS (10.1 months vs 7.2 months, HR=0.62, log-rank p=0.02) with a 38% reduction in the risk of death versus treatment with GnP alone.

The following table provides additional Phase 2 study results as of the November 22, 2025 cutoff date:

Safety Population	**Elraglusib/GnP (n=155)**	**GnP (n=78)**
Primary Endpoint: mOS (months) HR=0.62; log-rank p=0.02*	10.1	7.2
12-month OS (%) p=0.0004*	44.4	22.3
Number (%) of death events	128 (82.6)	74 (94.9)
18-month OS (%)	22.9	6.6
24-month OS (%)	12.9	2.6

*statistically significant

In addition, updated data showed there were numerically improved ORR, mPFS, and DCR in the elraglusib/GnP combination arm versus the GnP arm as noted in the below table.

Safety Population	**Elraglusib/GnP (n=155)**	**GnP (n=78)**
ORR (%)	28.4	21.8
mPFS (months)	5.6	5.1
DCR (%)	39.4	29.5

Figure 3 depicts the interim Kaplan-Meier estimate for mOS as of November 22, 2025 cutoff and other endpoints in the study, including primary and secondary endpoints and patients remaining on study for each treatment arm as well as landmark OS endpoints at 18- and 24-months.

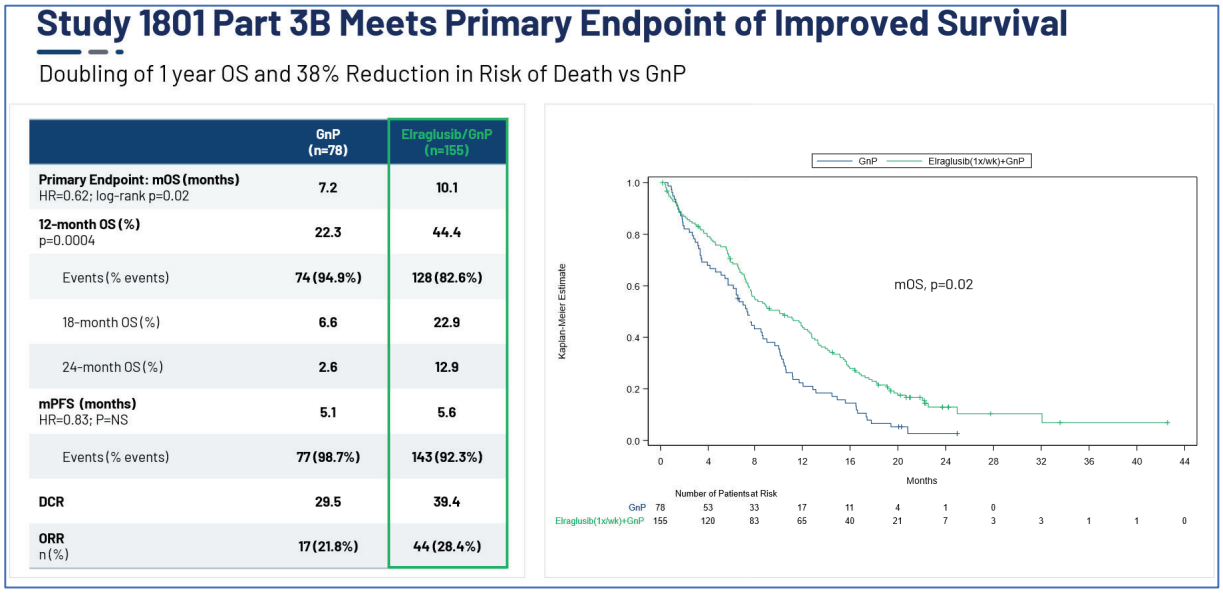

Figure 3: Unaudited Phase 2 data of elraglusib in mPDAC (data as of November 22, 2025 cutoff).

As with all preliminary analyses of interim data, this data should not be relied upon as a final analysis and is subject to change once full data analysis is complete.

Treatment-emergent adverse events ("TEAEs") and Serious Adverse Events ("SAEs") in the elraglusib/GnP combination arm were similar to those observed in the GnP arm, indicating a favorable risk-benefit profile for the elraglusib/GnP combination. TEAEs broadly encompass all adverse events observed while a patient is on study and could be due to the drug or drugs (if used in combination), the disease or something specific to a particular patient such as other diseases or illness. It is then up to the individual clinical investigator to decide which toxicities are due to elraglusib. The most common TEAEs attributed to elraglusib were transient visual disturbance and fatigue across both study parts, and the majority of TEAEs that occurred in ≥ 20% of patients were reported as Grade 1 or 2 (Figure 4). Visual disturbance affected 68.4% of patients (n=106/155) receiving elraglusib/GnP and 9.0% of patients (n=7/78) receiving GnP alone. Commonly reported symptoms were darkened vision, where patients described lights visually appearing brighter and skin tones visually appearing darker. Greater than 99% of visual disturbance cases were reported as mild or moderate (Grade 1 or 2). All cases of visual disturbance were transient, resolved completely, and lacked any associated retinal, ocular, or systemic toxicity. Fatigue, while also observed in ≥ 20% of patients, was also reported as mild or moderate (Grade 1 or 2) and did not interfere with daily life.

Figure 4 below is a summary of TEAEs of any grade reported in ≥20% of patients treated with elraglusib/GnP versus GnP alone as of November 22, 2025 data cutoff.

Patients, n (%)				
	Elraglusib/GnP (n=155)		GnP (n=78)	
Adverse Event	**Any Grade**	**Grade ≥3**	**Any Grade**	**Grade ≥3**
Any TEAE	155 (100)	140 (90.3)	77 (98.7)	62 (79.5)
Serious TEAE	87 (56.1)	82 (52.9)	44 (56.4)	43 (55.1)
Leading to Stoppage of Any Study Drug	43 (27.7)	26 (16.8)	22 (28.2)	17 (21.8)
Resulting in death	19 (12.3)	19 (12.3)	13 (16.7)	13 (16.7)
TEAEs of any Grade in ≥20% of Patients				
Visual Impairment	106 (68.4)	1 (0.6)	7 (9.0)	0
Fatigue	97 (62.6)	26 (16.8)	40 (51.3)	4 (5.1)
Neutropenia	97 (62.6)	83 (53.6)	32 (41.0)	25 (32.1)
Diarrhea	92 (59.4)	15 (9.7)	38 (48.7)	6 (7.7)
Nausea	90 (58.1)	11 (7.1)	38 (48.7)	4 (5.1)
Alopecia	71 (45.8)	0	27 (34.6)	0
Anemia	70 (45.2)	39 (25.2)	37 (47.4)	26 (33.3)
Decreased appetite	66 (42.6)	9 (5.8)	19 (24.4)	6 (6.7)
Thrombocytopenia	58 (37.4)	17 (11.0)	25 (32.1)	6 (7.7)
Vomiting	59 (38.1)	5 (3.2)	30 (38.5)	1 (1.3)
Edema peripheral	57 (38.1)	3 (1.9)	26 (33.3)	0
Constipation	49 (31.6)	3 (1.9)	24 (30.8)	1 (1.3)
Pyrexia	44 (28.4)	2 (1.3)	20 (25.6)	1 (1.3)
Abdominal pain	46 (29.7)	14 (9.0)	16 (20.5)	2 (2.6)
Weight decreased	46 (29.7)	5 (3.2)	17 (21.8)	3 (3.8)
Peripheral sensory neuropathy	40 (25.8)	4 (2.6)	18 (23.1)	0
Hypokalemia	35 (22.6)	8 (5.2)	24 (30.8)	4 (5.1)
Asthenia	33 (21.3)	9 (5.8)	19 (24.4)	5 (6.4)
Dysgeusia	32 (20.6)	0	16 (20.5)	0
Leukopenia	31 (20.0)	22 (14.2)	12 (15.4)	9 (11.5)
Neuropathy peripheral	21 (13.5)	1 (0.6)	18 (23.1)	0

Figure 4: TEAEs of Any Grade Reported in ≥20% of Patients Treated.

Additional updated data as of November 22, 2025 are shown in Figures 5 and 6. As with all interim data, this data should not be relied upon as a final analysis and is subject to change once full data analysis is complete.

Figure 5 summarizes additional details regarding the demographics and disease history of the enrolled patient population in each arm of the study.

Demographics	GnP (n=78)	Elraglusib /GnP (n=155)
Sex		
Female	35 (44.9%)	75 (48.4%)
Male	43 (55.1%)	80 (51.6%)
Age (years)		
n (%)	78 (100%)	155 (100%)
Mean (S.D.)	66.2 (9.9)	65.1 (9.1)
Median	68.0	65.0
Min, Max	42.0, 85.0	42.0, 86.0
Race		
Asian	2 (2.6%)	5 (3.2%)
Black or African American	6 (7.7%)	7 (4.5%)
White	65 (83.3%)	128 (82.6%)
Multiracial	0	1 (0.6%)
Unknown/Not Reported	5 (6.4%)	14 (9.0%)
Ethnicity		
Hispanic or Latino	0	8 (5.2%)
Not Hispanic or Latino	77 (98.7%)	141 (91.0%)
Unknown/Not Reported	1 (1.3%)	6 (3.9%)
Body Surface Area (BSA) (m2)		
n (%)	78 (100%)	155 (100%)
Mean (S.D.)	1.83 (0.26)	1.83 (0.23)
Median	1.82	1.81
Min, Max	1.31, 2.77	1.30, 2.62
Eastern Cooperative Oncology Group Performance Status		
0	31 (39.7%)	64 (41.3%)
1	45 (57.7%)	89 (57.4%)
2	2 (2.6%)	2 (1.3%)
Disease Status		
Metastatic at Initial Diagnosis	60 (76.9%)	108 (69.7%)
Metastatic at Study Entry	77 (98.7%)	154 (99.4%)
Site of Metastases		
Pancreas	68 (87.2%)	123 (79.4%)
Liver	61 (78.2%)	112 (72.3%)
Lymph Node	27 (34.6%)	69 (44.5%)
Lung	26 (33.3%)	59 (38.1%)

Figure 5: Patient demographics and disease history as of November 22, 2025 cutoff.

Figure 6 below is a graphical representation of survival ("mOS Swim Plot'") of each patient enrolled in the Phase 2 study in the elraglusib/GnP arm versus the GnP control arm.

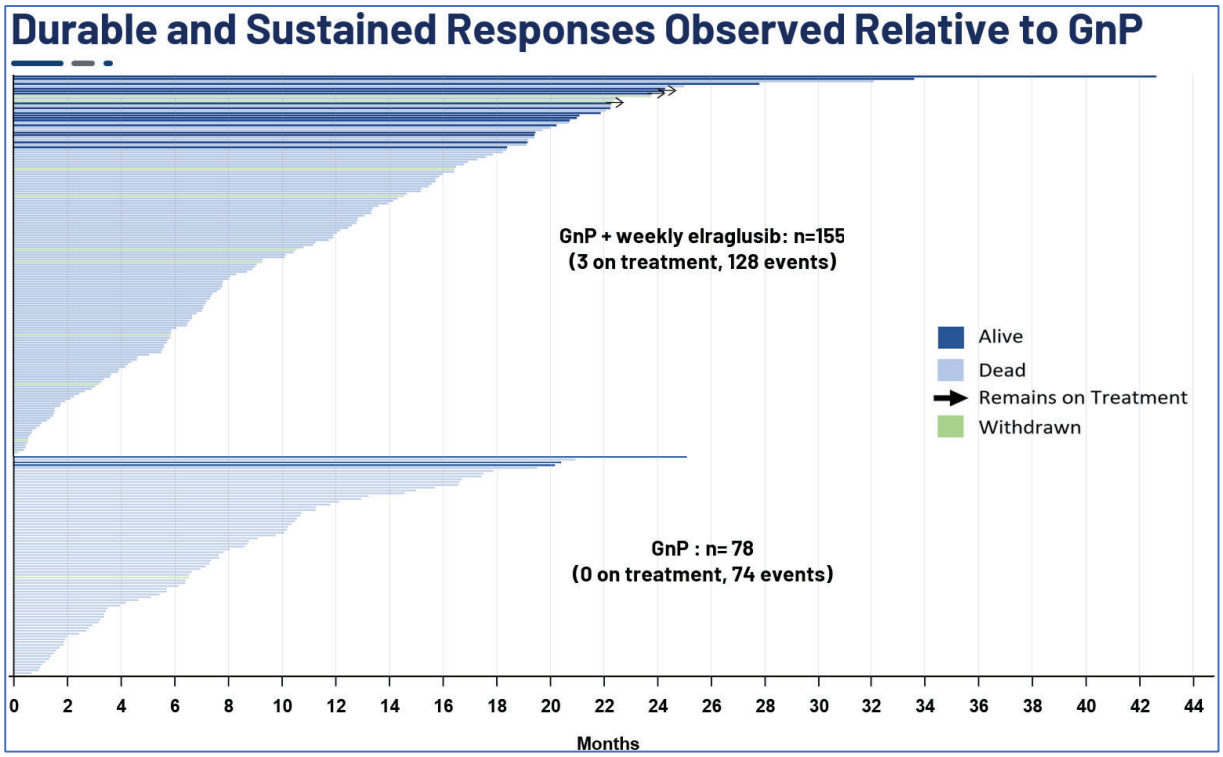

Figure 6: mOS Swim Plot as of November 22, 2025.

During the first half of 2026, we plan to meet with the FDA and EMA to discuss the design and execution of a Phase 3 global registration study to support potential product registration.

Elraglusib Injection for the Treatment of Pediatric Cancers

Elraglusib Injection is also being evaluated in pediatric cancer patients with recurrent/refractory solid cancers. The Actuate-1902 study was an open-label, multicenter Phase 1/2 study evaluating the safety and efficacy of elraglusib in 40 pediatric patients ages 3 – 21 with relapsed (>2 remissions)/refractory cancers, including EWS, neuroblastoma, Central Nervous System ("CNS") tumors, non-EWS sarcomas, and other refractory pediatric malignancies. This trial evaluated escalating doses of elraglusib as a single agent as well as in combination with irinotecan or cyclophosphamide/topotecan in the Phase 1 portion of the trial. The Phase 1 dose escalation portion of the trial was designed primarily to determine the maximum tolerated dose ("MTD") and/or RP2D of elraglusib as a single agent and in combination with chemotherapy. While an MTD was not reached, initial evidence of anti-tumor activity was observed, particularly when elraglusib was administered with a standard cyclophosphamide and topotecan regimen. Two Complete Metabolic Responses ("CMRs") were observed in patients with relapsed/refractory metastatic EWS and one Complete Response ("CR") was observed in a patient with relapsed/refractory metastatic neuroblastoma. The Phase 1 portion of this study was closed in July 2025. Key highlights from the Actuate-1902 study include:

Elraglusib in combination with cyclophosphamide and topotecan regimen:

- Clinical responses and disease control observed in 10 of 19 patients with relapsed/refractory EWS or neuroblastoma.
    - One patient with six prior treatments for EWS achieved a CMR with a 60% reduction in tumor size of a lung target lesion. This patient completed 30 weeks (Cycle 10) on treatment with long term treatment with elraglusib monotherapy continuing without disease progression outside of the study.
    - One patient with four prior treatments for EWS (+EWSR1 translocation or Ewing sarcoma breakpoint region 1) was identified as a CR (BOR) at week 9 (Cycle 3) with CT scan showing a 100% decrease in piriformis muscle tumor compared to baseline (CMR by Positron Emission Tomography or PET).
    - One patient with six prior treatments for unfavorable neuroblastoma histology (Indeterminate MYCN, ALK (anaplastic lymphoma kinase), and ploidy) had a first response at week 9 (Cycle 3) of stable disease ("SD"), with a BOR of a complete bone marrow response identified at week 27 (Cycle 9).
    - One patient with 10 prior treatments for DSRCT (Desmoplastic Small Round Cell Tumor) achieved a PR (52.6% decrease in liver/lung target lesions compared to baseline). Non-target lesions included multiple lung and liver lesions, which were not present at the end of treatment.
    - Six patients with prior treatments ranging from 2 to 11, achieved a BOR of stable disease.

Elraglusib in combination with irinotecan regimen:

- Four patients (neuroblastoma, ganglioneuroblastoma (a high-risk variant with an unfavorable prognosis)) achieved BOR of stable disease.
- One patient with neuroblastoma achieved a 35% reduction in tumor burden between baseline and week 9 (Cycle 3).
- One patient with ependymoma experienced stable disease with a prolonged time to progression of 54 weeks.

Based on these data, we identified Ewing sarcoma and neuroblastoma as new indications for further development of Elraglusib Injection. Given that Ewing sarcoma and neuroblastoma are very rare pediatric cancer indications, an international consortium of investigators and sites will be needed to advance this program to registration. In addition, we plan to pursue a number of development incentives in the United States and parallel programs in the EU. In July 2024, we received ODD from the FDA for elraglusib for the treatment of soft tissue sarcomas in the United States and Orphan Medical Product Designation from the EMA for the treatment of sarcoma. In October 2024, we received Rare Pediatric Disease Designation ("RPDD") from the FDA for the treatment of EWS. The ability to engage in further development in pediatric cancers will depend on our ability to raise sufficient additional capital to support this path. We believe that pursuing this development could be an efficient and rapid path to registration in the United States and Marketing Authorization in the EU.

Elraglusib Oral Tablet for the Treatment of Solid Tumors

We initially developed an oral liquid that was evaluated for bioavailability in a Phase 1 healthy volunteer study (Actuate-2203) in a single dose cross-over design such that each subject on the study received IV, oral liquid after fasting and oral liquid with food. Elraglusib oral liquid was greater than 50% bioavailable when given with food and was very well tolerated by healthy volunteers.

Consequently, we developed several oral tablet prototype formulations that were evaluated for bioavailability in dogs, and an oral tablet candidate was identified with greater than 95% orally bioavailable when given with food. In the study, the oral drug had an AUC24 (Area Under the serum Concentration vs. time curve for 0-24 hours) of 77,000 ng•h/mL (nanograms times hours per milliliter) after a single 250 mg oral tablet and 137,000 ng•h/mL after oral administration of 500 mg (2 x 250 mg tablets). We expect that steady state exposures of 77,000 ng•h/mL or greater will be possible with the Elraglusib Oral Tablet at well-tolerated doses in humans. We believe that we will be able to administer the Elraglusib Oral Tablet daily, which may allow the

drug to achieve steady state levels in plasma in patients resulting in continuous inhibition of the target GSK-3 in the tumor and tumor-associated cells. Based on the potential for daily dosing, we believe this will allow for additional opportunities to explore the anti-tumor activity of elraglusib with the oral tablet that could not be achieved with Elraglusib Injection.

Our lead clinical candidate tablet, the Elraglusib Oral Tablet, has been selected for further development, and we are planning a Phase 1/2 dose escalation study to identify the MTD and RP2D for Elraglusib Oral Tablet in adult patients with advanced, refractory cancers, subject to future funding. Once we have determined a RP2D, several Phase 2 studies have been identified for further clinical development of Elraglusib Oral Tablet based on data from the Actuate-1801 study in indications, including but not limited to, refractory, metastatic melanoma and refractory, metastatic colorectal cancer, and non-small lung cancer.

Investigator-Initiated Trials

In addition to company-sponsored trials, we have collaborated with a number of investigators through investigator-initiated trials ("IIT") to evaluate elraglusib in new indications and with new drug combinations. Two of these IITs will provide exploratory data on the combination of elraglusib and FOLFIRINOX as a first-line treatment for mPDAC and may provide a rationale for developing elraglusib in combination with FOLFIRINOX or NALIRIFOX as another first-line treatment for mPDAC. Since either GnP or FOLFIRINOX are currently used to treat the majority of patients with mPDAC, we believe that elraglusib has the potential to treat a large segment of patients diagnosed with mPDAC.

In August 2025, we supported commencement of a Phase 1b IIT with UPMC Hillman Cancer Center. The trial is evaluating elraglusib in combination with Incyte's PD-1 inhibitor, retifanlimab, and modified FOLFIRINOX ("mFOLFIRINOX") as front-line therapy in advanced pancreatic adenocarcinoma in up to 12 patients. This IIT is an open-label, single-arm RiLEY (NCT06896188) trial, led by Anwaar Saeed, MD, Associate Professor of Medicine, and Chief of the Gastrointestinal Medical Oncology at UPMC Hillman Cancer Center. The primary objective of the trial is to determine the RP2D for the combination regimen, while the secondary objectives include evaluation of ORR, DCR, mPFS, OS, and assessment of safety and tolerability. The trial is currently open for enrollment, and four patients have been enrolled as of February 28, 2026.

In February 2022, we supported commencement of a Phase 2 IIT to determine the safety, tolerability, and progression-free survival of the combination of elraglusib with FOLFIRINOX and losartan in adults with untreated metastatic pancreatic adenocarcinoma. The IIT is being led by Colin Weekes, MD Ph.D. at Massachusetts General Hospital and is supported by us and the Lustgarten Foundation. Additional sites participating in the study include The University of Colorado and the University of Washington's Fred Hutchinson Cancer Center. This study administers elraglusib by IV infusion twice weekly in combination with FOLFIRINOX administered once every 14 days and daily losartan in adults with pancreatic cancer who have not received any prior systemic therapy for advanced disease. A total of 49 patients have been enrolled in the study. We expect to receive all final data from this study, which is considered exploratory and may inform future development of elraglusib in 2026.

Our Market Opportunity

Treatment of Metastatic Pancreatic Ductal Adenocarcinoma ("mPDAC")

According to the American Cancer Society, the annual incidence of pancreatic cancer is expected to exceed 67,000 patients in the United States in 2026, and the majority of these patients will present with metastatic disease. The Pancreatic Cancer Treatment Market Size Report, 2030 by Grand View Research, estimates the current global market for treating pancreatic cancer was approximately $2.9 billion in 2024 and is expected to grow to $5.8 billion by 2030 based on the growing aging population and associated rise in lifestyle-related diseases.

Current first-line therapies for mPDAC consist of GnP, FOLFIRINOX, or irinotecan liposomal injection given with oxaliplatin, fluorouracil, and leucovorin ("NALIRIFOX"). NALIRIFOX was approved in February 2024 and may provide an alternative to FOLFIRINOX with a somewhat improved safety profile.

We are developing elraglusib for patients in mPDAC who have not previously received systemic treatment for their metastatic disease. Due to lack of early symptoms, approximately 80-90% of all patients with pancreatic cancer are unresectable, and present with advanced or metastatic disease. In addition, 80-90% of PDAC cases do not have a high tumor mutational burden in general, and are unlikely to respond to checkpoint inhibitors such as pembrolizumab. Pembrolizumab has been approved for patients with metastatic solid cancer with high tumor burden but is rarely used in metastatic pancreatic cancer for this reason. However, frequent mutations in KRAS and TP53 oncogenes drive pancreatic tumor growth and treatment resistance, often making PDAC refractory to chemotherapy.

A recent review of real-world clinical trials in *Future Oncology* showed that the mOS in patients with mPDAC treated with GnP ranged from approximately 3.6 to 9.8 months with an unweighted mOS of 6.9 months. Therefore, we believe the ability to extend survival by even a few months would be considered meaningful in this patient population.

We believe elraglusib may improve outcomes in first-line mPDAC regardless of the chemotherapy backbone used by doctors. Patients with mPDAC are often resistant or become resistant to the first-line chemotherapy backbones currently used to treat them. One of the mechanisms of action of elraglusib is the ability to enhance chemotherapy activity even in resistant tumors, and we believe this has been demonstrated in multiple animal tumor models. Elraglusib has shown the ability to enhance the activity of several chemotherapy drugs that comprise the current first-line backbones in mPDAC including gemcitabine, nab-paclitaxel and irinotecan, suggesting the potential for elraglusib to be used in combination with multiple first-line mPDAC treatments.

Treatment of Pediatric Cancers

EWS is a rare malignancy that occurs primarily in the bone or in the soft tissue around a bone. The tumor is most common in older children and adolescents, but it can occur at any age. According to American Cancer Society, Ewing sarcoma accounts for about 1% of all childhood cancers and approximately 200 children and adolescents in the United States are diagnosed annually with EWS. Treatment options include surgery, radiotherapy, chemotherapy, and tyrosine kinase inhibitors. The response to therapy is dependent on the stage of the tumor. Overall, the 5-year survival rates range from 81% for patients with localized disease to 41% for patients with metastatic disease. The five-year survival rate for patients who have recurrent (relapsed) disease is <30% with no known treatment regimens that meaningfully extend life in Ewing sarcoma patients with metastatic, refractory disease.

Neuroblastoma is a rare cancer of the early nerve cells, called neuroblasts, that make up the nerves in our bodies. According to American Cancer Society, neuroblastoma is the most common cancer in infants who are less than 1 year old. There are about 600 to 800 new cases of neuroblastoma each year in the United States. The 5-year survival rates range from 95% for lower risk patients to 60% for patients with higher risk disease per the American Cancer Society, and neuroblastoma claims more lives of children under the age of 5 than any other cancer.

The FDA has granted RPDD to elraglusib for our treatment of EWS and neuroblastoma. Rare Pediatric Disease Designation is granted by the FDA for serious or life-threatening diseases that affect fewer than 200,000 people in the United States and in which the serious or life-threatening manifestations primarily affect individuals less than 18 years of age. If, in the future, a New Drug Application ("NDA") for elraglusib for the treatment of Ewing sarcoma or neuroblastoma is approved by the FDA, we may be eligible to receive a Priority Review Voucher ("PRV") that could be utilized by us or potentially sold to another company for its use.

About GSK-3β

There are no approved high-affinity inhibitors of GSK-3β, and we believe elraglusib is one of the most advanced GSK-3β inhibitors in clinical development.

GSK-3β inhibition may exert anticancer activity through a variety of mechanisms that may be context and cancer type specific. For example, GSK-3β mediates signaling of oncogenic PI-3K but if this oncogene is not expressed in a particular tumor, this would not be a pathway that could be targeted by elraglusib in that tumor. Potential antitumor activity through GSK-3β inhibition may occur through multimodal mechanisms of action, including:

(1) Immune modulation;
(2) Inhibiting cell proliferation;
(3) Reducing tumor fibrosis;
(4) Decreasing immune evasion;
(5) Increasing apoptosis and disrupting DNA damage repair; and
(6) Inhibition of epithelial-mesenchymal transitions ("EMT").

GSK-3β plays an important role in immune cell function, as inhibition of GSK-3β can facilitate immune cell expansion, differentiation and activation including T and natural killer ("NK") cells. Inhibition of GSK-3β leads to inhibition of tumor cell proliferation as shown in multiple tumor model systems using elraglusib. A number of pathways have been implicated in the inhibition of cell proliferation mediated by GSK-3β inhibitors including MYC, Cyclin D1, TGFα, epidermal growth factor receptor, Ras, PI3K/Akt, and NF-κB. Also, a chronic inflammatory microenvironment is conducive to tumorigenesis (e.g., pancreatitis patients are known to have increased risk of pancreatic cancer), and tumors can undergo EMT, leading to increased metastasis, under inflammatory conditions. Further, GSK-3β has also been demonstrated to be a mediator of EMTs. Therefore, the inflammatory response designed to fight tumor progression also ends up promoting metastasis and tumor-associated fibrosis. In addition, a number of studies have suggested that the primary mechanism of GSK-3β -mediated apoptosis is through the NF-κB pathway. Studies have shown that eliminating or inhibiting GSK-3β in cancer cells is able to restore apoptosis to cells, leading to tumor cell death. These findings support GSK-3β as a potential therapeutic target to potentiate apoptosis in cancer cells. GSK-3β has been shown to be a mediator of a number of signaling pathways that regulate the transition of tumor cells from an epithelial to mesenchymal phenotype potentially contributing to tumor progression, a process known as EMT. Signaling through Wnt, Notch, TGF-β and Snail are known mediators of EMT, and their signaling is regulated through GSK-3β. Several toolkit GSK-3β inhibitors have been shown to inhibit EMT in tumor models suggesting that this is a class effect and highlighting a similar mechanism for elraglusib.

License Agreements

Northwestern University License Agreement

We licensed the exclusive worldwide rights to materials and non-exclusive rights to certain know-how relating to the use for therapeutic, diagnostic and commercial research purposes of elraglusib and related compounds in cancer and combination therapies from NU pursuant to that certain royalty-free license agreement between us and NU dated March 31, 2015, as amended on April 29, 2019 (as amended, the "NU License Agreement").

Pursuant to the NU License Agreement, NU granted us (i) a nonexclusive license to certain technical information developed in the laboratory of Dr. Mazar, and (ii) an exclusive license to all results obtained by Dr. Mazar and his collaborators at NU on the use of the GSK-3β inhibitor 9-ING-41 and related compounds used for the treatment of cancer and combination therapies. The term of the NU License Agreement continues in effect until the expiration of the last to expire of patent rights covering 9-ING-41 and related GSK-3 inhibitors (see the discussion under "*Intellectual Property"* below for a discussion of our expected patent terms), unless earlier

terminated by NU due to our making a general assignment for the benefit of creditors, initiation of bankruptcy proceedings by or against us or the appointment of a receiver or trustee to take possession of our property, or by either party following 90 days' notice of a material breach of the NU License Agreement that is not then cured. The NU License Agreement terms are subject to the provisions of the Bayh-Dole Act, including requiring us to substantially manufacture products related to the license in the United States, unless waived. While the drug substance ("DS") for elraglusib is manufactured by a supplier in China, the end drug product is substantially manufactured in the United States.

