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: 001-40874

Cingulate Inc.
(Exact name of registrant as specified in its charter)

Delaware	**86-3825535**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1901 W. 47th Place **Kansas City, KS**	
(Address of principal executive offices)	**66205** (Zip Code)

(913) 942-2300
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value $0.0001 per share	CING	The Nasdaq Stock Market LLC (Nasdaq Capital Market)
Warrants, exercisable for common stock	CINGW	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Securities registered pursuant to Section 12(g) of the Act: None

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the 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 and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant computed by reference to the closing price of the registrant's common stock on June 30, 2025 was approximately $19.4 million. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares outstanding of the registrant's common stock, par value of $0.0001 per share, as of March 13, 2026 was 11,628,613.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Cingulate Inc.
Annual Report on Form 10-K
For the Year Ended December 31, 2025

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of filing this annual report with the SEC and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about the following:

- our ability to maintain compliance with the continued listing requirements of The Nasdaq Stock Market LLC ("Nasdaq");
- our ability to obtain approval for CTx-1301 and the timing of any such approval;
- our lack of operating history and need for additional capital;
- our plans to develop and commercialize our product candidates;
- the timing of our planned clinical trials for our product candidates;
- the timing of our New Drug Application ("NDA") submissions for our product candidates;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the clinical utility of our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to identify strategic partnerships;
- our expected use of cash;
- our competitive position and projections relating to our competitors or our industry;
- our ability to identify, recruit, and retain key personnel;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2021 (the "JOBS Act");
- our plans to identify additional product candidates with significant commercial potential that are consistent with our commercial objectives; and
- our estimates regarding future revenue and expenses.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. You should refer to the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this annual report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. We operate in an evolving environment and new risk factors and uncertainties may emerge from time to time. It is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this annual report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should review the factors and risks and other information we describe in the reports we will file from time to time with the SEC.

PART I

ITEM 1. BUSINESS

Overview

We are a biopharmaceutical company using our proprietary Precision Timed Release™ ("PTR™") drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. With an initial focus on the treatment of Attention Deficit/Hyperactivity Disorder ("ADHD") and anxiety, we are identifying and evaluating additional therapeutic areas where our PTR technology may be employed to develop future product candidates. Our PTR platform incorporates a proprietary Erosion Barrier Layer ("EBL") designed to allow for the release of drug substance at specific, pre-defined time intervals, unlocking the potential for once-daily, multi-dose tablets.

We are targeting the ADHD treatment market, with an estimated US market size of approximately 100 million annual prescriptions of stimulants, as of September 2025. Furthermore, the average branded long-acting stimulant wholesale acquisition cost (WAC) is $495/Rx. It is reasonable to assume that a 1% market share capture would represent approximately $250 to $300 million in annual revenue less rebates and discounts in this marketplace. Stimulants are historically the most commonly prescribed class of medications for ADHD and accounted for approximately 90% of all ADHD medication prescriptions in the United States during the year ended September 30, 2025. For example, by contrast, non-stimulant medications are typically employed only in the second-line or adjunctive therapy setting. Extended-release, or long-acting, dosage forms of stimulant medications are most frequently deployed as the first-line treatment for ADHD. Most of these extended-release dosage forms are approved for once-daily dosing in the morning and were designed to eliminate the need for re-dosing during the day. However, with the current 'once-daily' extended-release dosage forms, most patients still receive a second or "booster" dose for administration later in the day (typically in the early afternoon) to achieve active-day coverage and suffer from a multitude of unwanted side effects as a result. We believe there is a significant, unmet need within the current treatment paradigm for true once-daily ADHD stimulant medications with lasting duration to better serve the needs of patients throughout the entire active-day.

Our two proprietary, first-line stimulant medications: CTx-1301 (dexmethylphenidate) and CTx-1302 (dextroamphetamine), are being developed for the treatment of ADHD across all three patient segments: children (ages 6 -12), adolescents (ages 13-17), and adults (ages 18+). Both CTx-1301 and CTx-1302 are designed to address the key shortcomings of currently approved stimulant therapies by: providing a near immediate onset of action (within 30 minutes); offering entire 'active-day' duration; eliminating the need for 'booster/recovery' doses of additional stimulant medications; minimizing or eliminating the rebound/crash symptoms associated with early medication 'wear-off;' and providing favorable tolerability with a controlled descent of drug blood levels. Furthermore, by eliminating the 'booster' dose, we believe our product candidates will provide important societal and economic benefits: reducing the abuse and diversion associated with short-acting stimulant medications; allowing physicians to prescribe one medication versus two; allowing patients to pay for one medication versus two; and allowing payers to reimburse one medication versus two.

We have also embarked on a program to develop CTx-2103 (buspirone), for the treatment of anxiety, which is one of the most common mental health concerns in the United States. In 2025, United States sales of buspirone accounted for over $1 billion of sales in the $15.2 billion anxiety and depression market. According to OptumRx Commercial data, the average patient takes 2.3 doses of buspirone per day. CTx-2103 is being designed as a true, once-daily administration of buspirone that incorporates our proprietary PTR™ drug delivery platform. Buspirone, an azapirone derivative and a 5-HT1A partial agonist, was the first non-benzodiazepine anxiolytic introduced for the treatment of generalized anxiety disorder. Buspirone may exhibit a decreased side-effect profile compared to other anxiolytic treatments. Unlike benzodiazepines and barbiturates, there is no associated risk of physical dependence or withdrawal with buspirone use due to the lack of effects on gamma-aminobutyric acid receptors. Furthermore, buspirone is not regulated as a controlled substance by DEA or under the Controlled Substances Act of 1970 (the "CSA").

CTx-1301

We completed a proof-of-concept trial in human subjects to validate our PTR platform and in October 2020, announced positive results from a Phase 1/2 study of CTx-1301 in ADHD patients establishing tolerability, comparative bioavailability, and dose proportionality of CTx-1301 versus Focalin® XR. In order to meet the pharmacology requirement for the CTx-1301 NDA submission, we completed a food effect study in October 2022 (25mg dose) and December 2024 (50mg dose). Each study demonstrated that CTx-1301 can be taken with or without food.

A Phase 3 adult dose-optimization study to assess the efficacy and safety, along with onset and duration, of CTx-1301 in adults with ADHD was initiated in December 2022 and completed in June 2023. Results were presented at the 2023 Psych Congress and were presented at the 2024 American Professional Society of ADHD and Related Disorders ("APSARD") in January 2024. This Phase 3 CTx-1301 study (NCT05631626) assessed efficacy and safety along with onset and duration of CTx-1301 in 21 adults (age range: 18-55 years) with ADHD in an adult laboratory classroom setting. The study did not achieve statistical significance on the primary efficacy endpoint but CTx-1301 demonstrated a trend toward significance in improving Permanent Product Measure of Performance ("PERMP") scores compared to the placebo. Clinical Global Impression Scale ("CGI-S") scores with CTx-1301 compared to placebo also showed significant improvements that were indeed statistically significant for this secondary endpoint. The treatment effect size of CTx-1301 in this trial was notable – starting at 30 minutes and demonstrated the ability of CTx-1301 to improve upon ADHD symptoms in patients over an entire active day.

In addition, we initiated two CTx-1301 Phase 3 clinical studies in pediatric and adolescent patients - a fixed dose study (NCT05286762) and a dose-optimized onset and duration study in a laboratory classroom setting (NCT05924594) – in the third quarter of 2023. Based on written communication with the Food and Drug Administration ("FDA") that further conduct of these pediatric and adolescent studies was not required for the submission of an NDA, we closed enrollment on both Phase 3 trials. Analysis of the safety data from the two closed Phase 3 trials and the 50mg dose food effect study revealed that no subjects experienced a serious treatment emergent adverse event ("TEAE"), a serious TEAE or a TEAE leading to death and there were no clinically relevant trends in TEAEs overall. A final analysis that combines both adult and pediatric safety and efficacy data was included in the NDA submission for CTx-1301 which was submitted to the FDA on July 31, 2025. The FDA accepted for review the NDA for CTx-1301 and assigned a PDUFA target action date of May 31, 2026. However, there can be no assurance that approval of CTx-1301 will occur on or about the PDUFA date or that approval of CTx-1301 will occur at all. See "*Risk Factors—We depend heavily on the success of CTx-1301. If we are unable to secure approval of CTx-1301, we will never be able to generate revenues from CTx-1301, and our ability to create stockholder value will be severely limited*" on page 46.

We were issued a first European patent for CTx-1301 for the treatment of ADHD on August 14, 2024 and a second European patent for CTx-1301 for the treatment of ADHD on December 17, 2025. The patent applications will include up to 30 European territories, including the United Kingdom, and will provide patent protection until 2042. We are awaiting prosecution of patents in the US and other geographies. On March 17, 2026 the United States Patent and Trademark Office (USPTO) issued a Notice of Allowance for a patent application covering CTx-1301.