In consideration of the license granted by NU, we issued 27,778 shares of our common stock to NU, which represented 5% of our then-outstanding fully-diluted shares and agreed to customary confidentiality and progress update obligations and to indemnify NU for any claims arising from our use of the licensed rights under the NU License Agreement.

UIC Exclusive License Agreement with Equity

The exclusive rights to Patent Rights (as defined in the UIC License Agreement and described further below) and Technical Information (as defined in the UIC License Agreement) surrounding GSK-3 inhibitors for Neurodegenerative Disorders were licensed through an Exclusive License Agreement with Equity between us and UIC, dated April 6, 2015, as amended on April 24, 2019 (as amended, the "UIC License Agreement"). Under the UIC License Agreement, the Patent Rights relate to certain patents relating to 3-Benzofuranyl-4-Indolyl Maleimides, the last of which is scheduled to expire on March 16, 2028, not including any Patent Term Extension ("PTE"), which we may apply for under Title II of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman"), 35 U.S.C. §156. The following summarizes the key terms set forth in the UIC License Agreement.

Pursuant to the UIC License Agreement, UIC granted us (i) an exclusive, nontransferable license, with the right to sublicense under UIC's rights in the Patent Rights, and (ii) a non-exclusive, non-transferable license, with the right to sublicense, to use UIC's rights in the Technical Information within the specified territory (which is where the Patent Rights exist for such rights and worldwide for the Technical Information) for all uses other than rights reserved by UIC for non-commercial purposes, including teaching, research and public service and publishing information included in the Patent Rights and the Technical Information. The term of the UIC License Agreement continues in effect until the later of (x) expiration of the last to expire of the Patent Rights, (y) notice from us that the use of the Technical Information has ceased, and (z) the expiration of the last form of market exclusivity for products using the licensed technology. The UIC License Agreement may also be earlier terminated by UIC in the event of certain breaches of its terms that are not cured following a notice period or initiation of bankruptcy proceedings by or against us or the imposition of any lien or encumbrance on the licensed technology. We may also terminate the UIC License Agreement for any reason following 90 days' notice.

In consideration of the license granted under the UIC License Agreement, we issued 46,528 shares of our common stock to UIC, which represented 5% of our capital stock on a fully-diluted basis as defined in the UIC License Agreement, and agreed to pay UIC (i) development milestones of up to $1.25 million, of which, up to $0.25 million is due upon the progress of clinical trials and $1.0 million is due upon the initiation of commercial sales (ii) increasing annual minimum royalty payments reaching $50,000 in year six and thereafter, (iii) royalty on net sales for product covered under the Patent Rights in the low single digits with a 50% reduction in royalties for products solely utilizing Technical Information, (iv) a declining percentage of sublicensing revenue based on the escalating stage of development upon a sublicensing event, and (v) the reimbursement of all patent and related expenses incurred by UIC covering the Patent Rights. We also agreed to customary confidentiality and progress update obligations, to indemnify UIC for any claims arising from our use of the licensed rights under the UIC License Agreement.

The UIC License Agreement obligates us or a sublicensee to commercialize the licensed technology, including to achieve the development events specified in the agreement, including progress through clinical trials and achieving commercialization. UIC may also identify feasible uses of the licensed technology and, unless we demonstrate that we are pursuing such development or such development is not feasible within a specified period, UIC may terminate the UIC License Agreement or the exclusivity of the licensed rights. As of the date hereof,

we have met all existing milestones as provided for in the UIC License Agreement. We are also responsible for the prosecution and maintenance of the licensed patents, at our expense and using commercially reasonable efforts. We have the sole right to enforce the licensed patents, at our expense. The UIC License Agreement terms are subject to the provisions of the Bayh-Dole Act, including requiring us to substantially manufacture products related to the license in the United States, unless waived. While the DS for elraglusib is manufactured by a supplier in China, the end drug product is substantially manufactured in the United States.

In addition, we entered into a sublicense and collaboration agreement dated August 28, 2017 with an unrelated entity that was covered under the UIC License Agreement, which sublicense agreement was later terminated on January 31, 2018. Under the UIC License Agreement, the Company owed UIC a certain percentage of amounts received under the sublicense agreement in the amount of $449,990. The Company paid UIC 10% of the sublicense fees in the amount of $44,999 and the remaining unpaid balance of $404,991 ("Deferred Amount") was originally due and payable to UIC in two installments: 50% due and payable on the one-year anniversary from the first commercial sale and 50% due on the second-year anniversary from the first commercial sale. The Deferred Amount is treated as debt and continues to accrue interest at a rate of five percent (5%) per annum, representing the prime rate as of the date of the agreement plus 1%, payable annually within 30 days following the second anniversary of the closing of the IPO and annually thereafter. On July 16, 2024, the Company and UIC entered an amendment to the UIC License Agreement ("UIC Amendment"). Pursuant to the UIC Amendment, the payment of the Deferred Amount and any accrued interest thereon is due upon the sooner of (i) termination of the UIC License Agreement by the Company, (ii) the Company ceases development of the licensed UIC technology, (iii) the Company consummates a Change in Control (as defined in the UIC License Agreement), (iv) the Company sublicenses the licensed technology or the developed product, (v) the one-year anniversary following approval of a NDA of a licensed product, or (vii) the Company executes a partnership agreement with any entity resulting in the payment to us above a specified milestone amount or the Company secures cumulative financing equal to or exceeding $200 million. In addition, the UIC Amendment provides that to the extent the Company secures equity financing equal to or exceeding $85 million through its IPO or otherwise, 50% of the Deferred Amount is due and payable within 30 days. The remaining 50% of the Deferred Amount shall be due and payable upon the first to occur of any of the events noted above in clauses (i) through (vii). Finally, the UIC Amendment provides that for as long as the Company or a sublicensee is selling the licensed product, the Company will pay all consideration provided for in the original UIC License Agreement and described above until the last to expire market exclusivity date, the period of which for all products in a jurisdiction will not exceed a total of seven (7) years beginning with the date regulatory approval is granted for the first licensed product in the jurisdiction, and such obligation will survive termination of the UIC License Agreement.

Collaboration Agreement

We entered into a Collaboration Agreement with Lantern Pharma in 2021 under which the parties are collaborating on utilization of Lantern Pharma's platform to develop novel biomarker-derived signatures for use with our product candidates. As part of the collaboration, Lantern Pharma received 13,889 restricted shares of our common stock, which vested upon meeting certain conditions of the collaboration, as well as the potential to receive additional shares if results from the collaboration are utilized in future development efforts. Certain affiliates of the Bios Equity Affiliated Funds (as defined below), which is our largest stockholder, beneficially owned greater than 10% of Lantern Pharma's common stock as of December 31, 2025. Through December 31, 2025, no revenue has been recognized by either party under this agreement.

Intellectual Property

The proprietary nature of, and protection for, our product candidates and their methods of use and compositions of matter are an important part of our strategy to develop and commercialize novel medicines, as described in more detail below. Our policy is to file patent applications to protect technology, inventions and improvements to inventions that are commercially important to the development of our product candidates and our business. We seek U.S. and foreign patent protection for a variety of technologies. We also intend to seek patent protection or rely upon trade secret rights to protect other technologies that may be used to discover and validate targets and identify and develop novel products. We seek protection, in part, through confidentiality and proprietary information agreements. We are a party to various other license agreements that give us rights to use specific technologies in our research and development.

As of December 31, 2025, we own or have licensed 119 issued patents and pending patent applications worldwide, including four pending international Patent Cooperation Treaty ("PCT") patent applications, which are material to the programs described in this Report. Three of these issued worldwide patents are owned by UIC, which has granted us exclusive license rights to the technology.

With respect to our elraglusib program, as of December 31, 2025, we own or exclusively in-license one patent family focused on the elraglusib molecule and/or related compounds. The exclusively in-licensed patent family for elraglusib and related compounds (the original patent in-licensed from UIC) includes one granted U.S. patent, one granted European patent (with validation in 5 countries) and one granted Canadian patent, which are directed to 3-Benzofuranyl-4-Indolyl Maleimides compounds. The U.S. patent is expected to expire in 2028.

Actuate subsequently discovered that elraglusib exists as only two polymorphs and filed composition of matter patents covering both polymorphs. The patent family covering "Polymorph I" is based on PCT/US2018/046203 9-ING-41 Polymorph I Composition of Matter and includes two granted patents in the U.S. (US 11,136,334 and 12,145,943) and three granted patents in Mexico, and two granted patents in Australia and Japan, one granted patent in each of China, Europe (with validation in 18 countries), Israel, and South Korea, and pending patent applications in Australia, Brazil, Canada, China, Hong Kong, Israel, Japan, Macao, South Korea, South Africa and the U.S., which are directed to a polymorph of a GSK-3β inhibitor, compounds, pharmaceutical compositions, methods of preparing and uses for treating cancers. The U.S. patent is expected to expire in 2038.

The patent family we own that covers elraglusib "Polymorph II" is based on PCT/US2018/056083 9-ING-41 Polymorph II Composition of Matter and includes two granted U.S. patents (US 11,407,759 and 12,116,374), one granted patent in each of Europe (validated in France, Austria, Belgium, Switzerland, Germany, Denmark, Spain, Finland, the United Kingdom, Greece, Ireland, and Italy) Australia, China, Mexico and Macao, South Korea, Japan, and Israel, and pending patent applications in Brazil, Canada, the European Patent Office, Japan, South Africa and the U.S., which are directed to a polymorph of a GSK-3β inhibitor, compounds, pharmaceutical compositions, methods of preparing and uses for treating cancers. The U.S. patent is expected to expire in 2038.

The patent family we own that covers oral dosage forms of elraglusib is based on PCT/US2023/069158. Patent applications are pending in Australia, Brazil, Canada, China, Europe, Israel, India, Japan, South Korea, Mexico, Hong Kong, South Africa, and the U.S.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be shortened if a patent is terminally disclaimed over another patent or as a result of delays in patent prosecution by the patentee, and a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent. Patent term may also be extended up to five years due to regulatory delay (Patent Term Extension or "PTE"). We may apply for PTE under Title II of the Hatch-Waxman Act for any one of the U.S. Patents, however there is no guarantee that PTE would be granted for any patent.

We intend to continue to regularly assess opportunities for seeking patent protection for those aspects of our discoveries that we believe provide a meaningful competitive advantage. However, because patent filings can be time-consuming and expensive, our ability to do so may be limited until such time as we are able to generate cash flow from operations or otherwise raise sufficient capital to continue to invest in our intellectual property. For example, maintaining patents in the United States and other countries requires the payment of maintenance fees which, if we are unable to pay, may result in loss of our patent rights. If we are unable to do so, our ability to protect our intellectual property or prevent others from infringing our proprietary rights may be impaired.

Commercial Plan

We intend to retain significant development and commercialization rights to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with a partner, in the

United States and other regions. We currently have no sales, marketing and commercial product distribution capabilities. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, in connection with the advancement of our product candidates. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure and manufacturing needs, the status of our pipeline and other factors, may all influence or alter our commercialization plans.

Manufacturing

We work with third-party suppliers and manufacturers to support the manufacturing of elraglusib for clinical studies and our research activities and, if we receive regulatory approval, we intend to rely on such third parties for commercial manufacture. We do not own or operate, and currently have no plans to establish any manufacturing facilities. We currently obtain our investigational product from these third-party manufacturers on a purchase order basis and do not have any long-term supply agreements in place. In order to de-risk our supply chain, and as we advance toward potential commercialization, we may enter into long-term supply agreements as well as evaluate additional product manufacturing sources.

Competition

The biotechnology and pharmaceutical industries, and the oncology sector in particular, are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property rights. While we believe that our development programs, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, government agencies and public and private research institutions, among others.

Any product candidates that we successfully develop and potentially commercialize will compete with currently approved therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products.

Our most advanced clinical asset, Elraglusib Injection (“elraglusib”) is being evaluated in a Phase 2 clinical trial as a first-line treatment for mPDAC. The current standard first-line treatments for mPDAC include GnP, FOLFIRINOX (5-fluorouracil, leucovorin, irinotecan, and oxaliplatin) or NALIRIFOX (liposomal irinotecan, 5-fluorouracil, leucovorin and oxaliplatin), and are associated with modest overall survival benefit.

We are developing elraglusib in combination with GnP as a first-line treatment for mPDAC. In addition, we are also supporting an ongoing IIT that will provide exploratory data on the combination of elraglusib and FOLFIRINOX as a first-line treatment for mPDAC. This may provide a rationale for developing elraglusib in combination with FOLFIRINOX or NALIRIFOX as another first-line treatment for mPDAC. Patients with mPDAC either have primary resistance to these chemotherapy backbones (e.g., do not respond when treated) or develop resistance quickly (responses with GnP, FOLFIRINOX and NALIRIFOX are transient and not very durable in most patients). Our management believes that elraglusib may improve outcomes in first-line mPDAC regardless of the chemotherapy backbone used, although the clinical data does not yet support this hypothesis. Nevertheless, since either GnP or FOLFIRINOX are currently used to treat the majority of patients with mPDAC and there is potential for combining elraglusib with either of these chemotherapy regimens based on our ongoing clinical studies, we believe that elraglusib has the potential to treat a large segment of patients diagnosed with mPDAC. Thus, our plan is to develop elraglusib in combination with the present first-line chemotherapy regimens used in the treatment of mPDAC, as exemplified by its lead program of elraglusib/GnP and later moving to combinations with either FOLFIRINOX or NALIRIFOX pending results of the IIT. If shown to be clinically meaningful, elraglusib plus standard of care chemotherapy combinations could eventually be used to treat a large segment of patients with mPDAC. In addition, we are also supporting a recently initiated Phase 1b IIT trial of elraglusib in combination with Incyte’s PD-1 inhibitor, retifanlimab, and modified FOLFIRINOX (“mFOLFIRINOX’) as a frontline therapy in advanced PDAC, representing another combination therapy that could expand the potential of elraglusib in first-line mPDAC.

Several other targeted therapies are also being evaluated in Phase 3 in mPDAC. The panRAS inhibitor daraxonrasib (RMC-6236, Revolution Medicines, Inc.) is being evaluated as a single agent in a Phase 3 trial (RASolute 303) in patients with previously untreated mPDAC. Arcus Biosciences, Inc. is also evaluating their small molecule inhibitor of CD73 (quemliclustat) in combination with GnP in a Phase 3 trial (PRISM-1) also in patients with previously untreated mPDAC. There are other studies combining immune checkpoint inhibitors, PARP inhibitors, various chemotherapies and other RAS inhibitors in patients with mPDAC including second-line studies. Ongoing studies with many of these agents in mPDAC are generally non-randomized at one or a limited number of sites, are too early to assess for commercial potential and may not represent a substantial competitive threat to elraglusib because of their lack of broad suitability for most mPDAC patients. For example, the PARP inhibitor Lynparza (olaparib) was recently approved as a maintenance therapy as it has been shown to significantly improve PFS and duration of response in patients with BRCA-mutated mPDAC who have not progressed following first-line platinum-based chemotherapy. However, BRCA mutations are only present in 4-7% of all PDAC patients. Olaparib is currently being evaluated as a therapeutic intervention in combination with a checkpoint inhibitor, pembrolizumab, in patients with mPDAC in BRCA1 mutated patients.

Despite these efforts, the vast majority of mPDAC patients still do not have an approved targeted therapy that can treat pancreatic cancer. If successful, we believe the elraglusib/chemotherapy combination would introduce the first broadly targeted agent, elraglusib, as a treatment option for patients with mPDAC and would have the potential to treat the majority of patients with mPDAC. A review of clinicaltrials.gov reveals that there are several randomized studies for any novel drug or drug combination (not just targeted) in patients with mPDAC previously untreated for metastatic disease, including the following:

- Onivyde® (Ipsen Pharma): Recently approved for first-line mPDAC when used as part of the NALIRIFOX regimen based on an improvement in mOS of 1.9 months (NALIRIFOX mOS of 11.1 months vs GnP mOS of 9.2 months).
- SBP-101 (Panbela Therapeutics, Inc.): A randomized, double-blind, placebo-controlled, multicenter study (ASPIRE) of standard treatment with GnP with or without SBP-101 in subjects previously untreated for mPDAC.
- Zolbetuximab and setidegrasib (Astellas): A randomized , open-label, Phase 2 study (8951-CL-5201) to assess the efficacy and safety of zolbetuximab (IMAB362) in combination with GnP as first-line treatment in subjects with claudin 18.2 (cldn18.2) positive, metastatic pancreatic adenocarcinoma. Astellas is also planning a Phase 3 trial in 2026 of setidegrasib combined with mFOLFIRINOX in first-line mPDAC.
- Mitazalimab (Alligator Pharmaceuticals): An open-label, multi-center Phase 1b/2 study (OPTIMIZE-1) to assess the clinical efficacy of mitazalimab in combination with chemotherapy in patients with mPDAC. Mitazalimab is a CD40 agonist hypothesized to overcome the suppressive immune environment in PDAC. OPTIMIZE-1 evaluated the combination of mitazalimab with mFOLFIRINOX in a single arm study in patients with previously untreated mPDAC and met its primary endpoint with an ORR of 42.1% and OS of 14.9 months. Previous clinical studies using the CD40 agonist sotigalimab combined with GnP in patients with previously untreated mPDAC did not meet their primary endpoint of 1 year OS compared to a historical 1-year OS of 35%.
- Daraxonrasib (Revolution Medicines, Inc.): A randomized Phase 3 trial (RASolute 303) in patients with first-line mPDAC that will evaluate daraxonrasib monotherapy and the combination of daraxonrasib plus GnP, each compared to a control arm with GnP treatment. This study was recently initiated in the fourth quarter of 2025.
- Quemliclustat (Arcus Biosciences, Inc.): A randomized, placebo-controlled, double-blind, Phase 3 trial (PRISM-1) of quemliclustat and chemotherapy versus placebo and chemotherapy in patients with treatment-naive mPDAC.
- Atebimetinib (Immuneering Corporation): A randomized, Phase 3 trial (MAPKeeper 301) of atebimetinib in combination with modified gemcitabine and nab-paclitaxel. This study is set to dose the first patient in mid-2026.
- Certepetide (Lisata Therapeutics): A randomized, placebo-controlled, Phase 2b trial (ASCEND) to measure the effect of adding certepetide, compared to placebo, to chemotherapy (gemcitabine and nab-paclitaxel) in patients who have untreated mPDAC.

- Zabilugene almadenorepvec (Theriva Biologics): A multicenter, open label, randomized, 2-parallel arm, Phase 2b trial (VIRAGE) evaluating intravenous zabilugene almadenorepvec in combination with first-line standard of care chemotherapy in patients with newly-diagnosed mPDAC.
- Pelareorep (Oncolytics Biotech): An open label, multi-indication biomarker, safety, and efficacy Phase 2 trial (GOBLET Cohort 5) to explore the safety and efficacy of pelareorep and mFOLFIRINOX with or without atezolizumab in patients with mPDAC.

There are several other treatments in development for locally advanced or mPDAC. The information cited above focuses only on select first-line treatments that are in clinical trials in mPDAC. Quite a few of these are very early stage and therefore little information is available on clinical activity to date. With the initial success of biomarker-driven targeted therapies, there is an effort to test additional targeted agents in mPDAC patients to determine if there is any synergy with standard chemotherapy regimens in the first-line setting. For instance, KRAS is mutated in over 90% of pancreatic cancer patients and there are several KRAS targeted agents in development. Other agents are being tested in KRAS mutant cancers more broadly by targeting other MAPK pathway members such as MEK and ERK1/2, though treatment-related toxicity has been reported with these agents. Additionally, these MAPK targeted agents are currently being evaluated in second-line and later settings. In the future, targeted agents may be able to be combined or used in series to provide a more flexible and tailored therapeutic approach for each individual patient. Additionally, the multifaceted and differentiated mechanism of action of elraglusib is likely to be synergistic with both cytotoxic and immunomodulatory therapeutics that may be approved in the future. Our management believes that this potential for combining elraglusib with future multi-therapy regimens is also feasible given the favorable safety profile of elraglusib as a single agent observed to date. Mechanistically, some of the targets inhibited by competitors (e.g., KRAS) intersect with the GSK-3 pathways and provide a rationale for potentially prioritizing these combinations with elraglusib in the future.

The above information includes corporate competitors that we are currently aware of and are currently conducting clinical trials or marketing in geographies where we currently anticipate conducting clinical trials for our product candidate. However, companies operating in other geographies and smaller and other early-stage companies may also prove to be significant competitors. In addition, academic research departments and public and private research institutions may be conducting research on compounds that could prove to be competitive.

Finally, many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. The pharmaceutical product candidates that we develop must be approved by the FDA before they may be legally marketed in the United States.

U.S. Pharmaceutical Product Development Process

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug and Cosmetic Act ("FDCA") and implementing regulations. Pharmaceutical products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time

during the product development process, approval process or after approval, may subject an applicant to administrative or judicial enforcement. Any regulatory enforcement action could have a material adverse effect on us. The process required by the FDA before a non-biological pharmaceutical product may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices ("GLP"), and other applicable regulations;
- Submission of an Investigational New Drug application ("IND"), which must become effective before human clinical studies may begin;
- Conduct of adequate and well-controlled human clinical studies according to current Good Clinical Practices ("GCP"), to establish the safety and efficacy of the proposed pharmaceutical product for its intended use;
- Submission to the FDA of an NDA for a new pharmaceutical product;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the pharmaceutical product is produced to assess compliance with current Good Manufacturing Practice standards ("cGMP"), to assure that the facilities, methods and controls are adequate to preserve the pharmaceutical product's identity, strength, quality and purity;
- Potential FDA inspection of the preclinical and clinical study sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

Before testing any pharmaceutical product with potential therapeutic value in humans, the pharmaceutical product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the pharmaceutical product candidate. These early studies are conducted using sound scientific procedures and require thorough documentation. The conduct of a single and repeat dose toxicology and toxicokinetic studies in animals must comply with federal regulations and requirements including GLP. The pharmaceutical product sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND becomes effective 30 days after receipt by the FDA, unless the FDA has concerns and notifies the sponsor. In such a case, the IND sponsor must resolve any outstanding concerns before the clinical study can begin. If resolution cannot be reached within the 30-day review period, the FDA can place the IND on clinical hold or the sponsor may withdraw the application. The FDA may also impose clinical holds on a pharmaceutical product candidate at any time before or during clinical studies due to safety concerns or regulatory non-compliance. Accordingly, it is not certain that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that can lead to suspension or termination of such clinical studies.

During the development of a new drug, sponsors are given opportunities to meet with the FDA to discuss progress. These formal meetings may occur prior to submission of an IND, at the end of Phase 1 clinical development (for certain investigational products), at the end of Phase 2 clinical development, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the sponsor to ask specific questions of the FDA, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical (registration) trial(s) that they believe will support approval of the new drug. A sponsor may be able to request a Special Protocol Assessment ("SPA"), the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analyses that will form the primary basis of an efficacy claim.

Conducting Clinical Studies

Clinical studies are voluntary research studies involving the administration of the pharmaceutical product candidate to healthy volunteers or patients under the supervision of qualified investigators, typically physicians independent of the clinical study sponsor's control. Clinical studies are conducted according to protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, how the results will be analyzed and presented and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical studies must be conducted in accordance with GCP requirements. Further, each clinical study must be reviewed and approved by an independent institutional review board ("IRB"), at, or servicing, each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and is tasked with considering such items as whether the safety risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB approves the informed consent that must be provided to each clinical study subject or his or her legal representative and will also monitor the clinical study to ensure patient safety until completed.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The pharmaceutical product is initially administered to healthy volunteers and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- Phase 2. The pharmaceutical product is studied in a limited patient population with the disease or condition to evaluate its effectiveness for a particular indication or indications and to determine the common short-term side effects and risks associated with the product.
- Phase 3. Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit of the product and provide an adequate basis for product labeling. The studies must be well-controlled and usually include a control arm for comparison. One or two Phase 3 studies may be required by the FDA for an NDA, depending on the disease severity and other available treatment options.
- Post-approval studies, or Phase 4 clinical studies, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.
- Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all. The FDA, the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the pharmaceutical product has been associated with unexpected serious harm to patients.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the pharmaceutical product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the pharmaceutical product candidate and, among other things, must include methods for testing the identity, strength, quality and purity of the final pharmaceutical product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the pharmaceutical product candidate does not undergo unacceptable deterioration over its shelf-life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the pharmaceutical product, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act ("PREA"), an NDA or a supplement thereof must contain data to assess the safety and effectiveness of the pharmaceutical 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. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any pharmaceutical product for an indication for which orphan designation has been granted. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant, and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

After the NDA submission is accepted for filing, the FDA reviews the NDA application to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel pharmaceutical products or pharmaceutical products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and 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. During the pharmaceutical product approval process, the FDA also will determine whether a risk evaluation and mitigation strategy ("REMS"), is necessary to assure the safe use of the pharmaceutical product. If the FDA concludes that a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to ensure consistent production of the product within required specifications.

Additionally, before approving an NDA, the FDA will typically inspect one or more clinical study sites to assure compliance with GCPs. If the FDA determines the application, manufacturing process or manufacturing facilities, or clinical study sites are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. In addition, the FDA will require the review and approval of product labeling.

The NDA review and approval process is lengthy and involved and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than the sponsor interprets the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA. The complete response letter usually describes all

of the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies.

Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical studies designed to further assess pharmaceutical product safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Development and Review Programs; Fast-Track Designation ("FTD") and Breakthrough Therapy Designation ("BTD")

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new pharmaceutical products that meet certain criteria. Specifically, new pharmaceutical products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. The Fast Track designation must be requested by the sponsor. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. With a Fast Track designated product, 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, if the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable and if the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for marketing approval, including a Fast Track program, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new pharmaceutical product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Pharmaceutical products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that the products may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a pharmaceutical product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

The FDA is also required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's

request. Elraglusib IV and elraglusib oral dosage forms may all be eligible for breakthrough therapy designation depending on the indication and pending clinical additional data.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation ("ODD") to a drug intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States, or in other limited cases. ODD provides for seven years of market exclusivity, independent of patent protection, to the company with ODD that brings a particular product to market. In addition, companies developing orphan drugs are eligible for certain incentives, including tax credits for qualified clinical testing.

To gain exclusivity, if a product that has ODD subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to the orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same active moiety for the same indication for seven years, except in limited circumstances, such as another drug's showing of clinical superiority over the drug with orphan exclusivity. In addition, doctors may prescribe products for off-label uses and undermine our exclusivity. Orphan drug exclusivity could block the approval of one of our product candidates for seven years if a competitor obtains approval for the same active moiety for the same indication before we do, unless we are able to demonstrate that our product is clinically superior.

A sponsor may request ODD of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain ODD for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first, approved product. More than one sponsor may receive ODD for the same product for the same rare disease or condition, but each sponsor seeking ODD must file a complete request for designation, and only the first sponsor that obtains approval for that drug for the orphan indication will obtain market exclusivity, effectively preventing the FDA from approving products under development by competitors for the same drug and same indication, unless the competitor is able to demonstrate that the product under development is clinically superior to the approved product or the approved product is not available in sufficient quantities. To permit the FDA to end another manufacturer's orphan exclusivity period, the FDA must determine that the manufacturer has demonstrated clinical superiority by showing the later drug is safer, more effective, or otherwise makes a major contribution to patient care.

We may plan to pursue ODD and exclusivity for some of our product candidates in the United States, the EU, and other geographies of interest for specific products. ODD 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. We cannot guarantee that we will obtain ODD for any products in any jurisdiction. Even if we are able to acquire ODD for a product, we cannot be sure that such product will be approved, that we will be able to obtain orphan drug exclusivity upon approval, if ever, or that we will be able to maintain any exclusivity that is granted.

Regulation Outside the United States

To market any medicinal product outside of the U.S., similar regulatory requirements, including adherence to GLP, Good Clinical Practices ("GCP") and Good Manufacturing Practice ("GMP"), collectively referred to as GxP to initiate clinical trials and, subsequently, to obtain marketing approval of a new pharmaceutical product are in place in each jurisdiction and vary country to country. Each regulatory jurisdiction will apply these regulations in their assessment of clinical trial applications and marketing authorization applications. The foreign regulatory approval process includes all the risks associated with FDA approval set forth above, as well as additional country-specific regulation. Failure to comply with applicable foreign regulatory requirements may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-clinical Studies, Clinical Trials, and Manufacturing

Similarly to the United States, the various phases of non-clinical and clinical research in the European Union ("EU"), United Kingdom ("UK") and Canada are subject to significant regulatory controls.