CoreRx, Inc., doing business as Bend Biosciences, a contract development and manufacturing organization ("CDMO"), will manufacture all clinical, registration, and, if approved, commercial batches of our lead ADHD candidate, CTx-1301. Manufacturing will occur at a suite within the CDMO's Gainesville, GA facility that is outfitted with equipment supplied by us.

In March 2023, we entered into a joint commercialization agreement with Indegene, Inc. ("Indegene") to partner in the commercialization of CTx-1301 in the United States pending FDA approval. The joint commercialization agreement was replaced with a master services agreement in May 2025 (the "Commercialization Agreement"). We are able to utilize Indegene for commercialization services for CTx-1301, including marketing, market access and pricing, commercial operations, and an unparalleled omnichannel on a fee for service basis in the United States.

In November 2025, we entered into a into a licensing and services master agreement with IQVIA Inc. ("IQVIA") to partner in the commercialization of CTx-1301 in the United States pending FDA approval. We are able to utilize IQVIA for commercialization services for CTx-1301, including field sales and national account management.

CTx-1302

We plan to initiate the clinical plan for CTx-1302 (dextroamphetamine), our second investigational asset for the treatment of ADHD, pending additional capital resources.

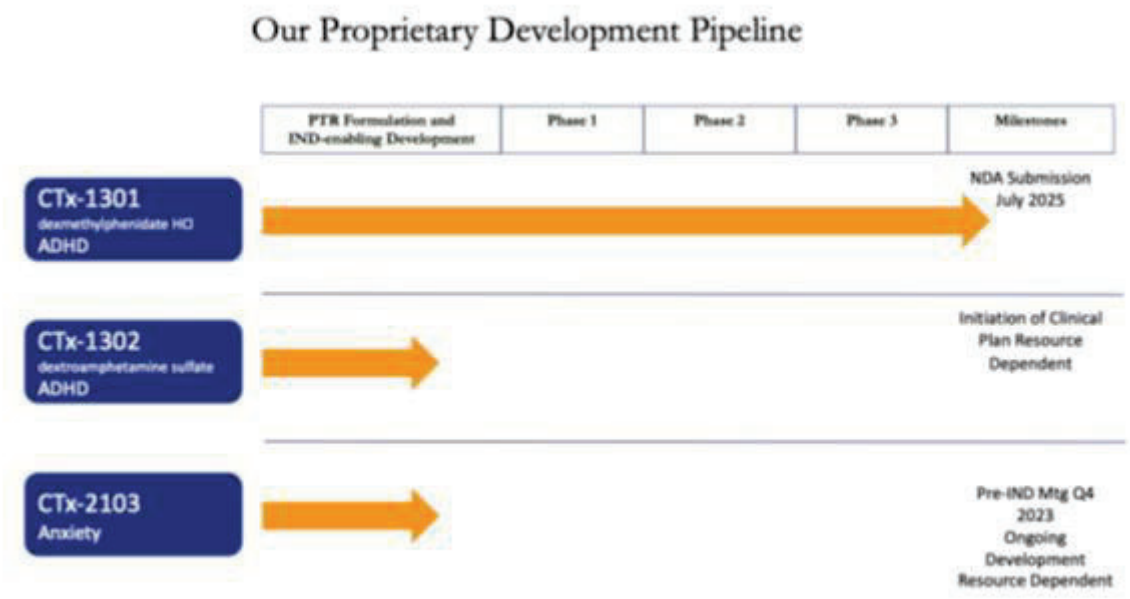
CTx-2103

CTx-2103 will be designed as a once-daily, modified-release tablet with clear differentiation and compelling advantages over standard treatment options which must be taken multiple times per day to maximize efficacy. We completed a formulation study in which the pharmacokinetics were evaluated for this trimodal tablet providing three precisely timed doses of buspirone versus one immediate release dose. In addition, scintigraphic imaging visualized transit of the tablets through the gastrointestinal tract to confirm both the site and onset of release, which will then be correlated with pharmacokinetic data to

establish the full release profile of the CTx-2103 formulation. Based on the pharmacokinetic profile seen in the data, CTx-2103 achieved a triple release of buspirone. These results provided the critical information required to allow us to request a Pre-IND meeting with the FDA to discuss the design of our clinical and regulatory program for CTx-2103 which occurred in the fourth quarter of 2023. We received input from the FDA regarding the regulatory pathway for CTx-2103, and the design of clinical studies for filing of an IND. Based on this FDA feedback, we believe that we can seek and win approval of CTx-2103 under the 505(b)(2) pathway, which typically requires less time and resources than the 505(b)(1) full NDA pathway. Additional capital resources will be required to continue the development of this product candidate.