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

Clinical trials of medicinal products humans must be conducted in accordance with national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines on GCP as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Clinical trials involve the administration of the investigational new drug or biological product to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCP, which is an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on patients and subsequent protocol amendments must be submitted to regulatory authorities for review and approval. Medicines used in clinical trials must be manufactured in accordance with regulatory requirements under GMP.

Legislation in EU, UK, and Canada

In the EU, the EMA conducts the scientific evaluation, supervision and safety monitoring of our innovative medicinal products that are eligible for the centralized marketing authorization procedure. Through the centralized procedure, pharmaceutical companies may submit to the EMA a single application for a marketing authorization valid in all the EU and the European Economic Area ("EEA") countries. The European Community ("EC") makes a legally binding decision based on the EMA's recommendation. The centralized procedure is mandatory for certain new products and optional for others.

In the UK, we are subject to rigorous and evolving regulation and standards in the UK, overseen primarily by the Medicines and Healthcare products Regulatory Agency ("MHRA"). In 2026, the UK will require a new, independent framework for the authorization and surveillance of medicinal products. This includes mandatory compliance with revised standards governing clinical trials, patient protections and the new International Reliance Framework for marketing authorizations.

In April 2026, clinical trials in the UK will be subject to the Medicines for Human Use (Clinical Trials) Amendment Regulations 2025, which introduced revised classification for trial modifications, enhanced transparency, and extended data retention requirements. We are also subject to ICH E6(R3) standards and, the UK's Cyber Security and Resilience Bill. The regulations are intended to protect the rights, safety and wellbeing of research participants and to simplify and harmonize regulatory processes. They apply to trials designed to generate information on the efficacy or safety of medicine.

In Canada, we are subject to rigorous and evolving regulation and standards by Health Canada under the Food and Drugs Act and the Food and Drug Regulations. Before receiving marketing authorization, we must conduct extensive preclinical and clinical trials, demonstrating safety, efficacy, and quality to Health Canada. The regulatory approval process is lengthy, expensive, and uncertain. Even if we obtain approval, our products remain subject to ongoing post-marketing surveillance, and failure to comply with Health Canada requirements, such as GMP and GCP, could result in product recalls, suspension of approvals, or penalties.

Marketing Authorization in the EU

The EMA is the scientific agency of the EU that coordinates the evaluation and monitoring of new and approved medicinal products such as drugs and biologics. It is responsible for the scientific evaluation of

applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors.

In the EU, we are required to apply for marketing authorizations under the centralized procedure to the EMA as the centralized procedure is mandatory for certain medicines, such as t orphan medicinal products, and advanced therapy medicinal products and those containing a new active substance indicated for the treatment of cancer. The marketing authorization granted under the centralized procedure by the EMA will be valid in all EEA Member States. The evaluation of a marketing authorization application by the EMA's Committee for Medicinal Products for Human Use ("CHMP:) takes up to 210 "active" days (excluding all "clock stops" for an applicant to address questions by the EMA–there are usually one or two clock stops that last three to six months and one to two months, respectively) but can be extended, should additional information be required by the CHMP. The European Commission makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's positive opinion.

An accelerated assessment procedure of 150 days may be implemented for drugs considered to be of major public health interest. There is also an internal re-examination procedure available in case the applicant disagrees with the CHMP opinion.

Regulatory Submissions

The EU Clinical Trials Regulation ("CTR") which was adopted in April 2014 and repeals the EU Clinical Trials Directive and went into full effect on January 31, 2025. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

The CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The clinical trial application ("CTA") must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal.

Conditional Approval

In specific circumstances, EU legislation (Article 14(7) Regulation (EC) No. 726/2004 and Regulation (EC) No. 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for products (including medicines designated as orphan medicinal products), if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs, and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Marketing Authorization Under Exceptional Circumstances

Marketing Authorization Under Exceptional Circumstances is a regulatory pathway in the EU allowing early access to medicines for rare diseases, emergencies, or ethical constraints preventing comprehensive data collection. It enables approval without a full efficacy/safety dossier, provided the benefit-risk balance is positive. Per Article 14(8) Regulation (EC) No 726/2004, products for which the applicant can demonstrate that comprehensive data (in line with the requirements laid down in Annex I of Directive 2001/83/EC, as amended) cannot be provided (due to specific reasons foreseen in the legislation) might be eligible for marketing authorization under exceptional circumstances. This type of authorization is reviewed annually to reassess the risk-benefit balance. The fulfillment of any specific procedures/obligations imposed as part of the marketing authorization under exceptional circumstances is aimed at the provision of information on the safe and effective use of the product and will normally not lead to the completion of a full dossier/approval.

Accelerated Approval Pathways

The EU and UK operate accelerated evaluation and assessment schemes, which include, at EU level, Priority Medicines ("PRIME") scheme and, at UK level, the Early Access to Medicines Scheme ("EAMS"), which may be granted in exceptional cases, often when there is unmet medical need for a life-threatening or serious debilitating condition and existing data show a positive benefit/risk balance that means the medicinal product is of a major public health interest. The CHMP of the EMA or the MHRA (or other national competent authority) will make this determination on a case-by-case basis and subject to meeting eligibility criteria. Accelerated assessment takes place within 150 days. Other regulatory facilitations for these pathways include additional scientific advice at key development milestones and frequent guidance and discussions throughout the approval process.

In the UK, the MHRA has launched the Innovative Licensing and Access Pathway (ILAP), a new accelerated assessment procedure for marketing authorization applications that enables companies to enter the UK market faster. The MHRA launched an International Recognition Procedure for Great Britain (England, Scotland and Wales) marketing authorization applications whereby the MHRA will, when considering such applications, recognize the approval of medicines by trusted reference regulators in Australia, Canada, Switzerland, Singapore, Japan, United States and EU following its own abbreviated assessment.

Pediatric Development

In the EEA, MAAs for new medicinal products must include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan ("PIP"), agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. We have received a class waiver for pediatric data in mPDAC.

Orphan Medicinal Products

In the EU and UK, under Regulation (EC) 141/2000 and the UK Human Medicines Regulations 2012 SI 2012 No. 1916 (as amended), respectively, medicinal products may be granted an orphan drug designation if they are used to treat or prevent life-threatening or chronically debilitating conditions that affect no more than five in 10,000 people in the EU/UK and for which there is no satisfactory method of diagnosis, prevention or treatment when the application is made, or when the medicinal product is of significant benefit to those affected by the condition. In addition, orphan drug designation can be granted to drugs used to treat or prevent life-threatening or chronically debilitating conditions which, for economic reasons, would be unlikely to be developed without incentives.

The application for orphan designation must be submitted to and approved by the EMA in respect of the EU or to the MHRA for Great Britain before an application is made for marketing authorization for the product. Medicinal products which benefit from orphan status can benefit from up to ten years of market exclusivity in respect of the approved indication. This prevents regulatory authorities in the EU or Great Britain from granting marketing authorizations for similar medicinal products for the same therapeutic indication, unless another applicant can show that the similar medicinal product in question is safer, more effective or clinically superior to the orphan-designated product or if the marketing authorization holder consents to the second orphan medicinal product application, or were the marketing authorization holder cannot supply the needs of the market.

The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify the maintenance of market exclusivity. Conversely, the 10- year exclusivity period can be further extended by two years, when pediatric studies are conducted in accordance with an agreed pediatric investigation plan ("PIP") and in completion of all the legal requirements. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

It is noted that the general pharmaceutical legislative framework, as well as the framework applicable to orphan and pediatric medicinal products in the EU, is under review. On April 26, 2023, the European Commission adopted a proposal for a new Regulation set to replace Regulation (EC) No 726/2004 and a new Directive to replace Directive 2001/83 on the Community Code relating to medicinal products for human use. Initial framework agreement was reached in December 2025; however, final legislation is undergoing final formal review by the European Parliament and Council. If made into law, this proposal will revise the existing general pharmaceutical legislation with new measures to encourage pediatric research, including incentives for completing pediatric investigation plans (PIPs) and introducing more flexible paths for pediatric medicines; however, may reduce applicable regulatory exclusivities which will significantly affect all medicinal products that will be authorized after the legislative changes have taken effect.

We have received Orphan Designation from the EMA for mPDAC and sarcoma in pediatric patients.

Period of Authorization and Renewals

A marketing authorization will be valid for five years in principle, and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by a national authority. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization will be valid for an unlimited period, unless the European Commission or the national authority decides on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization that is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization will cease to be valid, the so-called "sunset clause."

Regulatory Data Protection

EU legislation also provides for a system of regulatory data and market exclusivity. Upon receiving marketing authorization, new chemical entities approved on the basis of complete independent data package benefit from eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic or biosimilar (abbreviated) application. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be marketed until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first 8 years of those 10 years, the marketing authorization holder ("MAH") obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the innovator is able to gain the period of data exclusivity, another company nevertheless could also market another

version of the drug if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical test, preclinical tests and clinical trials. However, products designated as orphan medicinal products enjoy, upon receiving marketing authorization, a period of 10 years of orphan market exclusivity. Depending upon the timing and duration of the EU marketing authorization process, products may be eligible for up to five years' supplementary protection certificates ("SPCs"). Such SPCs extend the rights under the basic patent for the drug.

Clinical Trials Regulation and Data Sharing in the EU

In the EU/EEA, all initial clinical trial applications ("CTA") must be submitted through the Clinical Trials Information System ("CTIS") and ethics approval must be sought from an independent Ethics Committee. Under the EU Clinical Trials Regulation 536/2014, which has been in effect since January 31, 2022, replacing the EU Clinical Trials Directive 2001/20/EC, suspected unexpected serious adverse reactions to the drug during the clinical trial must be reported via the EudraVigilance database.

In the EU, Transparency Regulation No 1049/ 2001, EMA Policy 0043, EMA Policy 0070, as well as the Clinical Trials Regulation No 536/2014 set out the obligation for sponsors to make publicly available certain information stemming from clinical studies, whether proactively or in response to third party requests. Interested parties based in the EU may submit a request to the EMA to access information included in the marketing authorization application for authorized medicinal products. Commercially confidential information and protected personal data, however, may not be accessed.

The European Health Data Space Regulations (the "EHDS Regulations") came into force on March 26, 2025. The aims of the EHDS Regulations are to provide individuals with more control over their electronic health data, enable cross-border sharing of European Health Data (EHD) between national EU healthcare systems and facilitate the sharing of EHD for secondary research purposes. The EHDS Regulations impose new obligations but also create opportunities for companies engaged in health-related research to share and access health data on a large scale. Although the EHDS Regulations have come into force, key obligations will not apply until March 2029.

Data Privacy

We are subject to extensive privacy and data protection laws and regulations around the world concerning the collection, use and sharing of personal data. We are subject to privacy laws in connection with our clinical trial activities outside the United States such as the EU and UK General Data Protection Regulation ("GDPR"), non-compliance with which could result in administrative fines of up to the greater of 4% of global annual revenues or €20.0 million (under the EU GDPR) or £17.5m (under the UK GDPR). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. We routinely collect and use sensitive personal information relating to health. The legislative, regulatory and litigation landscape for privacy and data protection requirements is rapidly evolving and changing and may limit our ability to use data globally or across borders. Data protection requirements are not universal and can conflict between jurisdictions.

Compliance with local laws and regulations is made more complex by the lack of consistent standards, common definitions, or clear regulatory expectations. At the same time, enforcement of these laws and regulations is increasing and fines and penalties are also increasing. Any failure or perceived failure by us to comply with applicable privacy and data protection laws and regulations, including cybersecurity breaches or incidents, could subject us to significant fines and penalties, and/or litigation, as well as negatively impacting our reputation.

Regulatory Requirements After a Marketing Authorization ("MA") Has Been Obtained

Similar to the United States, MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the EU member states. The holder of a MA must establish and maintain a pharmacovigilance

system and appoint an individual qualified person for pharmacovigilance ("QPPV") who is responsible for the establishment and maintenance of that system and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAA must include a risk management plan ("RMP") describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The manufacturing of authorized drugs, for which a separate manufacturer's license is mandatory, must be conducted in compliance with the EMA's GMP requirements and comparable requirements of other national authorities, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. The EMA enforces its GMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a coordinating role for these inspections while the responsibility for carrying them out rests with the member states competent authority under whose responsibility the manufacturer falls. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU.

Reimbursement of Medicines in Europe

In the EU, pricing and reimbursement methods can differ in each Member State. Some Member States and the UK may require that health technology assessments ("HTA") be completed for the product to be recommended for funding under the NHS. The outcome of HTAs is decided on a national basis and some Member States may decide not to reimburse the use of medicines or may reduce the rate of reimbursement. As of January 12, 2025, EU Health Technology Regulation No. 2021/2282 has become applicable in respect of new oncology medicines. Regulation 2021/2282 imposes a new procedure, a joint clinical assessment at a centralized level, as a mandatory step for the assessment of the pricing and reimbursement of medicinal products by national authorities. It requires companies applying for products in scope to make relevant submissions for the joint clinical assessment, in line with a number of prespecified criteria.

In the UK, NICE is the body in England and Wales, which conducts HTAs and issues guidance on whether a product is considered to be "cost-effective" and therefore recommended for use and reimbursement under the national health service. This means that if a positive recommendation has been obtained, then the medicinal product will be widely available to patients in England and Wales. For avoidance of doubt, Scotland and Northern Ireland have their own HTA bodies which will conduct their own assessment.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain business practices in the biopharmaceutical industry. Applicable federal and state healthcare laws and regulations include the following:

- The federal healthcare Anti-Kickback Statute of 1972 prohibits, among other things, persons from knowingly and willfully soliciting, offering, 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 under federal healthcare programs such as Medicare, Medicaid, or other governmental programs. A person or entity does not need to have actual knowledge of the federal anti-kickback statute or specific intent to violate it to have committed a violation; in addition, items or services resulting from a violation of the federal anti-kickback statute may constitute a false or fraudulent claim for purposes of the False Claims Act;

- The federal False Claims Act of 1986 imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. This statute also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") of 2009 and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates" — independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity.
- The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities, which will provide coverage of outpatient prescription drugs.
- The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness.
- The Physician Payments Sunshine Act of 2010 requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members.
- The Patient Protection and Affordable Care Act of 2010 ("PPACA") includes measures to significantly change the way healthcare is financed by both governmental and private insurers and significantly impacts the U.S. pharmaceutical industry. Among the provisions of the PPACA of importance to the pharmaceutical and biotechnology industry are the following, among others: (i) extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (ii) expansion of eligibility criteria for Medicaid programs; and (iii) expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program.
- The Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction, or joint committee, to recommend proposals in spending reductions to Congress. The joint committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering automatic reductions to several government programs. These reductions include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013.

- The American Taxpayer Relief Act of 2012, reduced Medicare payments to several providers, among other things, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding.
- Depending upon the timing, duration and specifics of the FDA approval of the use of our pharmaceutical product candidates, some of our products to be licensed under U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process.
- The Biologics Price Competition and Innovation Act ("BPCI Act") authorizes the FDA to license a biological product that is biosimilar to an FDA-licensed biologic through an abbreviated pathway. The BPCI Act establishes criteria for determining that a product is biosimilar to an already-licensed biologic, or reference product, and establishes a process by which an abbreviated BLA for a biosimilar product is submitted, reviewed and approved.

Coverage and Reimbursement

Sales of our product candidates in the United States may depend, in part, on the extent to which the costs of the product candidates may be covered by third-party payers, such as government health programs, commercial insurance and managed health care organizations. These third-party payers are increasingly challenging the prices charged for medical products and services. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payers do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our product candidates after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our product candidates on a profitable basis.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA, EMA or other comparable regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. A payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. The conduct of such studies could be expensive and result in delays in our commercializing efforts. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which

we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

U.S. Healthcare Reform

In the United States, there have been and continue to be a number of significant legislative initiatives to contain healthcare costs. The PPACA contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs subject to the Medicaid Drug Rebate Program, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the PPACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the PPACA brought by several states without specifically ruling on the constitutionality of the PPACA.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, for single source and innovator multiple source drugs, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries, presidential executive orders and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Additional changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2027, unless additional Congressional action is taken; however, pursuant to the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") and subsequent legislation. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products. There have been several recent U.S. Congressional inquiries and proposed and enacted federal and state 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. The FDA published a final rule on October 1, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Service ("HHS") finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. 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, designed to encourage importation from other countries and bulk purchasing.

Most recently, on August 16, 2022, the Inflation Reduction Act of 2022 (the "IRA") was signed into law. Among other things, the IRA directs the HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price representing a significant discount from average prices to wholesalers and direct purchasers. The law will also, beginning in 2023, penalize drug manufacturers that

increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. Further, the IRA eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the IRA may be subject to legal challenges. It is currently unclear how the IRA will be implemented but it is likely to have a significant impact on the pharmaceutical industry. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

Although a number of these and other proposed measures may require authorization through additional legislation to become effective, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product if it is equal to or greater than $35 for a monthly supply or usual course of treatment. Prescription drugs and biological products that are in violation of these requirements will be included on a public list.

Any adopted health reform measure could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical 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, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future.

We expect that additional state and federal healthcare reform measures, as well as legal changes by foreign governments, will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Employees and Human Capital Resources

As of December 31, 2025, we had 12 full-time employees plus a number of contract workers, who manage and oversee all aspects of our operations, including nonclinical development, manufacturing, clinical development, and general and administrative functions. Nine employees were engaged in research and development activities. In addition, we currently work with numerous highly experienced consultants and contractors who provide management and oversight in manufacturing, analytical, clinical supply chain, regulatory, pharmacovigilance and safety, clinical operations, data management, statistics, non-clinical toxicology, nonclinical and clinical pharmacology, and medical affairs. Thus, we currently operate as a semi-virtual pharmaceutical company with expertise in numerous aspects of preclinical and clinical development.

None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Corporate Information

We are a Delaware corporation formed on January 16, 2015 as Apotheca Therapeutics, Inc. and changed our name to Actuate Therapeutics, Inc. on October 1, 2015. Our principal executive offices are located at 1751 River Run, Suite 400, Fort Worth, Texas 76107, and our telephone number is (817) 887-8455.

Our Internet address for corporate and investor information is www.actuatetherapeutics.com. The information contained on our website or connected to our website is not incorporated by reference into this Annual Report and should not be considered part of this Report.

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 Securities Exchange Act are available free of charge on or through our website at www.actuatetherapeutics.com under the "SEC Filings" heading on the "Investors" page as soon as reasonably practicable after such reports have been filed with or furnished to the SEC. They are also available for free on the SEC's website at www.sec.gov.

In addition, we use our website www.actuatetherapeutics.com as a means of disclosing material non-public information and for complying with our disclosure obligations under the Regulation FD. Such disclosures will be included on the Company's website under the heading "Investors." We also use social media accounts as a means of disclosing material non-public information, including accounts at:

- X account (formerly Twitter): @ActuateThera or https://x.com/ActuateThera
- LinkedIn: https://www.linkedin.com/company/actuate-therapeutics-inc./
- Facebook profile: https://www.facebook.com/profile.php?id=61572431561095

Accordingly, investors should monitor such portions of the Company's website and social media accounts, in addition to following the Company's press releases, SEC filings, corporate presentations, and public conference calls and webcasts (if any).

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Before you decide to invest in our common stock, you should consider carefully the risks described below, together with the other information contained in this Report, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes. We believe the risks described below are the risks that are material to us as of the date of this Report. The occurrence of any of the events or developments discussed in the risk factors below could have a material and adverse impact on our business, financial condition, results of operations and cash flows and, in such case, our future prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant operating losses for the foreseeable future. We may never generate revenue or achieve profitability, and if we do achieve profitability, it may not be sustained.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a relatively limited operating history upon which you can evaluate our business and prospects. We commenced operations in January 2015 and have not generated revenue from the sale of our products. Therefore, there is limited historical financial or operational information upon which to evaluate our performance. Our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. Many if not most companies in our industry at our stage of development never become profitable and are acquired or go out of business before successfully developing any product that generates revenue from commercial sales or enables profitability.

We have incurred losses since our inception and our accumulated deficit was approximately $154.6 million at December 31, 2025. Substantially all of our losses have resulted from expenses incurred in connection with our research and development activities and from general and administrative costs associated with our operations. We expect to continue to incur substantial and increasing operating losses over the next several years

as we continue the clinical development of, seek regulatory approval for and potentially commercialize elraglusib and any future product candidates, as well as operate as a public company.

The magnitude of our future losses and when, if ever, we will become profitable are uncertain. We do not have any products that have generated any revenues from commercial sales, and do not expect to generate revenues from the commercial sale of products in the near future, if ever. If we are unable to successfully develop, obtain requisite approval for and commercialize elraglusib or any future product candidates, we may never generate revenue. Our ability to generate revenue and achieve profitability will depend on, among other things:

- successful completion of the development of our product candidates;
- obtaining necessary regulatory approvals from the FDA and international regulatory agencies;
- establishing manufacturing, sales, and marketing arrangements with third parties;
- obtaining adequate reimbursement by third-party payers; and
- raising sufficient funds to finance our activities.

There can be no assurance we will be successful in all or any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, financial condition, and results of operations are expected to be materially and adversely affected.

To become and remain profitable, we must succeed in developing, obtaining regulatory approvals for, and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical studies of elraglusib and any future product candidates, acquiring or developing additional product candidates, obtaining regulatory approval for elraglusib and any future product candidates and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates, achieve our strategic objectives or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or our operations.

As of December 31, 2025, we had approximately $13.2 million in cash and cash equivalents and working capital of approximately $7.9 million. Based on our current operating plan, we estimate that our existing cash and cash equivalents as of the date of this Report will not satisfy the Company's operational and capital requirements beyond July 2026. Our estimates and assumptions regarding our operating costs may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned.

We have incurred and expect to continue to incur significant costs in the development of our sole drug candidate, elraglusib. Accordingly, in the near term, we intend to seek and will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, including as a result of financial and credit market deterioration or instability, market-wide liquidity shortages, geopolitical events or otherwise. If we are unable to raise capital in the near term or on attractive terms, we could be forced to delay, reduce or eliminate our research and development

programs or any future commercialization efforts, or even curtail or cease operations. Even if we secure necessary financing in the near term, we expect to continue to require substantial funding as the timing for and ability to generate sufficient funds from operations will remain uncertain until such time as we are able to progress elraglusib through development and potential commercialization.

We expect to finance our cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses, and other similar arrangements. However, as of the date of this Report, we have no agreements or understandings in place concerning our receipt of additional financing.

The foregoing conditions raise substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm included in its audit opinion for the year ended December 31, 2025 an explanatory paragraph that there is substantial doubt as to our ability to continue as a going concern.

Raising additional capital or acquiring or licensing assets by issuing equity or debt securities may cause dilution to our stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional capital when needed, we may be required to delay, reduce or eliminate our research and development programs or any future commercialization efforts, or even curtail or cease operations.

Risks Related to the Development and Commercialization of Our Product Candidates

We currently depend entirely on the success of elraglusib, which is our only product candidate. If we are unable to advance elraglusib in clinical development, obtain regulatory approval and ultimately commercialize elraglusib in a timely manner, our business will be materially harmed.

We currently only have one product candidate, elraglusib, which is in Phase 2 clinical development for the treatment of mPDAC as its lead indication. Our business presently depends entirely on our ability to successfully develop, obtain regulatory approval for, and commercialize elraglusib in a timely manner. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and may be able to better sustain the delay or failure of a lead product candidate. The success of elraglusib will depend on several factors, including the following:

- successful initiation and enrollment of clinical trials and completion of clinical trials with favorable results;
- acceptance of regulatory submissions by the FDA or comparable foreign regulatory authorities for the conduct of clinical trials of elraglusib and of our proposed designs of planned clinical trials of elraglusib;
- the frequency and severity of adverse events observed in clinical trials and preclinical studies;
- maintaining and establishing relationships with contract research organizations (“CROs”) and clinical sites for the clinical development of elraglusib, and ability of such CROs and clinical sites to comply with clinical trial protocols, GCPs and other applicable requirements;

- demonstrating the safety and efficacy of elraglusib to the satisfaction of applicable regulatory authorities, including by establishing a safety database of a size satisfactory to regulatory authorities;
- receipt and maintenance of regulatory approvals from applicable regulatory authorities, including approvals of NDAs from the FDA;
- maintaining relationships with our third-party manufacturers and their ability to comply with cGMPs as well as entering into agreements with our third-party manufacturers for, or establishing our own, commercial manufacturing capabilities at a cost and scale sufficient to support commercialization;
- establishing sales, marketing and distribution capabilities and launching commercial sales of elraglusib, if and when approved, whether alone or in collaboration with others;
- obtaining, maintaining, protecting and enforcing patent and any potential trade secret protection or regulatory exclusivity for elraglusib;
- maintaining an acceptable safety profile of elraglusib following regulatory approval, if any;
- maintaining and growing an organization of people who can develop and, if approved, commercialize, market and sell elraglusib; and
- acceptance and coverage of our products, if approved, by patients, the medical community and federal healthcare program and other third-party payors.

If we are unable to develop, obtain regulatory approval for, or if approved, successfully manufacture and commercialize elraglusib, or if we experience delays as a result of any of the above factors or otherwise, our business would be materially harmed.

We do not have and may never have any approved products on the market. Our business is highly dependent upon receiving approvals from various governmental agencies and will be severely harmed if we are not granted approval to manufacture and sell our product candidates.

In order for us to commercialize elraglusib for the treatment of mPDAC or for any other disease indication, or any other product candidate, we must obtain regulatory approvals of such treatment for the applicable indication. Satisfying regulatory requirements is an expensive process that typically takes many years and involves extensive compliance with requirements covering research and development, testing, manufacturing, quality control, labeling, and promotion of drugs for human use. To obtain necessary regulatory approvals, we must, among other requirements, complete clinical trials demonstrating that our products are safe and effective for a particular indication. In addition, before we can initiate clinical development for any future preclinical product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission, and we are also required to submit comparable applications to foreign regulatory authorities for clinical trials outside of the United States. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any future product candidates before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays or increase the costs of developing future product candidates. There can be no assurance that our products will prove to be safe and effective, that our preclinical or clinical trials will demonstrate the necessary safety and effectiveness of our product candidates, or that we will succeed in obtaining regulatory approval for any treatment we develop even if such safety and effectiveness are demonstrated.

Any delays or difficulties we encounter in our clinical trials may delay or preclude regulatory approval from the FDA or from international regulatory organizations. Any delay or preclusion of regulatory approval would be expected to delay or preclude the commercialization of our products. Examples of delays or difficulties that we may encounter in our clinical trials include without limitation the following:

- clinical trials may not yield sufficiently conclusive results for regulatory agencies to approve the use of our products;
- our products may fail to be more effective than current therapies, or to be effective at all;

- we may discover that our products have adverse side effects, which could cause our products to be delayed or precluded from receiving regulatory approval or otherwise expose us to significant commercial and legal risks;
- it may take longer than expected to determine whether or not a treatment is effective;
- we may fail to be able to enroll a sufficient number of patients in our clinical trials;
- patients enrolled in our clinical trials may not have the characteristics necessary to obtain regulatory approval for a particular indication or patient population;
- we may be unable to produce sufficient quantities of product to complete the clinical trials;
- the sites who conduct our clinical trials may fail to follow the trial protocols correctly, or there may be concerns regarding data integrity from one or more sites, which could require us to exclude certain data from our results, which may prolong the length of our trials and delay submissions to regulatory authorities;
- even if we are successful in our clinical trials, any required governmental approvals may still not be obtained or, if obtained, may not be maintained;
- if approval for commercialization is granted, it is possible the authorized use will be more limited than is necessary for commercial success, or that approval may be conditioned on completion of further clinical trials or other activities, which will cause a substantial increase in costs and which we might not succeed in performing or completing; and
- if granted, approval may be withdrawn or limited if problems with our products emerge or are suggested by the data arising from their use or if there is a change in law or regulation.

Any success we may achieve at a given stage of our clinical trials does not guarantee that we will achieve success at any subsequent stage, including without limitation final FDA approval.

We may encounter delays or rejections in the regulatory approval process because of additional government regulation resulting from future legislation or administrative action, or from changes in the policies of the FDA or other regulatory bodies during the period of product development, clinical trials, or regulatory review. In addition, legislative and regulatory agendas, as they relate to healthcare and pharmaceutical industries and the economy as a whole, of the Trump administration and the U.S. Congress currently remain uncertain. Failure to comply with any current or future applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production, or an injunction preventing certain activity, as well as other regulatory action against our product candidates or us. As a company, we have no experience in successfully obtaining regulatory approval for a product and thus may be poorly equipped to gauge, and may prove unable to manage, risks relating to obtaining such approval.