We believe that our PTR platform has the potential to provide patients and physicians with differentiated pharmaceutical treatment options that will enhance patient compliance and improve health outcomes in several additional therapeutic areas. We intend to leverage our PTR platform technology to expand and augment our clinical-stage pipeline by identifying and developing additional assets in other therapeutic areas where one or more active pharmaceutical ingredient ("APIs") need to be delivered several times a day at specific, pre-defined time intervals and released in a manner that would offer significant improvement over existing therapies. Our criteria for the selection of additional, future pipeline candidates will include the potential for $1 billion or more in peak annual sales, the potential to deliver a clearly differentiated therapeutic advantage and the potential to overcome unmet medical needs. We will consider potential in-licensing of additional assets or out-licensing the PTR platform as those opportunities arise.

Our Clinical Development Pipeline



Our Strategy

Our goal is to be a leading, innovative biopharmaceutical company focused on the development, manufacturing and commercialization of next generation pharmaceutical products that utilize our PTR drug delivery platform technology to create dosing schedules and drug release profiles that will improve the lives of patients suffering from a multitude of frequently diagnosed conditions. Key initial elements of our business strategy to achieve this goal are to:

- ***Obtain regulatory approval for CTx-1301 for the treatment of ADHD.*** In October 2020, we announced positive results from a Phase 1/2 study of CTx-1301 in ADHD patients establishing tolerability, comparative bioavailability, and dose proportionality of CTx-1301 versus Focalin® XR. A Phase 3 adult dose-optimization study to assess the efficacy and safety, along with onset and duration, of CTx-1301 in adults with ADHD was initiated in December 2022 and completed in June 2023. Results were presented at the 2024 APSARD in January 2024. In addition, we initiated two CTx-1301 Phase 3 clinical studies in pediatric and adolescent patients- a fixed dose study and a dose-optimized onset and duration study in a laboratory classroom setting – in the third quarter of 2023. Based on written communication with the FDA that further conduct of these pediatric and adolescent studies is not required for the

submission of an NDA, we closed enrollment on both Phase 3 trials. In addition, per FDA guidance, we completed a food effect study utilizing CTx-1301's highest dosage strength, 50-mg, in December 2024. An NDA was submitted to FDA on July 31, 2025 and accepted for review on September 29, 2025 and we were assigned a PDUFA target action date of May 31, 2026. Throughout the review process, the FDA has made several information requests, primarily related to CMC. We have been engaged with and responded to all information requests from the FDA received to date. In February 2026, the FDA conducted a pre-approval inspection of our CDMO's Gainesville, GA facility that is outfitted with equipment supplied by us for the manufacture of CTx-1301. Our CDMO was issued a Form 483 by the FDA at the conclusion of the inspection with three observations. Two observations were related to our CDMO's facility and one observation was specific to CTx-1301. Our CDMO is working on responses to these observations, with our input where relevant. There can be no assurance that approval of CTx-1301 will occur on or about the PDUFA date or that approval of CTx-1301 will occur at all. See "Risk Factors—We depend heavily on the success of CTx-1301. If we are unable to secure approval of CTx-1301, we will never be able to generate revenues from CTx-1301, and our ability to create stockholder value will be severely limited" on page 46.