Outside the United States, our ability to market a product is contingent upon receiving clearances from appropriate non-U.S. regulatory authorities. Non-U.S. regulatory approval typically includes all of the risks associated with FDA clearance discussed above as well as geopolitical uncertainties and the additional uncertainties and potential prejudices faced by U.S. pharmaceutical companies conducting business abroad. In certain cases, pricing restrictions and practices can make achieving even limited profitability very difficult.

Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Elraglusib or any future product candidates may not achieve favorable results or receive regulatory approval on a timely basis, if at all.

Drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials or preclinical studies will be conducted as planned, including whether we are able to meet expected timeframes for data readouts, or completed on schedule, if at all, and failure can occur at any time during the trial or study process, including due to factors that are beyond our control. Despite promising preclinical or clinical results, elraglusib or any other future product candidate can unexpectedly fail at any stage of clinical or preclinical development. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or clinical trials of elraglusib, any future product candidate, or a competitor's product candidate in the same class may not predict the results of later clinical trials of elraglusib or any future product candidate, and interim, topline or preliminary results of a clinical trial are not necessarily indicative of final results. Elraglusib or any future product candidate in later stages of clinical trials may fail to show the desired characteristics despite having progressed through preclinical studies and initial clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results.

Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Such setbacks have occurred and may occur for many reasons, including, but not limited to:

- clinical sites and investigators may deviate from clinical trial protocols, whether due to lack of training or otherwise, and we may fail to detect any such deviations in a timely manner;
- patients may fail to adhere to any required clinical trial procedures, including any requirements for post-treatment follow-up;
- our product candidates may fail to demonstrate safety efficacy in certain patient subpopulations, which has not been observed in earlier trials due to limited sample size, lack of analysis or otherwise;
- our clinical trials may not adequately represent the patient populations we intend to treat, whether due to limitations in our trial designs or otherwise, such as where one patient subgroup is overrepresented in the clinical trial; or
- others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability, or commercialization of the particular product candidate or product.

There can be no assurance that we will not suffer similar setbacks despite the data we observed in earlier or ongoing studies. Based upon negative or inconclusive results, we or any current or any future collaborator may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, which would cause us to incur additional operating expenses and delays and may not be sufficient to support regulatory approval on a timely basis or at all.

We may not be successful in our efforts to advance elraglusib in additional indications. We may expend our limited resources to pursue a new product candidate or a particular indication for elraglusib and fail to capitalize on more profitable or successful alternatives.

Because we have limited financial and managerial resources, we focus on the development of elraglusib for specific indications. We may fail to generate additional clinical development opportunities for elraglusib for a number of reasons, including that elraglusib may, in indications we are seeking or may seek in the future, be shown to have harmful side effects, limited to no efficacy or other characteristics that suggest it is unlikely to receive marketing approval and/or achieve market acceptance in such potential indications. Our resource allocation and other decisions may cause us to fail to identify and capitalize on viable potential product candidates or additional indications for elraglusib. Our spending on current and future research and development programs for new product candidates or additional indications for elraglusib may not yield any commercially viable product candidates or indications. If we do not accurately evaluate the commercial potential or target market for a particular indication or product candidate, we may fail to develop such product candidate or indication, or relinquish valuable rights to that product candidate through collaborations, license agreements and other similar arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such indication or product candidate, or negotiate less advantageous terms for any such arrangements than is optimal.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

If we experience delays or difficulties enrolling subjects to our clinical trials, our receipt of necessary regulatory approvals could be delayed or otherwise adversely affected.

Identifying, screening and enrolling patients to participate in clinical trials of our product candidates is critical to our success, and we may not be able to identify, recruit, enroll and dose a sufficient number of patients with the required or desired characteristics to complete our clinical trials in a timely manner. We may not be able to initiate or continue certain clinical trials for elraglusib or any future product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. The timing of our clinical trials depends on our ability to recruit patients to participate as well as to subsequently dose these patients and complete required follow-up periods. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including:

- the size and characteristics of the patient population;
- the proximity of patients to clinical sites;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- the risk that enrolled patients will not complete a clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidates being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development.

We will be required to identify and enroll a sufficient number of patients for each of our clinical trials and monitor such patients adequately during and after treatment. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting, which could adversely impact the outcomes of our trials and could have safety concerns for the potential patients. Potential patients for any planned clinical trials may also not meet the entry criteria for such trials. In particular, because our planned clinical trials of elraglusib are focused on indications with relatively small patient populations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

In addition, we may experience enrollment delays related to increased or unforeseen regulatory, legal and logistical requirements at certain clinical trial sites. These delays could be caused by reviews by regulatory authorities and contractual discussions with individual clinical trial sites. Any delays in enrolling and/or dosing patients in our planned clinical trials could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or in termination of the clinical trials altogether.

If patients are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar target populations, the availability of approved therapies, or the fact that enrolling in our trials may prevent patients from taking a different product, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of elraglusib or any future product candidates may be delayed. Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether.

Enrollment delays in these clinical trials may result in increased time and development costs for our product candidates, which could materially affect our financial condition.

As a company, we have not yet initiated nor completed a Phase 3 clinical trial and have limited experience in completing regulatory filings, and any delays in regulatory filings could materially affect our financial condition.

We will need to successfully complete clinical trials in order to obtain FDA or comparable foreign regulatory approval to market elraglusib or any future product candidates. Carrying out clinical trials and the submission of a successful NDA or other comparable foreign regulatory submission is a complicated process. As a company, we have not yet initiated nor completed a Phase 3 clinical trial of our product candidates, nor have we demonstrated the ability to obtain marketing approvals, manufacture product candidates at a commercial scale, or conduct sales and marketing activities necessary for the successful commercialization of a product. We may also choose to conduct a number of additional clinical trials of elraglusib in parallel over the next several years, which may be a difficult process to manage with our limited resources and which may divert attention of management. FDA or other regulatory authority could also require us to conduct additional trials which may further delay approval of our product. Consequently, we have no historical basis as a company by which you can evaluate or predict reliably our future success or viability.

As a result, we cannot be certain that our ongoing and planned clinical trials or preclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of elraglusib in those and other indications, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Interim, topline, and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials, based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Interim, topline, and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, such data should be viewed with caution until the final data are available. Interim, topline, and preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, interim or topline data and final data could significantly harm our business prospects.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate, or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize elraglusib and any future product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

We anticipate that many of our product candidates may be tested and, if approved, used in combination with third-party drugs and/or devices, some of which may still be in development, and we have limited or no control over the supply, regulatory status or regulatory approval of such drugs and/or devices.

We anticipate developing our product candidates for use in combination with other oncology pharmaceuticals, including chemotherapies and cellular and targeted therapies (e.g., immune checkpoint inhibitors). We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs or devices on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing platinum-based and other chemotherapies, or any other combination products, or any devices in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed. Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For our product candidates that may be used in combination with other chemotherapies, or any other combination products or any devices, the FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that there are adverse events tied to the interaction of elraglusib with any of the other therapies, or that any positive previous trial results are attributable to the combination therapy and not our product candidates. Moreover, following product approval, the FDA may require that products or devices used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product or device, this may require us to work with a third party to satisfy such a requirement. The ability to obtain cooperation from the third party may impact our ability to respond to the FDA's requests which could impact our ability to achieve regulatory approval. Moreover, developments related to the other product or device may impact our clinical trials as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the safety or efficacy profile of the other product or device, changes to the availability of the approved product or device, and changes to the standard of care.

In the event that any future collaborator or supplier of other chemotherapies, or any other products administered in combination, or any devices used, with our product candidates does not supply their products on commercially reasonable terms or in a timely fashion, we would need to identify alternatives for accessing these products. This could cause our clinical trials to be delayed and limit the commercial opportunities for our product candidates, in which case our business, financial condition, results of operations, stock price and prospects may be materially harmed.

We may seek additional Orphan Drug, Fast Track ("FTD"), Breakthrough ("BTD") or orphan and priority ("PRIME") designations for one or more of our current and future product candidates, but we might not receive any such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.

Our lead product candidate, elraglusib, has been given FTD from the FDA for development in the treatment of pancreatic cancer, and we may seek FTD for other indications or future product candidates. The FTD program is intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Specifically, biologics are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the application may be eligible for priority review. An NDA submitted for a Fast Track product candidate may also be eligible for rolling review, where 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. Fast Track designation does not ensure that we will

receive marketing approval or that approval will be granted within any particular timeframe or at all. We may not experience a faster development, regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. Additionally, the FDA may withdraw Fast Track designation, for reasons such as it comes to believe a drug candidate no longer adequately addresses an unmet medical need or 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. If we seek Fast Track designation for other indications, or if we pursue breakthrough or PRIME designations from FDA or EMA, respectively, we may not receive such designations. Many product candidates that have received Fast Track designation have ultimately failed to obtain approval.

We, or any future collaborators, may not be able to obtain and maintain orphan drug exclusivity for our product candidates in the United States and Europe.

Elraglusib has been granted orphan drug designation ("ODD") for the treatment of pancreatic cancer, glioblastomas, neuroblastoma and soft tissue sarcomas in the United States. We may seek additional ODD or regulatory incentives for other indications, for the oral dosage form of elraglusib, or for future product candidates in the United States, EU, Japan or Australia. We may not be able to obtain such designations.

While elraglusib currently has been granted ODD from the FDA for limited indications, we may not be able to maintain this orphan drug exclusivity. Further, even if we obtain ODD for a future product candidate or for elraglusib with respect to a different indication, we may not be able to maintain orphan drug exclusivity for that drug or indication. For example, ODD may be removed if the prevalence of an indication increases beyond the patient number limit required to maintain designation. Generally, if a drug with an ODD subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same product in the same indication for that time period. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. Moreover, even after an orphan drug is approved, the FDA can subsequently approve a different drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared to our product.

The FDA may reevaluate the Orphan Drug Act and its regulations and policies, and similarly the EMA may reevaluate its policies and regulations. We do not know if, when, or how the FDA or EMA may change their orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA and/or EMA may make to their orphan drug regulations and policies, our business could be adversely impacted.

It is uncertain whether product liability insurance will be adequate to address product liability claims, or that insurance against such claims will be affordable or available on acceptable terms in the future.

Clinical research involves the testing of new drugs on human volunteers pursuant to a clinical trial protocol. Such testing involves a risk of liability for personal injury to or death of patients due to, among other causes, adverse side effects, improper administration of the new drug, or improper volunteer behavior. Claims may arise from patients, clinical trial volunteers, consumers, physicians, hospitals, companies, institutions, researchers, or others using, selling, or buying our products, as well as from governmental bodies. In addition, product liability and related risks are likely to increase over time, in particular upon the commercialization or marketing of any products by us or parties with which we enter into development, marketing, or distribution collaborations. While we do have liability insurance coverage, regardless of their merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial volunteers;
- decreased demand for our products when approved;
- injury to our reputation and significant, adverse media attention; and
- potentially significant litigation costs, including without limitation, any damages awarded to the plaintiffs if we lose or settle claims.

There can be no assurance that suitable product liability insurance (at the clinical stage and/or commercial stage) will continue to be available on terms acceptable to us or at all, or that, if obtained, the insurance coverage will be appropriate and sufficient to cover any potential claims or liabilities.

If the market opportunities for our current and potential future drug candidates are smaller than we believe they are, our ability to generate product revenues may be adversely affected and our business may suffer.

The potential market opportunities for our product candidates are difficult to estimate and will depend in large part on the drugs with which our product candidates are co-administered and the success of competing therapies and therapeutic approaches. Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive therapy and who have the potential to benefit from treatment with elraglusib or any future product candidate are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe, and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with our product, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. If any of the assumptions prove to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities. Further, even if we obtain significant market share for elraglusib or any future product candidate, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Our product development efforts are at an early stage. We have not yet undertaken any marketing efforts, and there can be no assurance that future anticipated market testing and analyses will validate our marketing strategy. We may need to modify the products, or we may not be successful in either developing or marketing those products.

As a company, we have not completed the development or clinical trials of any product candidate and, accordingly, have not yet begun to market or generate revenue from the commercialization of any products. Obtaining approvals of these product candidates will require substantial additional research and development as well as costly clinical trials. There can be no assurance that we will successfully complete the development of our product candidates or successfully market them. We may encounter problems and delays relating to research and development, regulatory approval, intellectual property rights of product candidates, or other factors. There can be no assurance that our development programs will be successful, that our product candidates will prove to be safe and effective in or after clinical trials, that the necessary regulatory approvals for any product candidates will be obtained, or, even if obtained, will be as broad as sought or will be maintained for any period thereafter, that patents will issue on our patent applications, that any intellectual property protections we secure will be adequate, or that our collaboration arrangements will not diminish the value of our intellectual property through licensing or other arrangements.

Furthermore, elraglusib and any future product candidates may not be commercially successful. Even if elraglusib or any future product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, or the medical community. The commercial success of elraglusib or any future product candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications, and there can be no assurance that competitive products will not perform better and/or be marketed more successfully. Additionally, there can be no assurances that any future market testing and analyses will validate our marketing strategies. We may need to seek to modify the product labels through additional studies in order to be able to market them successfully to reach their commercial potential. If elraglusib or any future product candidates is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market, sell and distribute our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we ever commercialized a product. If elraglusib or any future product candidate ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. For example, if elraglusib is approved, we will need to scale up a cost-effective and reliable cold chain distribution and logistics network, which we may be unable to accomplish and which will require us to rely on third-party distributors. Failure to scale up our cold chain supply logistics, by us or third parties, could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for commercial supply.

We have no prior experience as a company with the marketing, sale or distribution of biopharmaceutical products and there are significant risks involved in the building and managing of a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to and develop appropriate compliance programs for sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

If we are unable to establish relationships with licensees or collaborators to carry out sales, marketing, and distribution functions or to create effective marketing, sales, and distribution capabilities, we will be unable to market our products successfully.

Our business strategy may include selling product candidates, out-licensing product candidates to or collaborating with larger firms with experience in marketing and selling pharmaceutical products. There can be no assurance that we will successfully be able to establish marketing, sales, or distribution relationships with any third-party, that such relationships, if established, will be successful, or that we will be successful in gaining market acceptance for any products we might develop. To the extent that we enter into any marketing, sales, or distribution arrangements with third parties, our product revenues per unit sold are expected to be lower than if we marketed, sold, and distributed our products directly, and any revenues we receive will depend upon the efforts of such third parties.

The successful commercialization of elraglusib or any future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as elraglusib or any future product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate.

Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high.

If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions and fines should we be found to be in violation of any applicable obligations thereunder.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and offer to reimburse patients only for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for elraglusib or any future product candidates.

Risks Related to Our Reliance on Third Parties

The termination of third-party licenses could adversely affect our rights to important technologies.

In connection with our efforts to expand our pipeline of product candidates, we may enter into certain licenses or other collaboration agreements in the future pertaining to the in-license of rights to additional candidates. Such agreements may impose various diligence, milestone payment, royalty, insurance or other obligations on us. If we fail to comply with these obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licensed intellectual property. Our existing licensing agreements with UIC and NU contain diligence obligations to maintain each license agreement.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple

interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our consolidated financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

We may also have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

Our current drug substance ("DS") manufacturer of elraglusib is in China, and it is unknown how current or future geopolitical relationships with China may affect our ability to obtain DS, increase our costs, delay clinical trials and potential regulatory approval, and adversely impact our financial condition.

We rely upon a single company located in China to manufacture the DS for our sole product candidate, elraglusib. This company manufactures DS under cGMP that is suitable for formulating into a therapeutic used in humans, which drug product manufacturing process is substantially completed in the United States. We do not have any exclusive contractual commitments for this company to manufacture for us in the future or to ever become a sole provider of DS and thus, we do have the ability to seek out other GMP manufacturers if needed. However, if we do not maintain this manufacturing and service relationship that is important to us and are not able to identify replacement suppliers, vendors and laboratories, our ability to obtain elraglusib for clinical trials and potential regulatory approval could be impaired or delayed and our costs could substantially increase, adversely impacting our financial condition.

We may be unable to identify additional manufacturers with whom we might establish appropriate arrangements on acceptable terms, if at all. Even if we are able to find replacement manufacturers, suppliers, vendors and service providers when needed, we may not be able to enter into agreements with them on terms and conditions favorable to us or there could be a substantial delay before such manufacturer, vendor or supplier, or a related new facility is properly qualified and registered with the FDA or other foreign regulatory authorities. A new manufacturer currently not qualified with the FDA would have to be educated in, or develop substantially equivalent processes for, production of our approved products after receipt of FDA approval. To qualify and receive regulatory approval for a new manufacturer could take as long as two years. The process of changing a supplier could have an adverse impact on our current clinical development programs if supplies of DS or materials on hand are insufficient to satisfy demand. Such delays could have a material adverse effect on our development activities and our business. Adverse changes in the political and economic policies of the Chinese government could have a material adverse effect on the overall economic growth of China, which could adversely affect our ability to conduct business in China. We are unable to predict the frequency and scope of such policy changes, any of which could materially and adversely affect our liquidity, access to capital and our ability to conduct business in China. Any failure on our part to comply with changing government regulations and policies could result in the loss of our ability to manufacture and develop our product candidates in China.

We rely on third parties for the manufacture and shipping of elraglusib for clinical development and expect to continue to do so for the foreseeable future. If we or our licensees, development collaborators, or suppliers are unable to manufacture our products in sufficient quantities or at defined quality specifications, or are unable to obtain regulatory approvals for the manufacturing facility, we may be unable to develop and/or meet demand for our products and lose time to market and potential revenues.

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial-scale manufacturing capabilities. We rely on a third-party manufacturer for the production of elraglusib and expect to continue to rely on third-party manufacturers for commercial manufacture if elraglusib or any future product candidates receive regulatory approval. The facilities used by third-party manufacturers to manufacture elraglusib or any future product candidate must be approved for the manufacture of such product candidate by the FDA and any comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit an NDA to the FDA or any comparable submission to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for the manufacture of products. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel.

If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture of elraglusib or any future product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market elraglusib or any future product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of elraglusib or any future product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of elraglusib or any future product candidates. We may not be successful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any we do identify. We may face competition for access to these manufacturers' facilities and may be subject to manufacturing delays if the manufacturers give other clients higher priority than they give to us. Even if we are able to identify an additional or replacement third-party manufacturer, the delays and costs associated with establishing and maintaining a relationship with such manufacturer may have a material adverse effect on us.

We depend on a third-party manufacturer for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. We obtain our supplies on a purchase order basis and do not have any long-term supply agreements in place. If we are unable to source these supplies on a timely basis, or establish longer-term contracts with suppliers, we will not be able to complete our clinical trials or studies on time and the development of our product candidates may be delayed.

We depend on a third-party manufacturer for certain drug substances, drug products, raw materials, samples, components and other materials used in our product candidates. We obtain our supplies on a purchase order basis and do not currently have long-term supply contracts with our supplier, and our supplier is not obligated to supply drug products to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our supplier could stop selling to us at commercially reasonable prices, or at all. While we intend to enter into long-term supply agreements in the future as we advance our clinical trials or commercialization plans, we may not be successful in negotiating such agreements on favorable terms, or at all. If we do enter into such long-term supply agreements, we could be subject to binding long-term purchase obligations that are less favorable than purchasing on a purchase order basis, and which may be harmful to our business, including in the event that we do not conduct our trials on planned timelines or utilize the drug products that we are required to purchase. Any change in our relationship with our supplier or changes to our arrangement with our supplier could adversely affect our business, financial condition, results of operations and prospects.

Furthermore, our supplier could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. Establishing additional or replacement suppliers for

these supplies, and obtaining regulatory clearance or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products or conduct timely trials, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, which could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on our supplier, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

We rely on third parties to conduct our non-clinical studies and clinical trials. If these parties do not successfully carry out their duties or meet deadlines, we may be unable to obtain regulatory approval for or commercialize our product candidates and adversely affect our financial condition.

We do not have the ability to independently conduct non-clinical studies and clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as contract research organizations or clinical research organizations, to conduct non-clinical studies and clinical trials on our product candidates. The third parties with whom we contract for execution of our non-clinical studies and clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs.

Although we rely on third parties to conduct our non-clinical studies and clinical trials, we remain responsible for ensuring that each of our non-clinical studies and clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA, EMA and other foreign regulatory authorities require us to comply with regulations and standards, including regulations commonly referred to as GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials.

In addition, the execution of non-clinical studies and clinical trials, and the subsequent compilation and analyses of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. Under certain circumstances, these third parties may be able to terminate their agreements with us upon short notice. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we may not be able to obtain, on a timely basis or at all, regulatory approval for or to commercialize the product candidate being tested in such trials, and as a result, our financial condition will be adversely affected.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties to manufacture elraglusib and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality and non-disclosure agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third

parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's or other third party's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure of such technology or information would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

Data provided by collaborators and other parties upon which we rely have not been independently verified and could turn out to be inaccurate, misleading, or incomplete.

We rely on third-party vendors, scientists, clinical trial investigators, and collaborators to provide us with significant data and other information related to our projects, clinical trials, and business. We do not independently verify or audit all of such data (including possibly material portions thereof). As a result, such data may be inaccurate, misleading, or incomplete.

In certain cases, we may need to rely on a single supplier for a particular manufacturing material or service, and any interruption in or termination of service by such supplier could delay or disrupt the commercialization of our products.

We rely on third-party suppliers for the materials used to manufacture our compounds. We currently have a sole source manufacturer for the DS for elraglusib, and, while we believe that a suitable alternative vendor would be available if needed, some of these materials may at times only be available from one supplier. Any interruption in or termination of service by such single source suppliers could result in a delay or disruption in manufacturing until we locate an alternative source of supply, which could, among other things, adversely impact our clinical trials and ability to obtain approval from the FDA for elraglusib or a future product candidate. There can be no assurance that we would be successful in locating an alternative source of supply or in negotiating acceptable terms with such prospective supplier.

We may also rely on certain third-party vendors located in China or who are owned by or are associated with certain Chinese companies to assist in non-clinical or clinical trials or provide laboratory services. It is unknown how current or future geopolitical relationships with China or specific Chinese-owned or associated vendors may affect our ability to complete our non-clinical or clinical trials.

We do not currently, but may in the future, rely upon one or more companies located in China, or are owned or operated by Chinese companies to provide non-clinical or clinical trial support services. If so, the process of changing these vendors could have an adverse impact on our current clinical development programs if they were no longer permitted to provide services or products due to geopolitical pressures, including legislative activities or executive orders aimed at prohibiting certain Chinese or Chinese-owned biotechnology companies from engaging in biotechnology or biopharmaceutical research activities. We could experience delays in finding suitable replacement service providers located outside China or not otherwise owned by or associated with Chinese companies, which could have a material adverse effect on our development activities and our business. We are unable to predict whether or when proposed legislative or executive actions would be effective, and whether such changes would materially and adversely affect our liquidity, access to capital and our ability to conduct business. Any failure on our part to comply with changing government regulations and policies could result in the loss of our ability to manufacture and develop our product candidates.

Risks Related to Our Intellectual Property

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market elraglusib or any future products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our products and technology.

If we and our third-party licensors do not obtain and preserve protection for key intellectual property rights, our competitors may be able to take advantage of our (and our licensors') development efforts.

We rely, and may in the future rely, upon a combination of patent, trade secret and trademark protection for elraglusib and any future product candidates and proprietary technologies to prevent third parties from exploiting our achievements, thus eroding our competitive position in our market. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information to our detriment. Our commercial success will depend in part on our ability to obtain, maintain, expand, enforce, and defend the scope, ownership or control, validity and enforceability of our intellectual property protection in the United States and other countries with respect to elraglusib and any future product candidates and other proprietary technologies we may develop. We may also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending patent applications from third parties. We have licensed patents on the original composition of matter patents covering elraglusib from UIC. In addition, we own and have filed several new composition of matter patent applications that cover elraglusib polymorphs, which expire in 2038, with possibility for patent term extensions ("PTEs").

The patent process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in obtaining and defending patents. These risks and uncertainties include without limitation the following:

- patents that may be issued or licensed may be challenged, invalidated, or circumvented; or may not provide any competitive advantage for other reasons;
- our licensors may terminate or breach our existing or future license agreements, thereby reducing or preventing our ability to exclude competition; termination of such license agreements may also subject us to risk of patent infringement of patents to which we no longer have a license;
- our competitors, many of whom have substantially greater resources than we do and have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets;
- intellectual property rights may subject to the risk of U.S. government 'march-in' rights under the Bayh-Dole Act. This legislation allows the federal government to intervene and grant licenses to third parties or take ownership of patents developed from federally funded research if it determines

that such action is necessary to meet public health or safety needs, or if we fail to meet the requirements of the Act. Such government action could limit our exclusive rights, potentially reducing the commercial value of our potential products;

- as a matter of public policy regarding worldwide health concerns, there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of domestic and international patent protection for cancer treatments that prove successful; and
- countries other than the United States may have less restrictive patent laws than those upheld by the U.S. courts; therefore, non-U.S. competitors could exploit these laws to create, develop, and market competing products. In some countries, the legal compliance with pharmaceutical patents, patent applications and other intellectual property regulations is very weak or actively evaded in some cases with government aid.

In addition, the U.S. Patent and Trademark Office ("USPTO") and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting their scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents may be substantially narrower than anticipated.

If we permit our patents to lapse or expire, we will not be protected and will have less of a competitive advantage. The value of our products may be greatly reduced if this occurs.

Our patents expire at different times and are subject to the laws of multiple countries. Some of our patents are currently near expiration and we may pursue PTEs for these where appropriate.

In addition to patents, we also rely on trade secrets and proprietary know-how. While we take measures to protect this information by entering into confidentiality and invention agreements with our consultants and collaborators, we cannot provide any assurances that these agreements will be fully enforceable and will not be breached, that we will be able to protect ourselves from the harmful effects of disclosure if they are not fully enforceable or are breached, that any remedy for a breach will adequately compensate us, that these agreements will achieve their intended aims, or that our trade secrets will not otherwise become known or be independently discovered by competitors. If any of these events for which we cannot provide assurances occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

The patent protection we obtain and preserve for our product candidates may not be sufficient to provide us with any competitive advantage.

We may be subject to competition despite the existence of intellectual property we license or own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially and adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may impact our ability to maintain a competitive edge in the market. While we hold patents and licenses, there's no guarantee that they will fully protect us from competitors who find ways to work around our intellectual property. If other companies create products that avoid infringing on our patents, it could significantly affect our financial performance.

Intellectual property disputes could require us to spend time and money to address such disputes and could limit our intellectual property rights.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our current and future patent applications may not result in patents being issued. Any issued patents may not afford sufficient

protection of elraglusib or any future product candidates or their intended uses against competitors, nor can there be any assurance that the issued patents will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or elraglusib or any future product candidates. Further, even if these patents are granted, they may be difficult to enforce. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, information disclosure, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. In the event we experience noncompliance events that cannot be corrected, and we lose our patent rights, competitors could enter the market, which would have a material adverse effect on our business.

The biopharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation and USPTO post-grant proceedings to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional interference proceedings declared by the USPTO to determine the priority and patentability of inventions. The defense and prosecution of intellectual property suits, USPTO proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term, including a patent term adjustment granted by the USPTO. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or USPTO post-grant and interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Even if a given patent or intellectual property dispute were settled through licensing or similar arrangements, our costs associated with such arrangements may be substantial and could include the payment by us of large, fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all. Even where we have meritorious claims or defenses, the costs of litigation may prevent us from pursuing these claims or defenses and/or may require extensive financial and personnel resources to pursue these claims or defenses. In addition, it is possible there may be defects of form in our current and future patents that could result in our inability to defend the intended claims. Intellectual property disputes arising from the aforementioned factors, or other factors, may materially harm our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them. Despite these efforts, these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States, including in foreign jurisdictions, are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our intellectual property, obtain, maintain, expand, enforce and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. The United States has recently enacted and is currently implementing wide ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, as well as other jurisdictions around the world, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Patent terms may be inadequate to protect the competitive position of elraglusib or any future product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. The patent term of a U.S. patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering elraglusib or any future product candidates are obtained, once the patent has expired, we may be vulnerable to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of elraglusib or any future product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, consultants, licensees, collaborators or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor, co-inventor or owner of trade secrets. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing elraglusib or any future product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as ownership of, or the right to use intellectual property that is important to elraglusib or any future product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse impact on the success of our business.

Our commercial success depends, in part, upon our ability or the ability of any of our future collaborators to develop, manufacture, market and sell our current or any future drug candidates and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary and intellectual property

rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights.

We or any of our future licensors or strategic partners, may be party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current or any potential future drug candidates and technologies, including derivation, reexamination, inter partes review, post-grant review or interference proceedings before the USPTO and similar proceedings in jurisdictions outside of the United States such as opposition proceedings. If we or our licensors or strategic partners are unsuccessful in any interference proceedings or other priority or validity disputes (including through any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents or our patent claims may be narrowed, invalidated, or held unenforceable. In some instances, we may be required to indemnify our licensors or strategic partners for the costs associated with any such adversarial proceedings or litigation. Third parties may also assert infringement, misappropriation or other claims against us, our licensors or our strategic partners based on existing patents or patents that may be granted in the future, as well as other intellectual property rights, regardless of their merit. There is a risk that third parties may choose to engage in litigation or other adversarial proceedings with us, our licensors or our strategic partners to enforce or otherwise assert their patent rights or other intellectual property rights. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents and other intellectual property rights are valid, enforceable and infringed, which could have a material adverse impact on our ability to utilize our developed technologies or to commercialize our current or any future drug candidates deemed to be infringing. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity by presenting clear and convincing evidence of invalidity. There is no assurance that a court of competent jurisdiction, even if presented with evidence we believe to be clear and convincing, will agree with our position on the validity of any U.S. patent.

Intellectual property rights of third parties could adversely affect our ability to commercialize our current or future technologies or drug candidates, and we might be required to litigate or obtain licenses from third parties to develop or market our current or future technologies or drug candidates, which may not be available on commercially reasonable terms, or at all.

There are numerous companies that have pending patent applications and issued patents broadly covering small molecules directed against the same targets as, or targets similar to, those we are pursuing. Our competitive position may materially suffer if patents issued to third parties or other third-party intellectual property rights cover our current or future technologies, drug candidates or elements thereof, or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize current or future technologies or drug candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property rights concerned, or enter into a license agreement with the intellectual property rights holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our current or future technologies or drug candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our current or future technologies or drug candidates.

Should such an infringement claim be successfully brought, we may be required to pay substantial damages or be forced to abandon our current or future technologies or drug candidates or to seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all. Third-party intellectual property rights holders may also actively bring infringement, misappropriation or other claims alleging violations of intellectual property rights against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or to continue costly, unpredictable and time-consuming litigation and may be prevented from, or experience substantial delays in, marketing our drug candidates. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our current or future technologies or drug candidates that are held to be infringing, misappropriating or otherwise violating third-party intellectual property rights. We might, if possible, also be forced to redesign current or future technologies or drug candidates so that we no longer infringe, misappropriate or violate the third-party intellectual property rights. Any of these events, even

if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business, which could have a material adverse effect on our financial condition and results of operations.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Some intellectual property which we own or have licensed, or which may acquire or license in the future, may have been, or may be, discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for United States industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we own or have licensed, or which we may acquire or license in the future, have been or may be generated using U.S. government funding and may therefore be subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future products and product candidates pursuant to the Bayh-Dole Act of 1980. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced using the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property and such requirement may be subject to interpretation as to compliance with the notion that a product is "substantially"

manufactured in the United States when components are sourced elsewhere and finally assembled or formulated within the United States. Any exercise by the government of any of the foregoing rights, or breach by us with respect to our obligations to comply with applicable requirements, could harm our competitive position, business, financial condition, results of operations and prospects.

Risks Related to Our Business Operations and Industry

We may be subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability or otherwise adversely affect our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. 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 products for which we obtain regulatory approval.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain consulting agreements and advisory board agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

The U.S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Since taking office in January 2025, the Trump administration has taken dramatic steps to freeze some federal funding and reduce the size of the federal workforce. It is not possible to predict the outcome of this congressional, executive, or regulatory activity, any of which could adversely affect us. Similarly, we cannot predict whether pending or future federal or state legislation or court proceedings will change various aspects of current government programs, nor can we predict the impact any such changes will have on our business operations or financial results, but the effects could be materially adverse. In addition, changes in the leadership of the FDA and other federal agencies under the new Trump administration can result in changes in the funding, operations and policies of the FDA and other federal agencies, which may negatively impact our clinical development plans, timelines, and the cost of product development.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases, and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher-than-expected acquisition and integration costs;
- write-downs of assets, goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our information technology systems, or those of any of our service providers, may fail or suffer security incidents and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary and confidential business information and personal information). Our information technology systems and those of our third-party service providers, strategic partners and other contractors or consultants are vulnerable to attack, damage and interruption from computer viruses and malware (e.g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. In addition, attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any material system failure, accident or security breach to date, if any such event, whether actual or perceived, were to occur, it could impact our reputation and/or operations, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on a third party to manufacture elraglusib, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any actual or perceived disruption or security incident affects our systems (or those of our third-party collaborators, service providers, contractors or consultants) or were to result in a loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information, or damage to, our confidential or proprietary data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of elraglusib or any future product candidates could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws.

We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. If our third-party vendors fail to protect their information technology systems and our confidential and proprietary information, we may be vulnerable to disruptions in service and unauthorized access to our confidential or proprietary information and we could incur liability and reputational damage. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular categories of personally identifiable information, which could result from incidents experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Although we currently hold cybersecurity insurance, the costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses.

Failure to comply with health privacy and other data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.

We and our service providers maintain and will maintain a large quantity of sensitive and/or regulated information, including confidential business and patient health information, personal data about our employees and collaborators, and information relating to our clinical trials. The global data protection landscape is rapidly evolving, and we, our service providers and our collaborators may be affected by or subject to existing, amended, or new laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, thus creating potentially complex compliance issues for us and our service providers, strategic partners and future customers. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In the United States, numerous federal and state laws and regulations, including federal health information privacy laws (e.g., HIPAA, as amended by the HITECH), state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators.

International data protection laws may also apply to health-related and other personal information we collect.

The legal framework around privacy issues is rapidly evolving, as various federal, state and foreign government bodies are considering adopting new privacy laws and regulations and providing guidance on current laws and regulations, which could result in significant limitations on or changes to the ways in which we can collect, use, host, store, or transmit personal data. Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.

Disruptions at the FDA and other government agencies caused by funding shortages, changes in personnel, or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to approved or licensed biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. Moreover, action by the Trump Administration to limit federal agency budgets or personnel, may result in reductions to the FDA's budget, employees, and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, future pandemics may lead to similar inspectional or administrative delays. If any future prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Effective collaboration with the FDA's Center for Drug Evaluation and Research ("CDER") for the approval of drug candidates is a highly demanding process which can result in increased time and expense to gain approvals.

Our lead drug development program, elraglusib, will be reviewed by CDER. Efficient and professional collaboration with the FDA's CDER is essential for the timely clinical testing, test evaluations, analysis and approval of our drug candidates. CDER has an outstanding record of drug approvals and substantial funds to operate a highly professional organization but is also very demanding as to the quality of clinical research and applications for marketing approvals for drug candidates.

We do not have in-house expertise and experience in the management of drug approvals, though members of our management team have gained certain drug-approval expertise and experience in their prior roles at other companies. We may also rely on qualified consultants and drug research organizations to aid in

our drug approval process; however, there is a meaningful risk that discussions and interactions inherent in the drug approval process and future developments or new improvements will result in delays, added expenses and new scientific/medical requirements which will cause adverse financial results and will likely impact the price of our stock.

Risks Related to our Common Stock

Concentration of ownership by our principal stockholders limits the ability of others to influence the outcome of director elections and other transactions requiring stockholder approval, creates the potential for conflicts of interest, may negatively impact our stock price and may deter or prevent efforts by others to acquire us, preventing our stockholders from realizing a control premium.

A significant percentage of our outstanding stock is currently held by funds affiliated with our chairman, Aaron G.L. Fletcher, (the "Bios Equity Affiliated Funds") and which beneficially own approximately 43% of our common stock outstanding as of December 31, 2025. As a result, the Bios Equity Affiliated Funds have a strong influence on corporate actions requiring stockholder approval, including the following actions:

- to elect or defeat the election of our directors;
- to amend or prevent amendment of our certificate of incorporation or bylaws;
- to effect or prevent a merger, sale of assets or other corporate transaction; and
- to control the outcome of any other matter submitted to our stockholders for vote.

The Bios Equity Affiliated Funds' significant interest in us also creates the potential for conflicts of interest which may be viewed unfavorably by minority stockholders, thereby hurting our stock price. In addition, the Bios Equity Affiliated Funds are not subject to any contractual restrictions on their ability to acquire additional shares of common stock. Any future purchases of equity securities, including in connection with any rights offerings or any alternative equity or equity-linked offering that we may conduct, could result in the Bios Equity Affiliated Funds again attaining beneficial ownership of a majority of our common stock. As a result of the Bios Equity Affiliated Funds' significant ownership and Dr. Fletcher's position as our Chairman, others may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

There was no public market for our common stock prior to the IPO in August 2024. An active, liquid and orderly market for our common stock may not be sustained, or we may in the future fail to satisfy the continued listing requirements of Nasdaq, and you may not be able to resell your shares at or above your purchase price or at all.

There was no public market for our common stock prior to the IPO. Although our common stock is listed on the Nasdaq Global Market, an active trading market for our common stock may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price or stockholders' equity requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

The trading price of the shares of our common stock could be highly volatile regardless of our operating performance, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for securities of biotechnology and pharmaceutical companies in particular have historically been highly volatile, and the market has from time-to-time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above their purchase price.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to obtain and maintain regulatory approval of elraglusib or any future product candidates or additional indications thereof, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements concerning the progress and results of our clinical trials, our ability to potentially obtain regulatory approval for and commercialize elraglusib or any of our future product candidates, including any requests we receive from the FDA for additional studies or data that result in delays in potentially obtaining regulatory approval or potentially launching elraglusib or any of our future product candidates, if approved;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- price and volume fluctuations in the overall stock market;
- our ability to enroll patients in future clinical studies;
- the failure of elraglusib or any of our future product candidates, if approved, to achieve commercial success;
- achievement of expected product sales and profitability;
- announcements of the introduction of new products by us or our competitors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of elraglusib of any of our future potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- sales of our stock by us, our insiders or our stockholders;
- healthcare reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs, divert our management's attention and resources and damage our reputation, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We do not intend to pay dividends in the foreseeable future and, as a result, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividends on our capital stock and we do not intend to pay any cash dividends in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. Any decision to pay dividends in the future will be at the discretion of our Board. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future potential gains as a return on their investments.

Delaware law and provisions in our amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the potential trading price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees or the underwriters of any offering giving rise to such claim.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty by any of our directors, officers or stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our amended and restated certificate of incorporation will also 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, including all causes of action asserted against any defendant to such complaint. These choice of 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 such lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risk Factors

Unstable market and economic conditions may have serious adverse consequences on our ability to raise funds, which may cause us to cease or delay our operations.

From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of presidential elections in the United States, military conflict, including the conflicts in the Middle East and between Russia and Ukraine, terrorism or other acts of violence or geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. In addition, in 2023, the closures of financial institutions and their placement into receivership with the Federal Deposit Insurance Corporation created bank-specific and broader financial institution liquidity risk and concerns. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if

adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, limit, reduce or abandon product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If current or future analysts who cover us downgrade our stock, or if we fail to meet the expectations of one or more of these analysts, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, once we lose our status as an "emerging growth company" and do not otherwise qualify as a "smaller reporting company" with less than $100.0 million in annual revenue, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

In addition, any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management Strategy

We have implemented and recently enhanced various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our critical computer systems, third-party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to our clinical studies, manufacturing, and employees. We engage an external entity to employ processes for assessing, identifying, and managing material risks from cybersecurity threats that are incorporated into our overall risk management system. These items are designed to help protect our information assets from internal and external threats and protect the integrity and confidentiality of our data. Our system includes procedural and technical safeguards, response plans, and reviews of our policies.

In addition, our recently enhanced information security process includes cybersecurity and prevention training for all employees and key consultants, including timely and relevant topics covering social engineering, phishing, mobile security, and data protection and the need for reporting incidents and suspicious events immediately.

Although we develop and maintain systems and controls designed to prevent cybersecurity threats from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with service providers, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

As of the date of this Report, we are not aware of any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition.

Cybersecurity Governance

Our senior management team conducts the regular assessment and management of material risks from cybersecurity threats, including review with our third-party service provider. All employees and consultants are directed to report to our senior management any irregular or suspicious activity that could indicate a cybersecurity threat or incident. The Audit Committee of our Board of Directors periodically reviews our cybersecurity assessment and management policies, as appropriate.

Item 2. Properties.

Our principal executive offices are located in Fort Worth, Texas, whereby we rent limited office space in a shared environment on a month-to-month basis beginning December 1, 2024 at an initial rate of $4,200 per month. Rent expense for the years ended December 31, 2025 and 2024 was $51,200 and $4,200, respectively. Prior to December 1, 2024, we utilized office space made available to us by our largest investor for administrative purposes at no cost to the Company. We believe that our current arrangement is sufficient to meet our needs for the foreseeable future and that any additional space we may require will be available on commercially reasonable terms. All research and development activities are undertaken at CROs or with academic collaborators.

Item 3. Legal Proceedings.

Information pertaining to legal proceedings is provided in Note 6 - Commitments and Contingencies, to the consolidated financial statements included in this Report and is incorporated herein by reference.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock, par value $0.000001 per share, commenced trading on the Nasdaq Global Market under the symbol "ACTU" since our IPO on August 13, 2024.

Holders of Common Stock

As of March 17, 2026, there were 84 holders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividends

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, current and anticipated capital requirements, business prospects and other factors our board of directors deems relevant, and subject to applicable laws and the restrictions contained in any future financing instruments.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2025 with respect to shares of common stock that may be issued under our equity compensation plans.

Plan Category	(a) Number of Securities to be Issued Upon the Exercise of Outstanding Options, Warrants and Rights	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights ($/share)	(c) Number of Shares Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity compensation plans approved by stockholders	2,476,830[1]	$6.51[2]	2,184,341[3]
Equity compensation plans not approved by stockholders	–	–	–
Total	2,476,830	–	2,184,341

(1) Consists of (i) options to purchase a total of 1,841,977 shares of common stock under the 2015 and 2024 Plans, (ii) 17,617 shares of our common stock that are subject to unvested RSAs under the 2015 Plan, and (iii) 617,236 shares of our common stock that are subject to outstanding RSUs under the 2024 Plan.

(2) The weighted average exercise price is calculated based solely on outstanding stock options. It does not take into account the shares of our common stock subject to outstanding RSAs or RSUs, which have no exercise price.

(3) Consists of 2,184,341 shares of our common stock reserved for issuance under the 2024 Plan. The 2024 Plan provides for an annual increase on the first day of each calendar year beginning January 1, 2025 and ending on and including January 1, 2034, equal to the lesser of (A) 5% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by the administrator. Effective January 1, 2025, the number of shares available for grant under the 2024 Plan increased by 976,581. The 2015 Plan terminated prior to the Company's IPO, and no additional awards will be granted under the 2015 Plan. Any outstanding awards under the 2015 Plan that are subsequently cancelled, forfeited or expire will become available for grant under the 2024 Plan.

Performance Graph

Not applicable.

Recent Sales of Unregistered Securities

During the year ended December 31, 2025, we sold 539,967 shares of our common stock to B. Riley Principal Capital II pursuant to a common stock purchase agreement dated March 27, 2025 for the net proceeds of $3,800,465. All shares of common stock issued and sold to B. Riley Principal Capital II were issued pursuant to Section 4(a)(2) of the Securities Act, as transactions not involving a public offering. Except for the proceeding, we did not issue any equity securities during the year ended December 31, 2025 that were not registered under the Securities Act and that have not otherwise been described in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved].

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

The following discussion and analysis of the financial condition and results of our operations should be read together with the consolidated financial statements and related notes of Actuate Therapeutics, Inc. included in Part II Item 8 of this Annual Report on Form 10-K ("Annual Report" or "Report").

This discussion and analysis contain forward-looking statements reflecting our management's current expectations that involve risks, uncertainties and assumptions. See the section entitled "Cautionary Note Regarding Forward-Looking Statements." Our actual results and the timing of events may differ materially from those described in or implied by these forward-looking statements due to a number of factors, including those discussed below and elsewhere in this Report, particularly those set forth under "Risk Factors."

Business Overview

We are a clinical stage biopharmaceutical company focused on developing therapies for the treatment of high impact, difficult to treat cancers through the inhibition of glycogen synthase kinase-3 (GSK-3). We are developing elraglusib, an ATP-competitive small molecule that is designed to enter cancer cells and block the function of the enzyme glycogen synthase kinase-3 beta ("GSK-3β"), a master regulator of complex biological signaling cascades, including those mediated by oncogenes, that lead to tumor cell survival, growth, migration, and invasion. We believe that the blockade of GSK-3β signaling ultimately results in the death of the cancer cells and the regulation of anti-tumor immunity. There are no approved high-affinity inhibitors of GSK-3β, and we believe elraglusib is one of the most advanced GSK-3β inhibitors in clinical development. Elraglusib was originally known as 9-ING-41 but was granted the elraglusib International Nonproprietary Names ("INN") and United States Adopted Names ("USAN") generic name in 2021.

We have exclusively licensed elraglusib, a proprietary and patent protected GSK-3 inhibitor developed in a collaboration between The Board of Trustees of the University of Illinois-Chicago ("UIC") and Northwestern University ("NU").

We believe elraglusib represents a "pipeline in a molecule" with a broad opportunity for us to potentially initiate and advance multiple drug development programs around our lead asset based on its multimodal mechanisms of action, data emerging from completed or ongoing clinical trials and non-clinical biological, cellular, and animal data. Animal tumor model data, clinical trial data and AI-based computational approaches have identified a number of areas of unmet clinical need in cancer treatment where elraglusib may play an interventional role, including pancreatic, metastatic melanoma, lung, colon, breast, renal, and ovarian cancer, leukemias and lymphomas, as well as some pediatric cancers including Ewing sarcoma, neuroblastoma and pediatric leukemias.

To date, we have treated over 500 patients with elraglusib as an IV injection ("Elraglusib Injection") in Phase 1 and Phase 2 studies. Our most advanced clinical indication is first-line metastatic pancreatic ductal adenocarcinoma ("mPDAC"). Our Phase 2 study in mPDAC, known as Actuate-1801 Part 3B study, is a randomized, controlled Phase 2 trial that enrolled 286 patients with no prior systemic treatment for metastatic disease. The primary endpoint for this study was mOS, with OS summarized throughout the study by estimates of 1-year survival. Updated data results presented at the American Society of Clinical Oncology ("ASCO") Genitourinary Cancers Symposium ("ASCO GI") in January 2026 utilizing a data cutoff as of November 22, 2025 showed that the trial met its primary endpoint, demonstrating a statistically significant improvement in mOS with elraglusib plus gemcitabine/nab-paclitaxel ("GnP") versus GnP alone. Data presented at ASCO GI included:

- Statistically significant benefit in mOS in the elraglusib/GnP arm vs GnP control arm (mOS 10.1 months vs. 7.2 months, p=0.02, HR=0.62);
- Near doubling of the 12-month survival rate, from 22.3% in the GnP arm to 44.4% in the elraglusib/GnP arm; and
- Almost fivefold increase in 24-month survival rate, from 2.6% in the GnP control arm to 12.9% in the elraglusib/GnP arm, emphasizing the potential for long-term clinical benefit.

In addition to treating mPDAC, Elraglusib Injection is also being evaluated in pediatric cancer patients with recurrent/refractory solid cancers. This study, Actuate-1902, is a Phase 1/2 study that evaluated escalating doses of elraglusib as a single agent as well as in combination with irinotecan or cyclophosphamide/topotecan in the Phase 1 portion of the trial. Patients in this Actuate-1902 study also experienced a number of objective responses in the combination chemotherapy arms, and based on this data, we identified Ewing sarcoma and neuroblastoma as new indications for further development of Elraglusib Injection, further expanding the potential of elraglusib.

We have developed several oral dosage forms of elraglusib, which we believe will allow us to expand the number of cancer indications that we are able to target and allow us to further explore more convenient dose delivery options for patients. A clinical candidate tablet, the Elraglusib Oral Tablet, has been selected for further development and, subject to future funding, we are planning a Phase 1 study to identify the maximum tolerated dose and RP2D for Elraglusib Oral Tablet in adult patients with advanced, refractory cancers. Once we have determined a RP2D, several Phase 2 studies have been identified for further clinical development of Elraglusib Oral Tablet, subject to additional funding, based on data from previous studies, including but not limited to, refractory, metastatic melanoma and refractory, metastatic colorectal cancer, and non-small cell lung cancer.

Components of Our Results of Operations

Since our inception in 2015, we have focused substantially all of our resources on organizing and staffing our Company, business planning, raising capital, establishing and maintaining our intellectual property portfolio, conducting research, preclinical studies, and clinical trials, establishing arrangements with third parties for the manufacture of elraglusib, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales since inception.

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development Expenses

Research and development expenses consist primarily of external and internal costs incurred in performing clinical and preclinical development activities. Our external research and development costs primarily consists of the cost incurred under agreements with hospitals to treat and monitor patients enrolled in our clinical trials, contract research organizations and contract manufacturers, consultants and other third parties to conduct and support our clinical trials and preclinical studies. Our internal research and development costs primarily include research and development personnel-related expenses such as employee compensation, employer taxes, group insurance benefits, and stock-based compensation.

We expense research and development costs as incurred. We currently only have one product candidate, elraglusib. Therefore, since our inception, substantially all of our research and development costs were related to the development of elraglusib. We track research and development expenses on an aggregate basis and not on an indication-by-indication or treatment setting-by-treatment setting basis.

Although research and development activities are central to our business model, the successful development of elraglusib and any future product candidates is highly uncertain. There are numerous factors associated with the successful development of any product candidate such as elraglusib, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased number of patients and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase substantially in connection with our ongoing and planned clinical and preclinical development activities in the near term and in the future, provided we are able to raise additional capital. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of elraglusib and any future

product candidates. Our future research and development expenses may vary significantly based on a wide variety of factors such as:

- the results of our clinical trials and preclinical studies of elraglusib and any future product candidates we may choose to pursue, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials and the number of countries in which the trials are conducted;
- the number of patients that participate in the trials, the drop-out or discontinuation rates of patients, and the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing elraglusib and any future product candidates;
- the costs, if any, of obtaining third-party drugs for use in our combination trials;
- the extent of changes in government regulation and regulatory guidance;
- the efficacy and safety profile of elraglusib and any future product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities; and
- the extent to which we establish additional collaboration, license, or other arrangements.

A change in the outcome of any of these variables with respect to the development of elraglusib or any future product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses such as employee compensation, benefits, and stock-based compensation, for our personnel in executive and other administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters and professional fees paid for accounting, auditing, consulting and tax services, as well as other costs such as insurance costs, board of director fees, investor and public relations, and travel expenses.

We anticipate our general and administrative expenses will increase in the future as we expand our operations, including increasing our headcount to support our continued research and development activities and preparing for later-stage clinical trials and potential commercialization of elraglusib. We also anticipate we will continue to incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance, and investor and public relations expenses associated with operating as a public company.

Other Income (Expense)

Change in Fair Value of Warrant Liability

We previously had outstanding warrants that required liability classification. The warrants were recorded at fair value upon issuance and were subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in other income (expense), net. The warrant liabilities were remeasured upon the closing of our IPO and marked to market to its fair value before being reclassified to equity.

Loss on Issuance of Related Party Convertible Notes Payable; Change in Estimated Fair Value of Related Party Convertible Notes Payable

Upon issuance of certain notes payable, we elected to apply the fair value option in accordance with Accounting Standards Codification ("ASC") 825, *Financial Instruments*. In certain circumstances, the estimated fair value at issuance may be greater than the principal amount at issuance. The fair value of these notes payable was

estimated at each reporting period while outstanding. These notes payable were converted into common stock upon the closing of the IPO in August 2024.

Interest Expense

Interest expense represents interest owed to UIC under our license agreement with UIC, whereby UIC agreed to defer amounts owed to UIC under a former sublicense agreement in the amount of $404,991.

Interest Income

Interest income represents interest earned on our cash and cash equivalents at the then prevailing market rates.

RESULTS OF OPERATIONS

Comparison of the Year Ended December 31, 2025 and 2024:

The following table summarizes our results of operations for the year ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	**2024**	**Change**
Operating expenses:			
Research and development	$ 10,292,620	$ 18,676,276	$ (8,383,656)
General and administrative	12,202,692	6,484,458	5,718,234
Total operating expenses	22,495,312	25,160,734	(2,665,422)
Loss from operations	(22,495,312)	(25,160,734)	2,665,422
Other income (expense):			
Change in estimated fair value of warrant liability (non-cash)	-	(78,903)	78,903
Gain on settlement of warrants (non-cash)	-	343,240	(343,240)
Loss on issuance of related party convertible notes payable at fair value (non-cash)	-	(400,000)	400,000
Change in estimated fair value of related party convertible notes payable (non-cash)	-	(2,192,507)	2,192,507
Interest expense	(20,250)	(18,717)	(1,533)
Interest income	287,710	222,293	65,417
Total other income (expense), net	267,460	(2,124,594)	2,392,054
Net loss	$ (22,227,852)	$ (27,285,328)	$ 5,057,476

Research and Development Expenses

The following table summarizes our research and development expenses for the year ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Change
External clinical trial expenses	$ 5,051,488	$ 13,387,974	$ (8,336,486)
Chemistry, Manufacturing & Control ("CMC") related costs	753,713	1,707,132	(953,419)
Preclinical and biomarker research	972,646	397,408	575,238
Personnel and consulting expenses	3,514,773	3,183,762	331,011
Total research and development expenses	$ 10,292,620	$ 18,676,276	$ (8,383,656)

The decrease in research and development expenses of $8,383,656 for the year ended December 31, 2025 compared to the prior year was primarily due to (i) a decrease in external clinical trial expenses of $8,336,486 mostly related to lower patient fees and CRO costs associated with fewer patients on study related to the randomized Phase 2 mPDAC trial (Actuate-1801 Part 3B) as the trial winds down and (ii) a decrease in CMC related costs of $953,419 primarily due to the timing of drug product manufacturing and stability studies. These decreases were partially offset by (i) an increase in preclinical and biomarker studies of $575,238, driven by new studies completed during 2025, and (ii) an increase in personnel and consulting expenses of $331,011, primarily due to higher non-cash stock-based compensation expense of $314,933.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the year ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Change
Personnel-related expenses	$ 7,605,193	$ 3,770,893	$ 3,834,300
Professional and consulting fees	3,085,658	1,937,282	1,148,376
Other expenses	1,511,841	776,283	735,558
Total general and administrative expenses	$12,202,692	$ 6,484,458	$ 5,718,234

The increase in general and administrative expenses of $5,718,234 for the year ended December 31, 2025 compared to the prior year was primarily due to (i) an increase in personnel-related expenses of $3,834,300 mostly due to an increase in non-cash stock-based compensation expense of $3,735,935 related to awards granted to employees, non-employee members of the board of directors, and consultants of the Company combined with an increase in payroll and related expenses primarily related to the hiring of the Company's chief financial officer in June 2024, an increase in base salaries for certain administrative employees, offset by a decrease in bonus expense, (ii) an increase in professional and consulting fees of $1,148,376 primarily due to an increase in (a) investor and public relation fees, (b) consulting fees associated with increased administrative support, and (c) legal fees related to routine corporate activities, which amounts were offset by a decrease in board member search fees and valuation services and (iii) an increase in other expenses of $735,558 primarily due to an increase in the cost of directors and officers insurance, board fees, listing fees, and other public company expenses.

Other Income (Expense)

Other income (expense), net, for the year ended December 31, 2025 and 2024 is comprised of the following:

- *Change in fair value of warrant liability* —During the year ended December 31, 2024, we recognized an increase in fair value of the warrant liability of $78,903 based on the estimated fair value of warrant liability using the Black-Scholes valuation model at August 14, 2024 (closing date of the Company's IPO). As of December 31, 2024, there were no Redeemable Convertible Preferred Stock Warrants outstanding and no related warrant liability.

- *Gain on settlement of warrants* — During the year ended December 31, 2024, we recognized a gain on settlement of warrants of $343,240 on the closing date of the Company's IPO, representing the difference between the estimated fair value at December 31, 2023 and the estimated fair value upon conversion of the warrants into shares of common stock on August 14, 2024.

- *Loss on issuance of related party convertible notes payable at fair value* — The loss on issuance of the Related Party Convertible Notes Payable of $400,000 for the year ended December 31, 2024 represents the difference between the estimated fair value of the Related Party Convertible Notes Payable on the issuance date and the principal amount of the note on the issuance date based on the valuation assumptions.

- *Change in estimated fair value of Related Party Convertible Notes Payable* — The change in the estimated fair value of the Related Party Convertible Notes Payable of $2,192,507 for the year ended December 31, 2024 represents the difference between the estimated fair value at issuance and the estimated fair value upon conversion into common stock on August 14, 2024.

- *Interest expense* — Interest expense for the year ended December 31, 2025 and 2024 represents interest accrued on amounts owed under a license agreement with UIC, whereby UIC agreed to defer amounts payable to UIC under a former sublicense agreement in the amount of $404,991 in exchange for an interest-bearing license payable.

- *Interest income* — Interest income for the year ended December 31, 2025 and 2024 represents interest earned on cash and cash equivalents based on the prevailing market rates. The increase in interest income for the year ended December 31, 2025 compared to the prior year is primarily due to a higher average cash balance on hand in 2025 compared to 2024.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. We expect to incur significant expenses and operating losses in the foreseeable future as we advance the clinical development of elraglusib and any future product candidates.

On March 27, 2025, we entered into a common stock purchase agreement (the "Committed Equity Facility") with B. Riley Principal Capital II ("B. Riley") giving the Company the right, but not the obligation, to sell to B. Riley over a 36-month period up to the lesser of (i) $50 million of newly issued shares of our common stock and (ii) 3,904,374 shares of the Company's common stock. During the year ended December 31, 2025, we received net proceeds of $3,800,465 in exchange for 539,967 shares of common stock sold under the Committed Equity Facility. As of December 31, 2025, we had 3,364,407 shares of common stock in remaining capacity under our Committed Equity Facility.

On June 25, 2025, we entered into a securities purchase agreement for a private placement of common stock and warrants with certain institutional and accredited investors, which closed on June 27, 2025 (the "June 2025 Private Placement"). Under the June 2025 Private Placement, the Company received aggregate net proceeds of $4,592,462 in

exchange for the issuance of 666,497 shares of common stock and warrants to purchase up to 666,497 shares of common stock.

On September 10, 2025, we entered into an underwriting agreement (the "Underwriter Agreement") with Lucid Capital Markets, LLC ("Underwriter") relating to an underwritten public offering of 2,142,858 shares of common stock plus an over-allotment option to purchase up to an additional 321,428 shares of common stock at the public offering price of $7.00 per share, less underwriting discounts and commissions and other offering expenses ("September 2025 Public Offering"). The offering closed on September 11, 2025, and the Company issued 2,464,286 shares of common stock to the Underwriter, including shares issued under the over-allotment option, in exchange for net proceeds of $15,573,966.

On November 28, 2025, we entered into an At Market Issuance Sales Agreement (the "ATM Agreement") with B. Riley Securities, Inc. and Craig-Hallum Capital Group LLC (each a "Sales Agent" and collectively the "Sales Agents") with respect to an "at the market" offering program (the "ATM Facility"), under which we may, from time to time, at our sole discretion, issue and sell through the Sales Agents, up to $100 million of shares of common stock. Pursuant to the ATM Agreement, we may sell the shares through the Sales Agents by any method permitted that is deemed an "at the market" offering as defined in Rule 415 under the Securities Act. The Sales Agents will use commercially reasonable efforts consistent with their normal trading and sales practices to sell the shares from time to time, based upon instructions from us, including any price or size limits or other customary parameters or conditions we may impose. We will pay the Sales Agents a commission of up to 3.0% of the gross sales proceeds of any common stock sold through the Sales Agents under the ATM Agreement, and we also have provided the Sales Agents with customary indemnification rights. During the year ended December 31, 2025, the Company did not sell any shares of common stock under the ATM Facility. As of December, we had $100 million in remaining capacity under our ATM Facility.

As of December 31, 2025, we had cash and cash equivalents of $13,159,423 and working capital of $7,936,503. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue our development of, seek regulatory approval for, and potentially commercialize elraglusib and potentially seek to discover and develop and/or license or acquire additional product candidates, conduct our ongoing and planned clinical trials and preclinical studies, continue our research and development activities, utilize third parties to manufacture elraglusib, hire additional personnel, expand and protect our intellectual property, and incur additional costs associated with being a public company. Based on our current operating plan, we estimate that our existing cash and cash equivalents as of the date of this Annual Report will not satisfy the Company's operational and capital requirements beyond July 2026 without raising additional capital. There can be no assurance that the Company will be able to raise sufficient proceeds in the future under the ATM Facility or Committed Equity Facility or any additional financing will be available to the Company on acceptable terms, if at all.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings, or other capital sources, including current or potential future collaborations, licenses, and other similar arrangements. As we seek additional financing in the near future, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our ability to raise additional funds may be adversely impacted by business conditions, global economic conditions, disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, and diminished liquidity and credit availability. To the extent we raise additional capital through the sale of equity or convertible debt securities, stockholders' ownership interest in our common stock will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments or declaring dividends. If we raise additional funds through collaborations or license agreements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity, debt, or other financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, or even cease operations.

Based on the above matters, we have concluded that there is substantial doubt regarding the Company's ability to continue as a going concern.

Material Cash Requirements for Known Contractual and Other Obligations

Research and Development Costs

We are continuing to invest in our elraglusib clinical trials and have entered into contractual obligations with each clinical trial site. Each contract shall continue until the completion of the trial at that site. Our clinical trial costs are dependent on, among other things, the size, number and length of our clinical trials.

Other Capital Requirements and Additional Royalty Obligations.

We enter into agreements in the normal course of business with various vendors, which are generally cancellable upon notice. Payments due upon cancellation typically consist only of payments for services provided or expenses incurred, including non-cancellable obligations of service providers, up to the date of cancellation.

Cash Flow Summary

The following table provides a summary of our cash flows for the year ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	**2024**
Net cash used in operating activities	$ (19,206,253)	$ (21,842,648)
Net cash provided by financing activities	23,724,054	27,525,611
Net change in cash and cash equivalents	$ 4,517,801	$ 5,682,963

Cash Flows From Operating Activities

Year Ended December 31, 2025 — Net cash used in operating activities for the year ended December 31, 2025 consisted of our net loss of $22,227,852 combined with cash used by a net change in operating assets and liabilities of $3,045,312, which amounts were offset by non-cash stock-based compensation expense of $6,046,661 and an increase in accrued interest on license payable of $20,250

Year Ended December 31, 2024 — Net cash used in operating activities for the year ended December 31, 2024 consisted of our net loss of $27,285,328 combined with the non-cash gain on settlement of the warrant liability of $343,240, which amounts were offset by (i) non-cash stock-based compensation expense of $1,995,793, (ii) a non-cash increase in the fair value of our warrant liability of $78,903, (iii) a loss on issuance of Related Party Convertible Notes Payable at fair value of $400,000, (iv) the change in estimated fair value of Related Party Convertible Notes Payable of $2,192,507, (v) an increase in accrued interest on license payable of $18,641, and (vi) cash provided by a net change in operating assets and liabilities of $1,100,076.

Cash Flows From Financing Activities

Year Ended December 31, 2025 —During the year ended December 31, 2025, net cash provided by financing activities consisted of net proceeds received of (i) $15,573,966 under the September 2025 Public Offering, (ii) $4,592,462 under the June 2025 Private Placement, (iii) $3,826,336 from the sale of common stock to B. Riley under the Committed Equity Facility, and (iv) $34,115 from the exercise of stock options, which amounts were offset by the payment of deferred offering costs of $302,825.

Year Ended December 31, 2024 — During the year ended December 31, 2024, net cash provided by financing activities primarily consisted of net proceeds received from the closing of the IPO and Overallotment Option of $22,025,611 (net of underwriting discounts and commissions and after payment of offering costs of $1,931,189), proceeds of $5,500,000 from the issuance of the Related Party Convertible Notes Payable, and proceeds of $200,000

from the issuance of a related party short-term loan, which amount was offset by the payment of the related party short-term loan of $200,000.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events, and various other factors we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to the accompanying consolidated financial statements included elsewhere in this Report, we believe the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Expenses and Related Accrued Expenses

In accordance with authoritative guidance, the Company charges research and development costs to operations as incurred. Research and development expenses consist primarily of personnel and related costs, external costs of outside vendors engaged clinical trials, contract manufacturers, consultants and other third parties to conduct and support our clinical trials and preclinical studies.

As part of the process of preparing our consolidated financial statements, we are required to estimate our research and development expenses as of each balance sheet date. This process involves reviewing open contracts, including clinical site contracts, and communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our research and development expenses as of each balance sheet date based on facts and circumstances known to us at that time. The significant estimates in our research and development expenses include the costs incurred for services performed by our vendors in connection with services for which we have not yet been invoiced. We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with contractors and vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-Based Compensation

In April 2015 and August 2024, the Company's Board of Directors ("Board") adopted the 2015 Stock Incentive Plan ("2015 Plan") and the 2024 Stock Incentive Plan ("2024 Plan"), respectively. Under the 2015 Plan and 2024 Plan, the Company periodically grants equity-based payment awards in the form of restricted common stock awards ("RSAs"), restricted stock units ("RSUs"), and stock options to employees, directors, consultants and non-employees and records stock-based compensation expenses for awards of stock-based payments based on their estimated fair value at the grant date.

The estimated fair value of service-based RSAs and RSUs are measured at the grant date based on the estimated fair market value of the Company's common stock on the date of grant and is recognized as expense over the requisite service period, which is generally the awards' vesting period. The estimated fair value of performance-based RSAs is measured at the grant date based on the estimated fair value of shares expected to be earned at the end

of the performance period, and is recognized as expense ratably over the performance period based upon the probable number of shares expected to vest.

The Company accounts for the grant of stock options based on the estimated fair value of the underlying option using the Black-Scholes valuation model on the date of grant and are recognized as expense in the consolidated statement of operations on a straight-line basis over the requisite service period, which is the vesting period. The Black-Scholes valuation model requires the input of subjective assumptions, including expected volatility, expected dividend yield, expected term, risk-free rate of return and the estimated fair value of the underlying common stock on the date of grant. Prior to the IPO, the Company regularly engaged a third-party valuation specialist to assist with estimates related to the valuation of the Company's common stock. Since the Company's IPO, the fair value of our common stock was determined based on the closing price of our common stock as reported on the date of grant on the primary stock exchange on which our common stock is traded.

The Company classifies stock-based compensation expense in the consolidated statements of operations in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified.

The Company recognizes forfeitures related to stock-based compensation awards as they occur.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recent Accounting Pronouncements

A description of recently issued accounting standards that may potentially impact our financial position, results of operations, and cash flows is included in Note 2 to our consolidated financial statements in this Report.

Emerging Growth Company Status and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). The JOBS Act permits an emerging growth company such as ours to take advantage of an extended transition period to comply with new or revised accounting standards. We have elected to avail ourselves of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (i) irrevocably elect to opt out of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. We will continue to remain an emerging growth company until the earliest of the following: (1) the last day of the fiscal year following the fifth anniversary of the date of the completion of the IPO; (2) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.235 billion; (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We are also a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

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

As a "smaller reporting company" as defined in Rule 12b-2 of the Exchange Act, we are not required to provide the information called for by this item.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements, together with the report of our independent registered public accounting firm, are included in this Annual Report on Form 10-K beginning on page F-1.

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

None.

Item 9A. Controls and Procedures.

Attestation Report of the Independent Registered Public Accounting Firm

This Annual Report does not include an attestation report of our independent registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies."

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and our principal financial officer, has evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of December 31, 2025. Based on such evaluation, our principal executive officer and our principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). We maintain internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, in designing and evaluating the disclosure controls and procedures, management recognizes that any system of internal control over

financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

As of December 31, 2025, our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on management's assessment, management has concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Trading Plans

During the quarter ended December 31, 2025, no director or officer of the Company adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement, as each term is defined in Item 408(a) of Regulation S-K.

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

Not applicable.

PART III

The information required by Part III is omitted from this Report because we will file a definitive proxy statement within 120 days after the end of our 2025 fiscal year pursuant to Regulation 14A for our 2026 Annual Meeting of Stockholders, or the 2026 Proxy Statement, and the information to be included in the 2026 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our 2026 Proxy Statement and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be contained in our 2026 Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be contained in our 2026 Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be contained in our 2026 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be contained in our 2026 Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(1) Financial Statements.

The consolidated financial statements of Actuate Therapeutics, Inc. filed as part of this Report are listed on the Index to Financial Statements on page F-1.

(2) Finance Statement Schedules.

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

(3) Exhibits.

The exhibits filed or furnished as part of this Report are set forth below.

Exhibit Number	Description of Document
3.1	Sixth Amended and Restated Certificate of Incorporation (incorporated by reference to Registrant's Current Report on Form 8-K as filed on August 14, 2024)
3.2	Amended and Restated Bylaws of Actuate Therapeutics, Inc. (incorporated by reference to Registrant's Current Report on Form 8-K as filed on August 14, 2024)
4.1	Form of Common Stock Certificate of Registrant (incorporated by reference to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 11, 2024)
4.2	Fourth Amended and Restated Investors' Rights Agreement, by and between the Registrant and certain of its stockholders, dated November 30, 2022 (incorporated by reference to Registrant's Registration Statement on Form S-1/A, filed with the SEC on May 24, 2024)
4.3	Form of Representative Warrant issued to Underwriter under IPO (incorporated by reference to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 11, 2024)
4.4	Form of Second Amended and Restated Warrant issued to holders of Convertible Redeemable Preferred Stock (incorporated by reference to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 11, 2024)
4.5	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Registrant's Annual Report on Form 10-K, filed with the SEC on March 13, 2025)
4.8	Form of Warrant, dated June 25, 2025, by and among Registrant and each of the purchasers party thereto under the Securities Purchase Agreement (incorporated by reference to Registrant's Current Report on Form 8-K as filed on June 26, 2025)
10.1±	Exclusive License Agreement with Equity, dated April 6, 2015, as amended, between The Board of Trustees of the University of Illinois and the Registrant (incorporated by reference to Registrant's Registration Statement on Form S-1/A, filed with the SEC on July 16, 2024)
10.2±	License Agreement, dated March 31, 2015, as amended, between Northwestern University and the Registrant (incorporated by reference to Registrant's Registration Statement on Form S-1, filed with the SEC on May 24, 2024)
10.3+	Actuate Therapeutics, Inc. 2015 Equity Incentive Plan, as amended, and form of grant agreements thereunder (incorporated by reference to Registrant's Registration Statement on Form S-1, filed with the SEC on May 24, 2024)
10.4+	Actuate Therapeutics, Inc. 2024 Equity Incentive Plan (incorporated by reference to Registrant's Registration Statement on Form S-1, filed with the SEC on May 24, 2024)
10.5+	Form of Stock Option Agreement under the Actuate Therapeutics, Inc. 2024 Stock Incentive Plan (incorporated by reference to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 11, 2024)

10.6+	Form of Restricted Stock Unit Agreement under the Actuate Therapeutics, Inc. 2024 Stock Incentive Plan (incorporated by reference to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 11, 2024)
10.7+	Non-Employee Director Compensation Policy (incorporated by reference to Registrant's Registration Statement on Form S-1/A, filed with the SEC on June 21, 2024)
10.8+	Employment Agreement, effective April 15, 2015 and as amended on each of February 5, 2016, September 28, 2017, September 23, 2018, January 29, 2019, August 1, 2022, January 27, 2023 December 12, 2023 and May 9, 2024, between Daniel Schmitt, and the Registrant (incorporated by reference to Registrant's Registration Statement on Form S-1, filed with the SEC on May 24, 2024)
10.9+	Employment Agreement, effective June 1, 2022, between Andrew P. Mazar, Ph.D., and the Registrant (incorporated by reference to Registrant's Registration Statement on Form S-1, filed with the SEC on May 24, 2024)
10.10+	Employment Agreement, effective June 1, 2024, between Paul Lytle, and the Registrant (incorporated by reference to Registrant's Registration Statement on Form S-1, filed with the SEC on May 24, 2024)
10.11	Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Registrant's Registration Statement on Form S-1, filed with the SEC on May 24, 2024)
10.12+	Tenth Amendment to Employment Agreement by and between Daniel Schmitt and the Registrant dated March 11, 2025 (incorporated by reference to Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 15, 2025)
10.13+	First Amendment to Employment Agreement by and between Andrew P. Mazar, Ph.D. and the Registrant dated March 11, 2025 (incorporated by reference to Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 15, 2025)
10.14+	First Amendment to Employment Agreement by and between Paul Lytle and the Registrant dated March 11, 2025 (incorporated by reference to Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 15, 2025)
10.15	Securities Purchase Agreement, dated March 27, 2025, by and between Registrant and B. Riley Principal Capital II, LLC (incorporated by reference to Registrant's Current Report on Form 8-K as filed on March 28, 2025)
10.16	Registration Rights Agreement, dated March 27, 2025, by and between Registrant and B. Riley Principal Capital II, LLC (incorporated by reference to Registrant's Current Report on Form 8-K as filed on March 28, 2025)
10.17	Form of Securities Purchase Agreement, dated June 25, 2025, by and among Registrant and each of the purchasers party thereto (incorporated by reference to Registrant's Current Report on Form 8-K as filed on June 26, 2025)
10.18	Form of Registration Rights Agreement, dated June 25, 2025, by and among Registrant and each of the purchasers party thereto (incorporated by reference to Registrant's Current Report on Form 8-K as filed on June 26, 2025)
10.19	At the Market Issuance Sales Agreement dated as of November 28, 2025 between Registrant, on the one hand, and B. Riley Securities, Inc. and Craig-Hallum Capital Group LLC, on the other (incorporated by reference to Registrant's Current Report on Form 8-K as filed on November 28, 2025)
19.1	Insider Trading Policy (incorporated by reference to Registrant's Annual Report on Form 10-K, filed with the SEC on March 13, 2025)
21.1*	Subsidiaries of the Registrant
23.1*	Consent of Crowe LLP, Independent Registered Public Accounting Firm
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as amended
32*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Clawback Policy of Actuate Therapeutics, Inc. (incorporated by reference to Registrant's Annual Report on Form 10-K, filed with the SEC on March 13, 2025)

101.INS*	XBRL Instance Document
101.SCH*	XBRL Schema Document
101.CAL*	XBRL Calculation Linkbase Document
101.DEF*	XBRL Definition Linkbase Document
101.LAB*	XBRL Label Linkbase Document
101.PRE*	XBRL Presentation Linkbase Document

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* Filed herewith

\+ Indicates management contract or compensatory plan.

± Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K on the basis that they are not material and would likely cause competitive harm to the registrant if disclosed.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACTUATE THERAPEUTICS, INC.

Dated: March 26, 2026

/s/ Daniel M. Schmitt
Daniel M. Schmitt. President and Chief Executive Officer, Director
(Principal Executive Officer)

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

Name	Position	Date
/s/ Daniel M. Schmitt Daniel M. Schmitt	President, Chief Executive Officer and Director (principal executive officer)	March 26, 2026
/s/ Paul Lytle Paul Lytle	Chief Financial Officer (principal financial and accounting officer)	March 26, 2026
/s/ Aaron G. L. Fletcher Aaron G.L. Fletcher, Ph.D.	Director and Chairperson	March 26, 2026
/s/ Jason Keyes Jason Keyes	Director	March 26, 2026
/s/ Amy Ronneberg Amy Ronneberg	Director	March 26, 2026
/s/ Roger Sawhney Roger Sawhney	Director	March 26, 2026
/s/ Todd Thomson Todd Thomson	Director	March 26, 2026
/s/ Daniel Zabrowski Daniel Zabrowski, Ph.D.	Director	March 26, 2026

ACTUATE THERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and the Board of Directors of Actuate Therapeutics, Inc.
Fort Worth, Texas

Opinion on the Financial Statements

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

Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring operating losses, has had negative operating cash flows and has not recognized any revenues since its inception. In addition, the Company has an accumulated deficit of $154,607,701 as of December 31, 2025 and is dependent on its ability to raise capital. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. Management has concluded there is substantial doubt regarding the Company's ability to continue as a going concern. The consolidated 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 audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Crowe LLP

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

Costa Mesa, California
March 26, 2026

Actuate Therapeutics, Inc.
Consolidated Balance Sheets

	December 31,	
	2025	**2024**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,159,423	$ 8,641,622
Prepaid assets and other current assets	483,996	566,278
Total current assets	13,643,419	9,207,900
Deferred offering costs and other assets	392,491	110,548
Total assets	$ 14,035,910	$ 9,318,448
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,524,190	$ 1,921,189
Other accrued expenses	3,567,404	5,921,908
Accrued compensation	588,304	888,449
Accrued interest, current	27,018	70,957
Total current liabilities	5,706,916	8,802,503
Long term liabilities:		
Accrued interest, less current portion	-	6,768
License payable	404,991	404,991
Total long-term liabilities	404,991	411,759
Total liabilities	6,111,907	9,214,262
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.000001 par value, 10,000,000 shares authorized, no shares issued or outstanding	-	-
Common stock, $0.000001 par value, 200,000,000 shares authorized, 23,245,203 and 19,531,636 shares issued and outstanding at December 31, 2025 and 2024, respectively	23	20
Additional paid-in capital	162,531,681	132,484,015
Accumulated deficit	(154,607,701)	(132,379,849)
Total stockholders' equity	7,924,003	104,186
Total liabilities and stockholders' equity	$ 14,035,910	$ 9,318,448

See accompanying notes to consolidated financial statements.

Actuate Therapeutics, Inc.
Consolidated Statements of Operations

	Year Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 10,292,620	$ 18,676,276
General and administrative	12,202,692	6,484,458
Total operating expenses	22,495,312	25,160,734
Loss from operations	(22,495,312)	(25,160,734)
Other income (expense):		
Change in estimated fair value of warrant liability	-	(78,903)
Gain on settlement of warrants	-	343,240
Loss on issuance of related party convertible notes payable at fair value	-	(400,000)
Change in estimated fair value of related party convertible notes payable	-	(2,192,507)
Interest expense	(20,250)	(18,717)
Interest income	287,710	222,293
Total other income (expense), net	267,460	(2,124,594)
Net loss	$ (22,227,852)	$ (27,285,328)
Weighted-average shares of common stock outstanding, basic and diluted	21,021,817	8,372,741
Net loss per share attributable to common stockholders, basic and diluted	$ (1.06)	$ (3.26)

See accompanying notes consolidated financial statements.

Actuate Therapeutics, Inc.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balances, December 31, 2023	24,678,355	$ 94,178,404	1,690,760	$ 2	$ 5,468,006	$ (105,094,521)	$ (99,626,513)
Issuance of common stock in initial public offering, net of underwriting discounts, commissions and offering costs of $3,734,389	-	-	3,220,000	3	22,025,608	-	22,025,611
Conversion of redeemable convertible preferred stock into common stock upon closing of initial public offering	(24,678,355)	(94,178,404)	13,710,379	14	94,178,390	-	94,178,404
Conversion of related party convertible notes payable into common stock upon closing of initial public offering	-	-	884,427	1	8,092,506	-	8,092,507
Reclassification of warrant liability to equity upon exchange of warrants to purchase redeemable convertible preferred stock for warrants to purchase common stock upon closing of initial public offering	-	-	-	-	485,172	-	485,172
Exercise of in-the-money warrants to purchase redeemable convertible preferred stock and conversion into common stock upon closing of initial public offering	-	-	26,070	-	238,540	-	238,540
Stock-based compensation expense	-	-	-	-	1,995,793	-	1,995,793
Net loss	-	-	-	-	-	(27,285,328)	(27,285,328)
Balances, December 31, 2024	**-**	**-**	**19,531,636**	**20**	**132,484,015**	**(132,379,849)**	**104,186**
Issuance of shares under underwritten public offering, net of underwriter discounts and issuance costs of $1,676,036	-	-	2,464,286	3	15,573,963	-	15,573,966
Issuance of shares under June 2025 Private Placement, net of issuance costs of $73,017	-	-	666,497	-	4,592,462	-	4,592,462
Issuance of shares under Committed Equity Facility, net of issuance costs of $603,655	-	-	539,967	-	3,800,465	-	3,800,465
Exercise of stock option awards	-	-	15,942		34,115	-	34,115
Issuance of vested and settled restricted stock units	-	-	26,875	-	-	-	-
Stock-based compensation expense	-	-	-	-	6,046,661	-	6,046,661
Net loss	-	-	-	-	-	(22,227,852)	(22,227,852)
Balances, December 31, 2025	**-**	**$ -**	**23,245,203**	**$ 23**	**$ 162,531,681**	**$ (154,607,701)**	**$ 7,924,003**

See accompanying notes to consolidated financial statements.

Actuate Therapeutics, Inc.
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2025	**2024**
Operating Activities:		
Net loss	$ (22,227,852)	$ (27,285,328)
Adjustment to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,046,661	1,995,793
Change in estimated fair value of warrant liability	-	78,903
Gain on settlement of warrant liability	-	(343,240)
Loss on issuance of related party convertible notes payable at fair value	-	400,000
Change in estimated fair value of related party convertible notes payable	-	2,192,507
Interest accrued on license payable	20,250	18,641
Changes in operating assets and liabilities:		
Prepaid assets and other current assets	82,282	(529,371)
Other assets	110,548	(110,548)
Accounts payable	(512,536)	(1,500,651)
Accrued compensation	(300,145)	610,949
Accrued interest	(70,957)	(70,957)
Other accrued expenses	(2,354,504)	2,700,654
Net cash used in operating activities	(19,206,253)	(21,842,648)
Financing Activities:		
Proceeds from issuance of shares of common stock under underwritten public offering, net of underwriting discounts and offering costs	15,573,966	-
Proceeds from issuance of shares of common stock under June 2025 Private Placement, net	4,592,462	-
Proceeds from issuance of shares of common stock under the Committed Equity Facility, net	3,826,336	-
Proceeds from the exercise of stock options	34,115	-
Proceeds from initial public offering, net of underwriting discounts and commissions	-	23,956,800
Payment of offering costs related to initial public offering	-	(1,931,189)
Proceeds from issuance of related party short-term loan	-	200,000
Payment of related party short-term loan	-	(200,000)
Proceeds from issuances of related party convertible notes payable	-	5,500,000
Deferred offering costs	(302,825)	-
Net cash provided by financing activities	23,724,054	27,525,611
Net change in cash and cash equivalents	4,517,801	5,682,963
Cash and cash equivalents, beginning of period	8,641,622	2,958,659
Cash and cash equivalents, end of period	$ 13,159,423	$ 8,641,622
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 70,957	$ 71,033
Cash paid for income taxes	$ 800	$ 800
Supplemental Schedule of Noncash Financing Activities:		
Conversion of redeemable convertible preferred stock into common stock upon initial public offering	$ -	$ 94,178,404
Reclassification of warrant liability to equity upon exchange of not in-the-money Series B and Series C Redeemable Convertible Preferred Stock Warrants for warrants to purchase common stock	$ -	$ 485,172
Exercise of in-the-money warrants to purchase redeemable convertible preferred stock and conversion into common stock upon initial public offering	$ -	$ 238,540
Conversion of related party convertible notes payable into common stock upon initial public offering	$ -	$ 8,092,507
Deferred offering costs, unpaid and accrued	$ 115,537	$ -
Deferred offering costs charged against Committed Equity Facility	$ 25,871	$ -

See accompanying notes consolidated financial statements.

1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Actuate Therapeutics, Inc. (the "Company") was incorporated in the State of Delaware on January 16, 2015 and is headquartered in Fort Worth, Texas. The Company is a clinical-stage biopharmaceutical company focused on developing novel therapies for the treatment of cancers through the inhibition of glycogen synthase kinase-3 ("GSK-3"). The Company's lead investigational product, elraglusib (formerly 9-ING-41), is a small molecule that is designed to enter cancer cells and block the function of the enzyme GSK-3β, thereby causing the death of the cancer cells and the regulation of anti-tumor immunity.

The Company has a 100%-owned Irish subsidiary, Actuate Therapeutics Limited, that is currently dormant.

Initial Public Offering

On August 14, 2024, the Company completed the closing of its IPO of 2,800,000 shares of common stock at an initial offering price to the public of $8.00 per share, before the underwriters' discount of $0.56 per share. Additionally, the underwriters exercised their option ("Overallotment Option") to purchase an additional 420,000 shares at the same price of $8.00 per share less the underwriters' discount on September 12, 2024. The Company's common shares began trading on the Nasdaq Global Market on August 13, 2024, under the symbol "ACTU". The Company received net proceeds of approximately $22 million, after deducting discounts and commissions of approximately $1.8 million and other offering expenses of approximately $1.9 million (or approximately $3.7 million in aggregate) for the issuance of 3,220,000 shares of common stock of the Company, including shares issued under the Overallotment Option.

Upon the closing of the Company's IPO and Overallotment Option, the Company issued the underwriters warrants to purchase up to 161,000 shares of common stock, representing 5% of the shares of common stock issued under the IPO and Overallotment Option, at an exercise price of $10.00 per share (see Note 8).

In addition, the Company's Redeemable Convertible Preferred Stock (see Note 7), Related Party Convertible Notes Payable (see Note 4) and in-the-money warrants to purchase the Company's Redeemable Convertible Preferred Stock (see Note 8) converted into or were automatically exercised for, as applicable, common stock immediately prior to the closing of the IPO.

Basis of Presentation

The Company's consolidated financial statements are presented in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and reflect the financial position, results of operations and cash flows for all periods presented. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Going Concern and Management's Plans

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As of December 31, 2025, the Company had cash and cash equivalents of $13,159,423 and working capital of $7,936,503. The Company has not generated any revenue and has incurred recurring operating losses since inception. The Company expects to continue to incur losses for the foreseeable future and therefore, the Company's ability to continue its operations is highly dependent on its ability to raise additional capital to fund its future operations.

On March 27, 2025, the Company entered into a common stock purchase agreement (the "Committed Equity Facility") with B. Riley Principal Capital II ("B. Riley") giving the Company the right, but not the obligation, to sell to B. Riley over a 36-month period up to the lesser of (i) $50 million of newly issued shares of our common stock and (ii) 3,904,374 shares of the Company's common stock. During the year ended December 31, 2025, we received net proceeds of $3,800,465 in exchange for 539,967 shares of common stock sold under the Committed Equity Facility. As of December 31, 2025, there were 3,364,407 shares of common stock in remaining capacity under the Committed Equity Facility (see Note 7).

On June 25, 2025, the Company entered into a securities purchase agreement for a private placement of common stock and warrants with certain institutional and accredited investors, which closed on June 27, 2025 (the "June 2025 Private Placement"). Under the June 2025 Private Placement, the Company received aggregate net proceeds of $4,592,462 (see Note 7).

On September 10, 2025, the Company entered into an underwriting agreement (the "Underwriter Agreement") with Lucid Capital Markets, LLC ("Underwriter") relating to an underwritten public offering of 2,142,858 shares of common stock plus an over-allotment option to purchase up to an additional 321,428 shares of common stock at the public offering price of $7.00 per share, less underwriting discounts and commissions and other offering expenses ("September 2025 Public Offering"). The offering closed on September 11, 2025 and the Company issued 2,464,286 shares of common stock to the Underwriter, including shares issued under the over-allotment option, in exchange for net proceeds of $15,573,966 (see Note 7).

On November 28, 2025, the Company entered into an At Market Issuance Sales Agreement (the "ATM Agreement") with B. Riley Securities, Inc. and Craig-Hallum Capital Group LLC (each a "Sales Agent" and collectively the "Sales Agents") with respect to an "at the market" offering program (the "ATM Facility"), under which the Company may, from time to time, at its sole discretion, issue and sell through the Sales Agents, up to $100 million of shares of common stock. Pursuant to the ATM Agreement, the Company may sell the shares through the Sales Agents by any method permitted that is deemed an "at the market" offering as defined in Rule 415 under the Securities Act. The Sales Agents will use commercially reasonable efforts consistent with their normal trading and sales practices to sell the shares from time to time, based upon instructions from us, including any price or size limits or other customary parameters or conditions we may impose. The Company will pay the Sales Agents a commission of up to 3.0% of the gross sales proceeds of any common stock sold through the Sales Agents under the ATM Agreement and also has provided the Sales Agents with customary indemnification rights. During the year ended December 31, 2025, the Company did not sell any shares of common stock under the ATM Facility. As of December 31, 2025, the Company had $100 million in remaining capacity under its ATM Facility (see Note 7).

There can be no assurance that the Company will be able to raise sufficient proceeds in the future under the Committed Equity Facility, the ATM Facility, or any additional financing will be available to the Company on acceptable terms, if at all.

Management anticipates, based on currently proposed plans and assumptions, that our cash and cash equivalents on hand will not satisfy the Company's operational and capital requirements beyond July 2026 without raising additional capital. As the Company continues to execute its business plan, it plans to seek financing for its operations through equity offerings, debt financings, or other capital sources. The Company's ability to raise additional capital may be adversely impacted by business conditions, global economic conditions, disruptions to, and volatility in, the financial markets in the United States and worldwide, among other matters, and it may not obtain this necessary capital when needed on acceptable terms, or at all. If events or circumstances occur such that the Company does not obtain additional funding, it may be necessary to significantly reduce our scope of operations to reduce the current rate of spending through actions such as the need to delay, limit, reduce, grant rights to develop or terminate its product development or even cease operations, which could have a material adverse effect on the Company's business, results of operations or financial condition. Based on the above matters, we have concluded that there is substantial doubt regarding the Company's ability to continue as a going concern.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The consolidated financial statements include the accounts of Actuate Therapeutics, Inc. and its wholly owned subsidiary, Actuate Therapeutics Limited. All material intercompany accounts and transactions have been eliminated in the consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions, and judgements that affect the reported amounts of assets, liabilities, expenses, and related disclosures in the accompanying notes. The Company bases its estimates, assumptions and judgements on historical experience when available and on various factors that it believes to be reasonable under the circumstances as of the date of the accompanying consolidated financial statements including stock-based compensation expense, accrued expenses (including accrued expenses related to research and development ("R&D") as described below), and the recoverability of the Company's net deferred tax assets and related valuation allowance. In addition, other factors may affect estimates, including the expected business and operational changes, the sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Actual results could

differ materially from the estimates and assumptions used in the preparation of the accompanying consolidated financial statements under different assumptions or conditions.

Accrued Expenses Related to R&D Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our R&D expenses as of each balance sheet date. This process involves reviewing open contracts, including clinical site contracts, and communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our R&D expenses as of each balance sheet date based on facts and circumstances known to us at that time. The significant estimates in our R&D expenses include the costs incurred for services performed by our vendors in connection with services for which we have not yet been invoiced. We base our expenses related to R&D activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with contractors and vendors that conduct R&D on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. Advance payments for goods and services that will be used in future R&D activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Segment Reporting and Geographic Concentrations

The Company manages its operations as a single operating segment in the U.S. (see Note 13).

Cash and Cash Equivalents

The Company considers all highly liquid investments acquired with a maturity of three months or less from the purchase date that can be liquidated without prior notice or penalty to be cash equivalents. Cash and cash equivalents includes bank demand deposits, U.S. treasury bills and money market funds that invest primarily in U.S. government treasuries.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company deposits cash and cash equivalents with high credit quality financial institutions in the U.S. Deposits held in checking and money market accounts may, from time to time, exceed the federally insured amounts. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant risk in its cash and cash equivalents. The primary objectives of the Company's investment portfolio are the preservation of capital and maintenance of liquidity.

The Company is subject to risks common to companies in the biopharmaceutical industry, including, but not limited to, risks related to the successful development and commercialization of product candidates, fluctuations in operating results and financial risks, the ability to successfully raise additional funds when needed, protection of proprietary rights and patent risks, patent litigation, compliance with government regulations, dependence on key personnel and collaboration partners, and competition from competing products in the marketplace.

Deferred Offering Costs

The Company capitalized as deferred offering costs all direct and incremental legal, professional, accounting and other third-party fees incurred in connection with the Company's equity offerings. Deferred offering costs will be offset against offering proceeds upon the completion of an offering or during the offering period as proceeds are received on a pro rata basis. In the event that an offering is abandoned, deferred offering costs will be expensed in the period of abandonment in the consolidated statement of operations.

Fair Value of Financial Instruments

Authoritative guidance requires disclosure of the fair value of financial instruments. The Company applies fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures. The carrying amount of certain of the Company's financial instruments, including cash and cash equivalents, accounts payable and accrued liabilities, approximate their estimated fair values primarily due to the short-term nature of the instruments or based on information

obtained from market sources and management estimates. The Related Party Convertible Notes Payable (see Note 4) and the Redeemable Convertible Preferred Stock Warrant Liability (see Note 8) were carried at fair value until the closing of the IPO based on unobservable market inputs. The Company measures the fair value of certain of its financial liabilities on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values.

Financial assets and liabilities carried at fair value which is not equivalent to cost will be classified and disclosed in one of the following three categories:

- Level 1 — Quoted prices (unadjusted) in active markets for identical assets and liabilities;
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as unadjusted quoted prices for similar assets and liabilities, unadjusted quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques and significant management judgment or estimation.

The Company reviews the fair value hierarchy classification at each reporting date. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. The Company did not have any transfers of assets and liabilities between the levels of the fair value measurement hierarchy during the years presented. As of December 31, 2025 and 2024, there were no financial assets or liabilities carried at fair value which were not equivalent to cost.

Comprehensive Loss

There were no differences between net loss and comprehensive loss presented in the consolidated statements of operations for the years ended December 31, 2025 and 2024.

R&D Expenses

In accordance with authoritative guidance, the Company charges research and development costs to operations as incurred. Research and development expenses consist primarily of personnel and related costs, external costs of outside vendors engaged clinical trials, contract manufacturers, consultants and other third parties to conduct and support our clinical trials and preclinical studies.

Patent Costs

Patent fees and patent related costs in connection with filing and prosecuting patent applications are expensed as incurred and are classified as general and administrative expenses in the accompanying consolidated statements of operations.

Fair Value Option of Accounting for Related Party Convertible Notes Payable

When financial instruments contain various embedded derivatives which may require bifurcation and separate accounting of those derivatives apart from the entire host instrument, if eligible, ASC 825, *Financial Instruments* ("ASC 825") allows issuers to elect the fair value option ("FVO") of accounting for those instruments. The FVO may be elected on an instrument-by-instrument basis and is irrevocable unless a new election date occurs. The FVO allows the issuer to account for the entire financial instrument at fair value with subsequent remeasurements of that fair value recorded through the statements of operations at each reporting period until the conversion or payment of the Related Party Convertible Notes Payable balance. A financial instrument is generally eligible for the FVO if, amongst other factors, no part of the convertible, or contingently convertible, instrument is classified in stockholders' equity.

Based on the eligibility assessment discussed above, the Company concluded that its Related Party Convertible Notes Payable were eligible for the FVO and accordingly elected to apply the FVO to its Related Party Convertible Notes Payable in accordance with ASC 825. Accordingly, the Related Party Convertible Notes Payable were measured at fair value on their issuance dates and remeasured at estimated fair value at the end of each reporting period with changes in fair value recognized as a component of other income (expense) in the consolidated statements of operations. The primary reason for electing the fair value option was to address simplification and cost-benefit considerations that result from accounting for hybrid financial instruments at fair value in their entirety versus bifurcation of the embedded derivatives from the debt hosts.

The estimated fair values of the Related Party Convertible Notes Payable were determined using valuation models that incorporated assumptions and estimates. The Company assessed these assumptions and estimates at each financial reporting period as additional information impacting the assumptions was obtained. Assumptions in the models included but were not limited to equity value, volatility, time to a conversion event, risk-free rate and scenario weightings. The fair value measurements of the Related Party Convertible Notes Payable were based on significant inputs that were not observable in the market and represented a Level 3 measurement (see Note 5). The change in fair value related to accrued interest was also included within the single line of change in fair value of Related Party Convertible Notes Payable in the consolidated statements of operations.

In addition, in certain circumstances, the estimated fair value at issuance may be greater than the face value at issuance. The loss on issuance of the Related Party Convertible Notes Payable of $400,000 recorded during year ended December 31, 2024 represented the difference between the estimated fair value of the Related Party Convertible Notes Payable and the gross proceeds received on the issuance date based on the assumptions, including the proximity in time to the anticipated IPO, the discount on conversion of the Related Party Convertible Notes Payable, and the increased probability-weighted IPO scenario. In connection with the closing of the Company's IPO, the Related Party Convertible Notes Payable were converted into common stock and no amounts are outstanding as of December 31, 2024 (see Note 4).

Redeemable Convertible Preferred Stock

The Company recorded all shares of Redeemable Convertible Preferred Stock at their respective fair values on the dates of issuance, net of issuance costs. Redeemable Convertible Preferred Stock was recorded outside of permanent equity because while it was not mandatorily redeemable, in certain events considered not solely within the Company's control, such as a merger, acquisition, or sale of all or substantially all of the Company's assets, each referred to as a "deemed liquidation event," the Redeemable Convertible Preferred Stock could become redeemable at the option of the holders of at least a majority of the then outstanding preferred shares. The Company did not adjust the carrying value of the Redeemable Convertible Preferred Stock to its liquidation preference because a deemed liquidation event obligating the Company to pay the liquidation preference to holders of shares of Redeemable Convertible Preferred Stock did not occur prior to conversion and was subsequently not triggered upon the closing of the Company's IPO when all shares of Redeemable Convertible Preferred Stock converted into shares of common stock (see Note 7).

Redeemable Convertible Preferred Stock Warrants

The Company's Redeemable Convertible Preferred Stock Warrants (see Note 8) required liability classification and accounting as the underlying Redeemable Convertible Preferred Stock was considered contingently redeemable and could have obligated the Company to transfer assets to the holders at a future date upon occurrence of a deemed liquidation event. The warrants were recorded at their estimated fair value upon issuance and were subject to remeasurement to estimated fair value at each balance sheet date, with changes in the estimated fair value recognized as a component of other income (expense) in the accompanying consolidated statements of operations. The Company adjusted the warrant liability for changes in estimated fair value until the earlier of the exercise, conversion, or expiration of the Redeemable Convertible Preferred Stock Warrants. In July 2024, the Redeemable Convertible Preferred Stock Warrants were amended to provide that if underlying Redeemable Convertible Preferred Stock Warrants were out-of-the-money based on the initial public offering price in the IPO, the out-of-the-money Redeemable Convertible Preferred Stock Warrants would convert into warrants to purchase common stock with an exercise price per share that reflected the Conversion Ratio (see Note 7) then in effect for the underlying Redeemable Convertible Preferred Stock. Accordingly, the Redeemable Convertible Preferred Stock Warrants were remeasured upon the closing of the IPO and marked to market to their fair value before being reclassified to equity.

Stock-Based Compensation

In April 2015 and August 2024, the Company's Board of Directors ("Board") adopted the 2015 Stock Incentive Plan ("2015 Plan") and the 2024 Stock Incentive Plan ("2024 Plan"), respectively, which are more fully described in Note 9.

The Company periodically grants equity-based payment awards in the form of restricted common stock awards ("RSAs"), restricted stock units ("RSUs"), and stock options to employees, directors and non-employees and records stock-based compensation expenses for awards of stock-based payments based on their estimated fair value at the grant date.

The estimated fair value of service-based RSAs is measured at the grant date based on the estimated fair market value of the Company's common stock on the date of grant and is recognized as expense over the requisite service period, which is generally the awards' vesting period. The estimated fair value of performance-based RSAs is measured at the grant date based on the estimated fair value of shares expected to be earned at the end of the performance period, and is recognized as expense ratably over the performance period based upon the probable number of shares expected to vest.

The Company accounts for the grant of stock options based on the estimated fair value of the underlying option using the Black-Scholes valuation model on the date of grant and are recognized as expense in the consolidated statement of operations on a straight-line basis over the requisite service period, which is the vesting period. The Black-Scholes valuation model requires the input of subjective assumptions, including expected volatility, expected dividend yield, expected term, risk-free rate of return and the estimated fair value of the underlying common stock on the date of grant. Prior to the IPO, the Company regularly engaged a third-party valuation specialist to assist with estimates related to the valuation of the Company's common stock.

The Company classifies stock-based compensation expense in the consolidated statements of operations in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified.

The Company recognizes forfeitures related to stock-based compensation awards as they occur.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, Redeemable Convertible Preferred Stock, convertible notes payable, warrants to purchase Redeemable Convertible Preferred Stock, unvested RSAs, and outstanding stock options and RSUs are considered to be potentially dilutive securities when outstanding (see Note 10). As of August 14, 2024, Redeemable Convertible Preferred Stock, convertible notes payable, warrants to purchase Redeemable Convertible Preferred Stock were no longer outstanding, and therefore were no longer considered to be potentially dilutive securities during the year ended December 31, 2025. In addition, included in the basic and diluted net loss per share calculation were RSUs awarded to an executive officer that had vested in August 2025, but the issuance and delivery of the shares were deferred. The number of shares underlying vested and unsettled RSUs at December 31, 2025 was 272,055.

Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the Redeemable Convertible Preferred Stock and common stock subject to repurchase are considered participating securities. The Redeemable Convertible Preferred Stock did not have a contractual obligation to share in the Company's losses, and unvested RSAs subject to repurchase is considered an unvested stock-based compensation award for accounting purposes. As such, the net loss is attributed entirely to common stockholders. Because the Company has reported a net loss for the reporting periods presented, the diluted net loss per common share is the same as basic net loss per common share for those periods.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes" ("ASC 740"). In accordance with authoritative guidance, deferred tax assets and liabilities are recorded for temporary differences between the financial reporting and tax bases of assets and liabilities using the current enacted tax rate expected to be in effect when the differences are expected to reverse. A valuation allowance is recorded on deferred tax assets unless realization is considered more likely than not.

The Company evaluates its tax positions taken or expected to be taken in the course of preparing the Company's tax returns to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority. Tax positions not deemed to meet the "more-likely-than-not" threshold are not recorded as a tax benefit or expense in the current year. The Company recognizes interest and penalties, if any, related to uncertain tax positions in interest expense. No interest and penalties related to uncertain tax positions were accrued at either December 31, 2025 or 2024.

The Company follows authoritative guidance which requires the evaluation of existing tax positions. The Company files in the federal and various state jurisdictions. Management has analyzed all open tax years, as defined by the statute of limitations, for all major jurisdictions. Open tax years are those that are open for examination by taxing authorities. Tax years covering the years from 2020 to 2024 are the only open years for the Company as of the issuance date of these consolidated financial statements.

The Company also has elected to utilize research credits against the employer portion of payroll tax as it is considered a qualified small business under the Internal Revenue code. Due to the uncertainty of utilizing the research credits, the Company accounts for the credits against research and development expenses in the accompanying consolidated financial statements when the related expense is incurred.

Recently Adopted Accounting Standards

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures". The guidance includes the requirement that public business entities, on an annual basis, disclose specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5% of the amount computed by multiplying pretax income (or loss) by the applicable statutory income tax rate). It also requires that all entities disclose, on an annual basis, the amount of income taxes paid (net of refunds received) disaggregated by federal (national), state, and foreign taxes and the amount of income taxes paid (net of refunds received) disaggregated by individual jurisdictions in which income taxes paid (net of refunds received) is equal to or greater than 5% of total income taxes paid (net of refunds received) and requires that all entities disclose income (or loss) from continuing operations before income tax expense (or benefit) disaggregated between domestic and foreign and income tax expense (or benefit) from continuing operations disaggregated by federal (national), state, and foreign. Lastly, the guidance eliminates the requirement for all entities to disclose the nature and estimate of the range of the reasonably possible change in the unrecognized tax benefits balance in the next 12 months or make a statement that an estimate of the range cannot be made. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The guidance should be applied on a prospective basis. Retrospective application is permitted. The Company adopted the guidance as of December 31, 2025 with no material impact on the Company's consolidated financial statements upon adoption.

On July 4, 2025, the U.S. H.R.1, an act to provide for reconciliation pursuant to title II of H.Con.Res.14. (the One Big Beautiful Bill Act or "OBBA") was enacted. The OBBA introduces multiple tax law and other legislative changes, including modifications to income tax provisions such as domestic research and development expenses, capital expenditures, and U.S. taxation of international earnings; the repeal or acceleration of the sunset of certain tax credits under the 2022 Inflation Reduction Act and elimination of certain penalties for violations of certain regulatory credit programs. We have recognized the effects of the OBBA provisions in our financial results to the extent they are applicable to the year ended December 31, 2025.

Recently Issued Accounting Standards Not Yet Adopted

Accounting standards not listed below were assessed and determined not to be applicable or are expected to have minimal impact on the Company's 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". This amended guidance requires disaggregation of specific expense categories in the notes to the financial statements and a qualitative description of the remaining expense amounts not separately disaggregated. This standard becomes effective for reporting companies with annual reporting periods beginning after December 15, 2026, and requires prospective application with an option to apply it retrospectively. The Company anticipates adopting this standard in its Annual Report on Form 10-K for the year ending December 31, 2027. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

3. OTHER ACCRUED EXPENSES

Other accrued expenses as of December 31, 2025 and 2024 consisted of the following:

	December 31, 2025	December 31, 2024
Accrued clinical trial costs	$ 3,169,433	$ 5,483,846
Other accrued expenses	397,971	438,062
Total other accrued expenses	$ 3,567,404	$ 5,921,908

4. RELATED PARTY CONVERTIBLE NOTES PAYABLE

On February 20, 2024, March 27, 2024, and May 8, 2024, the Company issued convertible promissory notes in the amount of $3,000,000, $1,500,000, and $1,000,000, respectively, to Bios Clinical Opportunity Fund, LP, a fund affiliated with a current member and a former member of the board of directors of the Company and a majority shareholder, which notes accrued interest at a rate of 7% per annum and would mature on August 16, 2024, as amended ("Maturity Date"). Principal and accrued interest were due and payable on the Maturity Date, subject to an automatic conversion upon a Qualified Financing (as defined below) or the Company's first firm commitment underwritten initial public offering of its common stock or at the option of the holder, convertible into shares of Series C Redeemable Convertible Preferred Stock.

In the event the Company either completed a financing of at least $5,000,000 in gross proceeds ("Qualified Financing") or closed the Company's first firm commitment underwritten initial public offering of its common stock before the Maturity Date, the Related Party Convertible Notes Payable were to automatically convert into (i) in the case of a Qualified Financing, that number of shares of capital stock issued in such Qualified Financing (the "Qualified Financing Securities") equal to the quotient obtained by dividing the outstanding principal amount of the Related Party Convertible Notes Payable plus all accrued and unpaid interest thereon by eighty percent (80%) of the per share price at which shares are to be sold in such Qualified Financing or (ii) in the case of an initial public offering, such number of shares of common stock equal to the outstanding principal amount of the Related Party Convertible Notes Payable plus all accrued and unpaid interest thereon, divided by eighty percent (80%) of the initial public offering price.

Transaction fees of the related party in the amount of $50,000 that were withheld by the related party were expensed as incurred in accordance with ASC 825.

Prior to the closing of the Company's IPO, the fair value of the Related Party Convertible Notes Payable was estimated at each reporting period using a scenario-weighted binomial lattice model to calculate equity values at different points in time leading up to a conversion event. Assumptions in the model include but are not limited to the following: equity value, conversion price, accrued interest, volatility, risk-free interest rate, dividend yield, time to a conversion event, and scenario weightings. Accrued interest on the Related Party Convertible Notes Payable was included in the determination of the estimated fair value.

In connection with the closing of the Company's IPO, the Company issued Bios Clinical Opportunity Fund, LP 884,427 shares of its common stock upon the conversion of the Related Party Convertible Notes Payable, including accrued interest thereon, at a conversion price of $6.40 per share, representing 80% of the IPO price of $8.00 per share. The Related Party Convertible Notes Payable was marked to market to its fair value on the conversion date before being reclassified to equity. The aggregate fair value at the time of conversion was calculated by multiplying the number of shares of common stock issued upon conversion by the fair value per share on the conversion date, which was the closing price of the Company's common stock on the Nasdaq Global Market on the closing date of the IPO.

The following table sets forth the changes in the estimated fair value of the Company's Related Party Convertible Notes Payable for the year ended December 31, 2024:

Balance as of January 1, 2024	$ -
Principal amount of Related Party Convertible Notes Payable issued	5,500,000
Loss recorded at issuance (see Note 2)	400,000
Change in fair value	2,192,507
Conversion into common stock	(8,092,507)
Balance as of December 31, 2024	$ -

5. COMMITMENTS AND CONTINGENCIES

Operating Lease

On December 1, 2024, the Company rented office space on a month-to-month basis with no long-term commitment, representing a short-term lease. As a result, the Company has elected to apply the short-term lease exemption to its office lease and therefore has not recorded a right of use ("ROU") asset and related lease liability in accordance with ASC 842, "Leases" ("ASC 842"). Rent expense recorded during the years ended December 31, 2025 and 2024 was $51,200 and $4,200, respectively, which amount is included in general and administrative expenses in the accompanying consolidated statements of operations.

Legal

The Company may be involved, from time to time, in legal proceedings and claims arising in the ordinary course of its business. Such matters are subject to many uncertainties and outcomes and are not predictable with assurance. While management believes that such matters are currently insignificant, matters arising in the ordinary course of business for which the Company is or could become involved in litigation may have a material adverse effect on its business and financial condition. To the Company's knowledge, the Company is not subject to any ongoing or pending legal proceedings.

Indemnities and Guarantees

We have made certain indemnities and guarantees, under which we may be required to make payments to a guaranteed or indemnified party, in relation to certain transactions. We indemnify our officers and directors to the maximum extent permitted under the laws of the State of Delaware. The duration of these indemnities and guarantees varies and, in certain cases, is indefinite. These indemnities and guarantees do not provide for any limitation of the maximum potential future payments we could be obligated to make. Historically, we have not been obligated to make any payments for these obligations and no liabilities have been recorded for these indemnities and guarantees in the accompanying consolidated balance sheets.

6. LICENSES AND AGREEMENTS

UIC License Agreement

On April 6, 2015, the Company entered into an Exclusive License Agreement with Equity (the "UIC License Agreement") with The Board of Trustees of the University of Illinois ("UIC"), whereby, UIC granted the Company (a) an exclusive, nontransferable license, with the right to sublicense under UIC's rights in the Patent Rights (as defined in the UIC License Agreement), and (b) a non-exclusive, non-transferable worldwide license, with the right to sublicense, to use UIC's rights in the Technical Information (as defined in the UIC License Agreement) for all uses. In consideration of the license granted under the UIC License Agreement, the Company agreed to pay UIC (i) development milestones of up to $1.25 million, of which, up to $0.25 million is due upon the progress of clinical trials and $1.0 million is due upon the initiation of commercial sales, (ii) annual minimum royalty payments, increasing to $50,000 in year six and each year thereafter, (iii) royalty on net sales for product covered under the Patent Rights in the low single digits with a 50% reduction in royalties for products solely utilizing Technical Information, (iv) a declining percentage of sublicensing revenue based on the escalating stage of development upon a sublicensing event, and (v) the reimbursement of all patent and related expenses incurred by UIC covering the Patent Rights. For the years ended December 31, 2025 and 2024, the Company incurred minimum royalties and other reimbursable expenses to UIC in the aggregate amount of $62,008 and $75,000, respectively, which amounts were included in general and administrative expenses in the accompanying consolidated statements of operations.

In addition, the Company entered into a sublicense and collaboration agreement dated August 28, 2017 with an unrelated entity that was covered under the UIC License Agreement, which sublicense agreement was later terminated on January 31, 2018. Under the UIC License Agreement, the Company owed UIC a certain percentage of amounts received under the sublicense agreement in the amount of $449,990. The Company paid UIC 10% of the sublicense fees in the amount of $44,999 and the remaining unpaid balance of $404,991 ("Deferred Amount") was originally due and payable to UIC in two installments: 50% due and payable on the one-year anniversary from the first commercial sale and 50% due on the second-year anniversary from the first commercial sale. The Deferred Amount is treated as debt and continues to accrue interest at a rate of five percent (5%) per annum, representing the prime rate as of the date of the agreement plus 1%. On July 16, 2024, the Company and UIC entered into an amendment to the UIC License Agreement ("UIC Amendment"). Interest is due and payable annually within 30 days following the second anniversary of the closing of the IPO and annually thereafter. In addition, the UIC Amendment provides for payment of the Deferred Amount and any accrued interest thereon upon the sooner of (i) termination of the UIC License Agreement by the Company, (ii) the Company ceases development of the licensed UIC technology, (iii) the Company consummates a Change in Control (as defined in the UIC License Agreement), (iv) the Company sublicenses the licensed technology or the developed product, (v) the one-year anniversary following approval of a NDA of a licensed product, or (vii) the Company executes a partnership agreement with any entity resulting in the payment to us above a specified milestone amount or the Company secures cumulative financing equal to or exceeding $200 million. In addition, the UIC Amendment provides that to the extent the Company secures equity financing equal to or exceeding $85 million through its IPO or otherwise, 50% of the Deferred Amount is due and payable within 30 days. The remaining 50% of the Deferred Amount shall be due and payable upon the first to occur of any of the events noted above in clauses (i) through (vii). Finally, the UIC Amendment provides that for as long as the Company or a sublicensee is selling the licensed product, the Company will pay all consideration provided for in the original UIC License Agreement and described above until the last to expire market exclusivity date, the period of which for all products in a jurisdiction will not exceed a total of seven (7) years beginning with the date regulatory approval is granted for the first licensed product in the jurisdiction, and such obligation will survive termination of the UIC License Agreement.

As of December 31, 2025, interest payable to UIC was $27,018 included in the accompanying consolidated balance sheet. As of December 31, 2024, interest payable to UIC was $77,725, of which, $70,957 was classified as current and $6,768 was classified as non-current, which amounts are included in the accompanying consolidated balance sheet.

7. STOCKHOLDERS' EQUITY

Authorized and Issued Capital

The Company's authorized capital consists of 200,000,000 shares of common stock, $0.000001 par value per share, and 10,000,000 shares of preferred stock, $0.000001 par value per share. As of December 31, 2025 and 2024, there were 23,245,203 and 19,531,636 shares of common stock issued and outstanding, respectively. There were no shares of preferred stock outstanding as of December 31, 2025 and 2024.

Reverse Stock Split

On May 31, 2024, the Company's board of directors approved a 1-for-1.8 reverse stock split of its issued and outstanding shares of common stock and stock option awards, which was effected on June 7, 2024. All issued and outstanding shares of common stock (including outstanding RSAs), stock option awards and per share data have been adjusted in these consolidated financial statements, on a retrospective basis, to reflect the reverse stock split for all periods presented. The par value of the common stock and preferred stock was not adjusted as a result of the reverse stock split.

The shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. In addition, the conversion price for each series of the Company's Redeemable Convertible Preferred Stock, which automatically converted into shares of common stock upon the closing of the IPO, were proportionally adjusted. Fractional shares resulting from the reverse stock split were rounded up to the nearest whole share.

Funding Agreements

November 2025 ATM Facility

On November 28, 2025, the Company entered into an ATM Agreement, under which the Company may, from time to time, at its sole discretion, issue and sell through the Sales Agents, up to $100 million of shares of common stock. Pursuant to the ATM Agreement, the Company may sell the shares through the Sales Agents by any method permitted that is deemed an "at the market" offering as defined in Rule 415 under the Securities Act. The Sales Agents will use commercially reasonable efforts consistent with their normal trading and sales practices to sell the shares from time to time, based upon instructions from the Company, including any price or size limits or other customary parameters or conditions we may impose. The Company will pay the Sales Agents a commission of up to 3.0% of the gross sales proceeds of any common stock sold through the Sales Agents under the ATM Agreement and also has provided the Sales Agents with customary indemnification rights. During the year ended December 31, 2025, the Company did not sell any shares of common stock under the ATM Facility. As of December 31, 2025, the Company had $100 million in remaining capacity under its ATM Facility (see Note 14).

September 2025 Public Offering

On September 10, 2025, the Company entered into an underwritten public offering of 2,142,858 shares of common stock plus an over-allotment option to purchase up to an additional 321,428 shares of common stock at the public offering price of $7.00 per share, less underwriting discounts and commissions and other offering expenses. Upon closing the September 2025 Public Offering on September 11, 2025 ("Closing Date"), the Company issued 2,464,286 shares of common stock to the Underwriter, including shares issued under the over-allotment option, in exchange for net proceeds of $15,573,966, after deducting underwriter discounts and commissions and other offering expenses of approximately $1,676,036. In addition, the Company agreed, subject to certain exceptions, not to sell any shares of its capital stock or any securities convertible into or exercisable or exchangeable for shares of capital stock for a period of seventy-five (75) days from the Closing Date.

June 2025 Private Placement

On June 25, 2025, the Company entered into a securities purchase agreement for a private placement of common stock and warrants with certain institutional and accredited investors, including Bios 2024 Co-Invest, LP. Dr. Aaron G.L. Fletcher, the Chairman of the Company's Board of Directors, is a Managing Partner and co-founder of Bios Partners, of which Bios 2024 Co-Invest, LP is an affiliate entity. Upon closing of the June 2025 Private Placement on June 27, 2025, the Company issued and sold an aggregate of (i) 666,497 shares of common stock of the Company at a purchase price of $7.00 per share, and (ii) issued warrants to purchase up to an aggregate of 666,497 shares of common stock at an exercise price of $7.00 per share (see Note 8). The Company received aggregate gross proceeds of $4,665,479 from the June 2025 Private Placement, before deducting fees and

offering expenses of $73,017, of which the Company received gross proceeds of $499,996 from Bios 2024 Co-Invest, LP in exchange for 71,428 shares of common stock and warrants to purchase 71,428 shares of common stock.

Pursuant to the securities purchase agreement, the Company entered into a registration rights agreement ("Registration Rights Agreement") with the investors, pursuant to which the Company agreed to register for resale the shares of common stock and shares of common stock underlying the warrants ("Registrable Securities"). Under the Registration Rights Agreement, the Company agreed to file a registration statement with the U.S. Securities and Exchange Commission (the "SEC"), covering the resale of the shares of common stock, which was filed on July 25, 2025 prior to the filing deadline. The registration statement was declared effective by the SEC on August 4, 2025. The Company also agreed to use reasonable efforts to keep such registration statement effective until the earlier of (i) the date on which the Purchasers have resold all the Registrable Securities covered thereby or (ii) the date on which the Registrable Securities may be resold by the investors without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144 ("Rule 144") of the Securities Act, 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 addition, certain liquidated damages provisions will apply to the Company in the event that the registration is not effective or its use has been suspended beyond specified grace periods, as described in the Registration Rights Agreement.

Committed Equity Facility

On March 27, 2025, the Company entered into a Committed Equity Facility with B. Riley giving the Company the right, but not the obligation, to sell to B. Riley over a 36-month period up to the lesser of (i) $50 million of newly issued shares of our common stock and (ii) 3,904,374 shares of the Company's common stock. The price per share of common stock sold to B. Riley is determined by reference to the daily volume weighted-average price of the Company's common stock as defined within the Committed Equity Facility less a 3% discount, subject to certain limitations and conditions, as calculated on each day the Company sells shares of its common stock under the Committed Equity Facility. The total net proceeds that the Company will receive under the Committed Equity Facility will depend on the quantity, frequency and prices at which the Company sells common stock to B. Riley.

Upon the initial satisfaction of the conditions to B. Riley's obligation to purchase shares under the Committed Equity Facility, including that a registration statement registering the resale by B. Riley of the shares of common stock under the Securities Act is declared effective by the SEC and a final prospectus relating thereto is filed with the SEC (which occurred on April 16, 2025), we have the right, but not the obligation, from time to time at our sole discretion, to deliver one or more notices to direct B. Riley to purchase a specified number of shares of common stock on any trading day, not to exceed the lesser of: (i) 1,000,000 shares of common stock and (ii) up to 50.0% of the total aggregate number (or volume) of shares of our common stock traded on Nasdaq during the applicable trading day, provided the closing sale price of our common stock on Nasdaq on the trading day immediately prior to such purchase date is not less than $1.00.

In addition, we will not sell, and B. Riley will not purchase any shares pursuant to the Committed Equity Facility, which, when aggregated with all other shares of common stock then beneficially owned by B. Riley and its affiliates, would result in the beneficial ownership by B. Riley and its affiliates of more than 4.99% of our outstanding voting power or shares of common stock.

Moreover, under the applicable Nasdaq rules, in no event may we issue to B. Riley more than 3,904,374 shares of common stock (representing 19.99% of the shares of common stock outstanding immediately prior to the execution of the Committed Equity Facility) unless (i) we obtain stockholder approval in accordance with applicable Nasdaq rules, or (ii) the average price per share paid by B. Riley for all of the shares of common stock that we direct B. Riley to purchase from us pursuant to the Committed Equity Facility equals or exceeds $7.56 per share (representing the lower of (a) the official closing price of our common stock on Nasdaq immediately preceding the execution of the Committed Equity Facility and (b) the average official closing price of our common stock on Nasdaq for the five consecutive trading days immediately preceding the execution of the Committed Equity Facility, as adjusted to take into account the payment of the Cash Commitment Fee (as defined below) to B. Riley).

As consideration for B. Riley's commitment to purchase shares of common stock at the Company's direction, the Company agreed to pay B. Riley a cash commitment fee in the amount of up to $500,000 (the "Cash Commitment Fee"), which represents 1.0% of B. Riley's $50,000,000 total aggregate purchase commitment under the Committed Equity Facility. The Cash Commitment Fee will be earned and paid by withholding cash amounts equal to 10% of the total aggregate purchase price payable by B. Riley to the Company in connection with each purchase effected under the Committed Equity Facility, until such time as B. Riley shall have earned and received from such cash withholdings a total aggregate amount in cash equal to $500,000. As of December 31, 2025, the Company has paid to B. Riley an aggregate Cash Commitment Fee of $440,412.

In addition, the Company reimbursed B. Riley for the reasonable legal fees and disbursements of B. Riley's legal counsel and other expenses in the amount of $125,000 and agreed to future quarterly reimbursements of $5,000 during the term of the Committed Equity Facility.

We have the right to terminate the Committed Equity Facility at any time, at no cost or penalty, upon ten (10) trading days' prior written notice to B. Riley. In addition, there are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages under the Committed Equity Facility, other than a prohibition (with certain limited exceptions) on entering into specified variable rate transactions, as defined.

During the year ended December 31, 2025, B. Riley purchased 539,967 and shares of common stock under the Committed Equity Facility in exchange for net proceeds to the Company of $3,800,465, after deducting the 3% discount, the earned Cash Commitment Fee, and other offering expenses in the aggregate amount of $603,655.

Redeemable Convertible Preferred Stock

On August 14, 2024, the closing date of the Company's IPO, all shares of Redeemable Convertible Preferred Stock were automatically converted into 13,710,379 shares of common stock.

Reserved Shares

As of December 31, 2025, the Company reserved the following shares of common stock for issuance upon the (i) exercise of outstanding warrants, (ii) issuance of shares reserved under the Committed Equity Facility, (iii) exercise of issued and outstanding stock option awards and restricted stock unit awards, and (v) to reserve the remaining shares available for grant under the 2024 Stock Incentive Plan ("2024 Plan"):

	December 31, 2025
Shares of common stock reserved under the Committed Equity Facility	3,364,407
Shares reserved for issuance under the 2024 Plan	2,184,341
Stock option awards issued and outstanding	1,841,977
Warrants issued and outstanding to purchase common stock	922,096
Restricted stock unit awards issued and outstanding	617,236
Total	8,930,057

8. WARRANTS

As of December 31, 2025, the following warrants to purchase shares of common stock were outstanding:

	Warrants Outstanding	Exercise Price per Share	Expiry Date
June 2025 Private Placement Warrants	666,497	$7.00	Warrant Expiry Date (defined below)
Underwriter warrants issued under IPO	161,000	$10.00	August 12, 2027
Warrants originally issued in conjunction with Series B Redeemable Convertible Preferred Stock	76,376	$10.55	August 13, 2026
Warrants originally issued in conjunction with Series C Redeemable Convertible Preferred Stock	18,223	$9.42	August 13, 2026
Total	922,096		

June 2025 Private Placement Warrant

Upon closing of the June 2025 Private Placement on June 27, 2025 (see Note 7), the Company issued warrants to purchase up to an aggregate of 666,497 shares of common stock at an exercise price of $7.00 per share. The warrants are exercisable on a cash only basis at any time after the date of issuance and expire 20 days following the earliest to occur of (i) the U.S. Food and Drug Administration ("FDA") issuing Breakthrough Therapy Designation ("BTD") for elraglusib and (ii) the date that the FDA provides written communication available to the Company of its determination as to whether the Company may pursue registration

for elraglusib using its currently available Phase 2 data or data from a Phase 3 clinical trial ("Warrant Expiry Date"). The warrants issued under the June 2025 Private Placement were classified as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date. The warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of shares of common stock upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, the warrants do not provide any guarantee of value or return.

Warrants Issued Under IPO

Upon the closing of the Company's IPO and Overallotment Option, we issued the underwriters warrants to purchase up to 161,000 shares of common stock, representing 5% of the shares of common stock issued under the IPO and Overallotment Option, at an exercise price of $10.00 per share ("Underwriter Warrants"), representing 125% of the initial offering price. The Underwriter Warrants were not exercisable prior to February 8, 2025 (or 180-days from the effective date of the registration statement) and expire on August 12, 2027. The Underwriter Warrants can only be exercised on a cashless basis. The Underwriter Warrants met the criteria for equity classification and were recorded as a component of additional paid-in capital at the time of issuance.

Redeemable Convertible Preferred Stock Warrants and Warrant Liability

On June 30, 2023, in connection with issuance of the Series C Redeemable Convertible Preferred Stock, the Company issued the placement agent warrants to purchase 18,223 shares of Series C Redeemable Convertible Preferred Stock at an exercise price of $9.42 per share ("Series C Redeemable Convertible Preferred Stock Warrants" or "Series C Warrants").

On September 7, 2018, in connection with convertible promissory note payable agreements, the Company agreed to issue the noteholders warrants to purchase shares of Series B-1 Redeemable Convertible Preferred Stock ("Series B Redeemable Convertible Preferred Stock Warrants" or "Series B Warrants"). Warrants to purchase 76,376 shares of Series B-1 Redeemable Convertible Preferred Stock were issued at an exercise price of $5.27 per share and warrants to purchase 76,376 shares of Series B-1 Redeemable Convertible Preferred Stock were issued at an exercise price of $10.55 per share.

The Company remeasured the fair value of the Series B Warrants and Series C Warrants at the end of each reporting period, with any adjustments being recorded as a component of other income (expense) in the accompanying consolidated statements of operations.

Upon the closing of the IPO on August 14, 2024, the Series B Warrants issued at an exercise price of $5.27 per share (in-the-money warrants) were automatically exercised and settled on a cashless basis for shares of our Series B Redeemable Convertible Preferred Stock, and such shares of Series B Redeemable Convertible Preferred Stock were subsequently converted into 26,070 shares of our common stock. The fair value at the time of settlement of $238,540 was calculated by multiplying the number of shares of common stock issued upon settlement by the fair value per share on the settlement date, which was the closing price of the Company's common stock on the Nasdaq Global Market on the closing date of the IPO. Upon the settlement of the in-the-money warrants, the Company recorded a gain on settlement of $343,240 on August 14, 2024. In addition, upon the closing of the IPO, the remaining out-of-the money Series B Warrants and Series C Warrants were amended in July 2024 to become exercisable for the same number of shares of common stock with an exercise price of $10.55 and $9.42 per share, respectively, and exercisable for a period of two years after the closing date of the IPO or through August 13, 2026.

The estimated fair value of the warrant liability for the Series B Warrants and Series C Warrants was $0 as of December 31, 2024. The following table sets forth the changes in the estimated fair value of the warrant liability in connection with the Company's Series B Warrants and Series C Warrants for the year ended December 31, 2024:

Estimated fair value as of December 31, 2023	$ 988,049
Change in fair value	78,903
Exercise of in-the-money warrants to purchase redeemable convertible preferred stock and conversion into common stock upon closing of IPO	(238,540)
Gain on settlement of in-the-money warrants upon conversion into common stock upon closing of IPO	(343,240)
Reclassification of warrant liability to equity upon exchange of warrants to purchase redeemable convertible preferred stock for warrants to purchase common stock upon closing of IPO	(485,172)
Balance as of December 31, 2024	$ -

During the year ended December 31, 2024, the aggregate increase in the fair value of the Series B Warrants and Series C Warrants was $78,903.

During the year ended December 31, 2024, the increase in fair value of the in-the-money Series B Warrants was $96,050. Prior to settlement, the fair value of the in-the-money Series B Warrants was determined using the Black-Scholes valuation model with the following assumptions:

	In-the-Money Series B Warrants Prior to Settlement
Expected term (in years)	4.04
Expected volatility	127.26%
Weighted average risk-free interest rate	5.25%
Expected dividend yield	0.00%
Fair value of convertible preferred stock	$8.82

The out-of-the money Series B Warrants and Series C Warrants were remeasured upon the closing of the IPO and marked to market to its aggregate fair value of $485,172 before being reclassified to equity. During the year ended December 31, 2024, the decrease in fair value of the out-of-the-money Series B Warrants and Series C Warrants was $17,147. The fair value of the out-of-the money Series B Warrants and Series C Warrants as of August 14, 2024, the closing date of the Company's IPO, was determined using the Black-Scholes valuation model with the following assumptions:

	Out-of-the Money Series B Warrants	Out-of-the Money Series C Warrants
Expected term (in years)	2.0	2.0
Expected volatility	111.47%	111.47%
Weighted average risk-free interest rate	3.97%	3.97%
Expected dividend yield	0.00%	0.00%
Fair value of convertible preferred stock	-	-
Fair value of common stock per share	$9.15	$9.15

9. EQUITY COMPENSATION PLANS

Stock Incentive Plans

In connection with the Company's IPO, our board of directors adopted and our stockholders approved our 2024 Plan, which became effective on August 12, 2024, the effective date of the registration statement for the Company's IPO. The purpose of the 2024 Plan is to enhance the Company's ability to attract, retain and motivate individuals by providing these individuals with equity ownership and incentive opportunities. All of the Company's employees, as well as all of the Company's non-employee directors and other consultants, advisors and other persons who provide services to the Company are eligible to receive incentive awards under the 2024 Plan, including stock options grants, stock appreciation rights ("SARs"), restricted stock awards ("RSAs"), restricted stock units ("RSUs"), and other awards. Up to 3,316,444 shares of common stock were originally reserved for future issuance under the 2024 Plan, which number included 496,801 shares of common stock reserved for issuance under the 2015 Plan as of the closing date of the IPO. In addition, the number of shares of common stock available for issuance under the 2024 Plan is subject to an annual increase on the first day of each calendar year beginning on January 1, 2025 and ending on and including January 1, 2034 equal to the lesser of (i) 5% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as determined by the Board. As of December 31, 2025, there were 2,184,341 shares available for grant under the 2024 Plan.

In addition, the Company had previously adopted the 2015 Stock Incentive Plan (the "2015 Plan"). As of December 31, 2025, there were 349,626 stock options outstanding and 17,617 unvested RSAs outstanding under the 2015 Plan. On August 12, 2024, the effective date of the 2024 Plan, there were no remaining shares available for grant under the 2015 Plan.

Restricted Stock Awards

There were no RSAs granted during the years ended December 31, 2025 and 2024. At December 31, 2025, the total estimated unrecognized compensation cost related to unvested service-based RSAs and unvested performance based RSAs was approximately $11,000 and $42,000, respectively. The unrecognized cost related to service-based RSAs is expected to be recognized over the remaining weighted average vesting period of 0.30 years. The unrecognized cost related to performance-based RSAs will be recognized ratably over the performance period based upon the probable number of shares expected to vest. During the years ended December 31, 2025 and 2024, there was no expense recorded for the outstanding performance-based RSAs.

The following summarizes our RSAs transaction activity for years ended December 31, 2025 and 2024:

	Restricted Common Stock Award Shares (#)	Weighted Average Grant Date Fair Value ($)
Unvested balance at December 31, 2023	169,030	2.21
Granted	-	-
Vested	(122,567)	2.11
Forfeited	-	-
Unvested balance at December 31, 2024	46,463	2.48
Granted	-	-
Vested	(28,846)	2.11
Forfeited	-	-
Unvested balance at December 31, 2025	17,617	3.10

Restricted Stock Units

At December 31, 2025, the total estimated unrecognized compensation cost related to unvested RSUs was approximately $1,653,000. This cost is expected to be recognized over the remaining weighted average vesting period of 0.60 years.

The following summarizes our RSUs transaction activity for the years ended December 31, 2025 and 2024:

	Restricted Common Stock Unit Shares (#)	Weighted Average Grant Date Fair Value ($)
Outstanding at December 31, 2023	-	-
Granted	544,111	9.15
Vested and settled	-	-
Forfeited	-	-
Outstanding at December 31, 2024	544,111	9.15
Granted	300,000	8.43
Vested and settled	(26,875)	8.34
Forfeited	(200,000)	8.23
Outstanding at December 31, 2025	617,236	9.13
Awards vested at December 31, 2025	272,055	9.15
Awards nonvested at December 31, 2025	345,181	9.12

Stock Options

The following summarizes our stock option transaction activity for the years ended December 31, 2025 and 2024:

	Number of Shares	Weighted-Average Exercise Price (per share)($)	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value ($)
Outstanding at December 31, 2023	265,566	2.14		
Options granted	542,751	7.13		
Options exercised	-	-		
Options canceled and forfeited	(27,778)	4.68		
Outstanding at December 31, 2024	780,539	5.52		
Options granted	1,077,380	7.16		
Options exercised	(15,942)	2.14		
Options canceled and forfeited	-	-		
Outstanding at December 31, 2025	1,841,977	6.51	8.85	1,137,506
Vested and expected to vest as of December 31, 2025	1,841,977	6.51	8.85	1,137,506
Exercisable as of December 31, 2025	589,821	5.57	8.44	820,334

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between the Company's closing stock price on the last trading day of 2025 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on the last trading day of 2025. This amount changes based on the fair market value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2025 was $131,362.

As of December 31, 2025, total unrecognized stock-based compensation cost related to stock options was approximately $5,539,000. This cost is expected to be recognized over the weighted average remaining period of 1.42 years.

The following table provides the assumptions used in determining the estimated fair value of stock option awards granted during the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Weighted average expected volatility	99.27%	92.54%
Weighted average risk-free interest rate	4.00%	3.75%
Expected dividend yield	0.00%	0.00%
Weighted average expected term (in years)	5.72	5.72

The following table summarizes the stock-based compensation expense recorded in the accompanying consolidated statements of operations during the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Research and development	$ 462,466	$ 147,533
General and administrative	5,584,195	1,848,260
Total	$ 6,046,661	$ 1,995,793

The Company has not recognized and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance related to its net deferred tax assets.

10. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders:

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (22,227,852)	$ (27,285,328)
Denominator:		
Weighted-average shares of common stock outstanding, basic and diluted	21,021,817	8,372,741
Net loss per share attributable to common stockholders, basic and diluted	$ (1.06)	$ (3.26)

The potential dilutive effect of Redeemable Convertible Preferred Stock and Related Party Convertible Notes outstanding during the periods prior to their exercise were calculated using the if-converted method assuming the conversion of underlying instruments as of the earliest period reported or at the date of issuance, if later, but are excluded if their effect is anti-dilutive. The potential dilutive effect of outstanding stock options, outstanding warrants, outstanding RSUs, and unvested RSAs during the period are calculated in accordance with the treasury stock method, but are excluded if their effect is anti-dilutive.

The number of whole shares of common stock that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect were as follows:

	As of December 31,	
	2025	2024
Options issued and outstanding	1,841,977	780,539
Warrants issued and outstanding	922,096	255,599
Unvested restricted stock unit awards issued and outstanding	345,181	544,111
Unvested RSAs	17,617	46,463
Total	3,126,871	1,626,712

11. INCOME TAXES

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes" ("ASC 740"), which requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a full valuation allowance.

The provision (benefit) for income taxes for the years ended December 31, 2025 and 2024 is as follows:

	December 31,	
	2025	2024
Current		
Federal	$ -	$ -
State	800	800
Foreign	-	-
Total current	800	800
Deferred		
Federal	(4,076,182)	(5,918,525)
State	(68,960)	(35,752)
Foreign	-	-
Change in valuation allowance	4,145,142	5,954,277
Total deferred	-	-
Income tax provision	$ 800	$ 800

The income tax provision is included in general and administrative expenses in the accompanying consolidated statements of operations. Deferred tax assets and liabilities reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and amounts used for income tax purposes. Significant components of our deferred tax assets as of December 31, 2025 and 2024 are as follows:

	December 31,	
	2025	2024
Deferred tax assets (liabilities):		
Capitalized R&D, net of amortization	$ 8,771,836	$ 8,914,944
Other	1,667,435	590,030
Net operating loss carryforwards	18,249,620	14,295,945
Research and development tax credits	13,277,728	13,908,401
Total deferred tax assets	41,966,619	37,709,320
Valuation allowance	(41,966,619)	(37,709,320)
Net deferred tax assets	$ -	$ -

Upon adoption of ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, the reconciliation of the effective income tax rate at the Federal statutory rate for the year ended December 31, 2025 is as follows:

	December 31, 2025	
	Amount	**Percentage**
Statutory federal income tax rate	$ (4,667,681)	21.00%
State income tax rate, net of federal income tax effect	632	0.00%
Tax credits:		
Research and development tax credits	(440,198)	1.98%
Change in valuation allowance	5,008,947	(22.54%)
Nontaxable and nondeductible items:		
Other	99,100	(0.44%)
Effective income tax	800	0.00%

The reconciliation of taxes at the federal statutory rate to our provision for (benefit from) income taxes for the year ended December 31, 2024 in accordance with the guidance prior to the adoption of ASU 2023-09 was as follows:

	December 31, 2024
Statutory federal income tax rate	21.00%
Research and development tax credits	6.23%
Other	(2.00%)
Change in valuation allowance	(25.23%)
Effective income tax rate	0.00%

Upon adoption of ASU 2023-09, cash paid for income taxes, net of refunds, during the years ended December 31, 2025 and 2024 was as follows:

	December 31,	
	2025	**2024**
Federal	$ -	$ -
State (California)	800	800
Total cash paid for income taxes, net of refunds	$ 800	$ 800

As of December 31, 2025 and 2024, the Company had gross federal income tax net operating loss ("NOL") carryforwards of $86,521,657 and $67,858,056, respectively, and federal research tax credits of $13,277,728 and $13,908,401, respectively. Of the federal NOL carryforwards, $3,010,902 will expire beginning in 2035 and $83,510,755 has an indefinite life while the federal research tax credits will expire by 2044. In addition, the Company has state NOL carryovers of $696,277 that will carry forward indefinitely.

Utilization of U.S. net operating losses and tax credit carryforwards may be limited by "ownership change" rules, as defined in Sections 382 and 383 of the Code. Similar rules may apply under state tax laws. The Company has not conducted a study to date to assess whether a limitation would apply under Sections 382 and 383 of the Code as and when it starts utilizing its net operating losses and tax credits. The Company will continue to monitor activities in the future. In the event the Company previously experienced an ownership change, or should experience an ownership change in the future, the amount of net operating losses and research and development credit carryovers available in any taxable year could be limited and may expire unutilized.

Federal net operating losses incurred in tax years beginning before December 31, 2017, are subject to a 20 year carry forward period and net operating losses incurred after December 31, 2017, can be carried forward indefinitely but will be subjected to the 80% taxable income limitation. In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion, or all, of the deferred tax asset will be realized. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during periods in which those temporary differences become deductible.

Due to the uncertainty surrounding the realization of the benefits of its deferred assets, including NOL carryforwards, the Company has provided a 100% valuation allowance on its deferred tax assets at December 31, 2025 and 2024.

12. RELATED PARTY TRANSACTIONS

On June 25, 2025, the Company entered into a securities purchase agreement for a private placement of common stock and warrants with certain institutional and accredited investors, including Bios 2024 Co-Invest, LP. Dr. Aaron G.L. Fletcher, the Chairman of the Company's Board of Directors, is a Managing Partner and co-founder of Bios Partners, with which Bios 2024 Co-Invest, LP is affiliated. The Company received $499,996 from Bios 2024 Co-Invest, LP in exchange for 71,428 shares of common stock and warrants to purchase 71,428 shares of common stock (see Note 7).

On August 12, 2024, we issued to Bios Clinical Opportunity Fund, LP, a fund affiliated with a current member and a former member of the board of directors of the Company and a majority shareholder, a promissory note in the principal amount of $200,000 ("August Note") in exchange for net proceeds of $200,000. The August Note accrued interest at a rate of 7% per annum and was due and payable on the earlier of (i) the closing of the IPO or (ii) August 16, 2024, as amended. The August Note was paid in full on August 14, 2024, including accrued interest thereon.

On February 20, 2024, March 27, 2024, and May 8, 2024, the Company issued convertible promissory notes in the amount of $3,000,000, $1,500,000, and $1,000,000, respectively, to Bios Clinical Opportunity Fund, LP (see Note 4).

13. SEGMENT REPORTING

The Company manages its operations as a single operating segment. which includes all activities related to the development and potential commercialization of novel therapies for the treatment of cancer, for the purposes of assessing performance and making operating decisions. The determination of a single business segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker ("CODM"). The Company's CODM is its President and Chief Executive Officer, who reviews and evaluates consolidated net income (loss) for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods.

In addition to the significant expense categories included within consolidated net income (loss) presented on the Company's Consolidated Statements of Operations, see below for disaggregated amounts that comprise research and development expenses for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
External clinical trial expenses	$ 5,051,488	$ 13,387,974
Personnel and consulting expenses	3,514,773	3,183,762
Preclinical and biomarker research	972,646	397,408
Chemistry, Manufacturing & Control ("CMC") related costs	753,713	1,707,132
Total research and development expenses	$ 10,292,620	$ 18,676,276

In addition, the Company has a wholly-owned subsidiary, Actuate Therapeutics Limited, which is a dormant entity with no assets, liabilities or operations in any foreign countries.

14. SUBSEQUENT EVENTS

The Company has evaluated all subsequent events and transactions through the date these consolidated financial statements were issued, to ensure these financial statements include appropriate disclosure of events both recognized in the financial statements and events which occurred but were not recognized in the financial statements. The Company has concluded that no subsequent event has occurred that requires disclosure, except as described herein.

Sales under November 2025 ATM Facility

After the year ended December 31, 2025 through March 25, 2026, we sold 197,059 shares of common stock under the ATM Facility at a weighted-average price of $2.68 per share for net proceeds of approximately $516,000 (see Note 7).

Annual Stock Option Grants

On February 9, 2026, the Company approved the annual grant of 775,000 stock options to employees and other service providers to be granted on April 1, 2026, including the following amounts to be granted to the Company's executive officers: Mr. Schmitt, 237,000 stock options; Mr. Lytle, 105,000 stock options; and Dr. Mazar, 105,000 stock options (the "Annual Option Grants"). The Annual Option Grants will vest as to 25% on the first anniversary of the grant date with the remaining 75% vesting in equal monthly installments during the 36 months following the first anniversary of the grant date.

1751 River Run, Suite 400, Fort Worth, TX 76107
www.actuatetherapeutics.com