- ***Successfully commercialize CTx-1301***. If we receive FDA approval for CTx-1301, pursuant to the Commercialization Agreement, we will partner with Indegene in the commercialization of CTx-1301. Indegene's comprehensive commercialization infrastructure includes marketing, market access and pricing, commercial operations, and an unparalleled omnichannel platform. In addition, we are now focusing on third party logistics services to ensure commercial availability.
- ***Advance clinical trials for CTx-2103 for the treatment of anxiety.*** In September 2022, we announced that data from the human formulation study for CTx-2103 demonstrated its ability to deliver a single administration of triple-release buspirone. These results provided the critical information required to allow us to request a Pre-IND meeting with the FDA to discuss the design of our clinical and regulatory program for CTx-2103 which occurred in the fourth quarter of 2023. We will use results from the human formulation study and feedback from FDA to design the clinical program for CTx-2103, which will be designed as a once-daily, multi-dose tablet with what we believe will be clear differentiation and compelling advantages over standard treatment options. Development of CTx-2103 (buspirone) for the treatment of anxiety will require additional capital resources.
- ***Advance development of CTx-1302 for the treatment of ADHD.*** We plan to initiate a clinical plan for CTx-1302 (dextroamphetamine), our second investigational asset for the treatment of ADHD, pending additional capital resources.
- ***Maximize the potential of our PTR platform to develop additional product candidates in new indications with significant unmet medical need and billion-dollar revenue potential.*** We intend to use our PTR drug delivery platform technology and the streamlined 505(b)(2) development pathway to develop additional therapeutic assets in other therapeutic areas where one or more active pharmaceutical ingredients need to be administered several times a day at specific, pre-defined time intervals and released in a manner that would offer significant improvement over existing therapies. We believe this will lead to improved patient compliance and better health outcomes. Further indications we intend to evaluate include insomnia, non-opioid pain, Alzheimer's, hypothyroidism, psychosis, depression, cardiovascular disorders, Parkinson's disease, migraine, oral oncology, xerostomia (dry mouth) and bipolar disorder, among others.
- ***Acquire or in-license additional assets or programs to complement our portfolio and/or leverage our technology.*** We continuously evaluate potential partnering opportunities or asset acquisitions that can bolster our current product candidate portfolio and provide substantial value to our organization. We intend to focus on early to mid-stage development product candidates to generate clinical data and potentially move to later stages of development and ultimately on to commercialization.
- ***Out-license our PTR platform to other companies and license our product candidates in the United States and internationally.*** We may seek and evaluate opportunities to license our current assets and the PTR drug delivery platform technology to other companies looking to serve large patient populations with unmet needs and/or looking to transform multiple daily dosing to once daily administration to satisfy patient needs. We also evaluate opportunities to license our product candidates to third parties for use in the United States and internationally.
- ***Further strengthen our intellectual property portfolio***. We intend to continue to manage and expand our diverse intellectual property portfolio and maintain our trade secrets and know-how focused on our PTR platform, current and future pipeline candidates, and proprietary manufacturing process. We believe these activities will be critical to protect our platform and product candidates from potential competitors that may try to compete with our therapeutic assets and compression tableting approach.

Our Team

Our founders and management team have many years of experience in the biopharmaceutical space, holding management positions at leading biopharmaceutical companies, including Pfizer Inc., Novartis International AG, and Sanofi S.A., among others. Our team possesses substantial experience and expertise across the spectrum of drug development and commercialization of pharmaceutical products, including multiple psychiatric and nervous system products.

Shane J. Schaffer, our Co-Founder and Chief Executive Officer, has held senior leadership roles at Pfizer Inc., Novartis International AG and Sanofi S.A. and has over 25 years of experience in drug development and commercialization. Dr. Matthew Brams, our Co-Founder and Chief Medical Officer, has over 30 years of clinical experience managing patients in the field of adult and child psychiatry and has been involved in the research, development, and evaluation of multiple ADHD medications. Dr. Raul R. Silva, our Co-Founder and Chief Science Officer, is a practicing child and adolescent psychiatrist who has served as Associate Professor and Vice Chairman of Child and Adolescent Psychiatry at NYU School of Medicine in New York City. Bryan Downey, our Chief Commercial Officer, has over 25 years of commercial leadership in the biopharmaceutical industry, including senior leadership roles at Sanofi S.A. and Jubilant Pharma, and served as President and CEO of Alfasigma USA. Nilay Patel, our Chief Legal Officer, has over 20 years of legal, compliance, and operational leadership in the pharmaceutical industry, including senior legal positions at Grifols S.A. and served as Chief Legal Officer at Ironshore Pharmaceuticals.

ADHD Overview and Drawbacks of Current Therapies

ADHD is a chronic neurobehavioral and developmental disorder that affects millions of children, adolescents and adults. In the United States, many of the children and adolescents aged 4-17 that have been diagnosed with ADHD demonstrate clinical ADHD symptoms that persist into adulthood. Adult ADHD prevalence in the United States is estimated to be significantly larger than the size of the child and adolescent segment combined. Total prescriptions of extended-release stimulants in the United States continue to grow by 10.2% annually, for the 12-months ended September 2025.

ADHD is marked by an on-going pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning and/or development. According to the American Academy of Child and Adolescent Psychiatry, common manifestations of ADHD in children and adolescents include:

Hyperactivity: Children always seem to be in motion. A child who is hyperactive may move around touching or playing with whatever is around or talk continually. During story time or school lessons, the child might squirm around, fidget, or get up and move around the room. Some children wiggle their feet or tap their fingers. A teenager or adult who is hyperactive may feel restless and need to stay busy all the time.

Impulsivity: Children often blurt out comments without thinking first. They may often display their emotions without restraint. They may also fail to consider the consequences of their actions. Such children may find it hard to wait in line or take turns. Impulsive teenagers and adults tend to make choices that have a small immediate payoff rather than working toward larger delayed rewards.

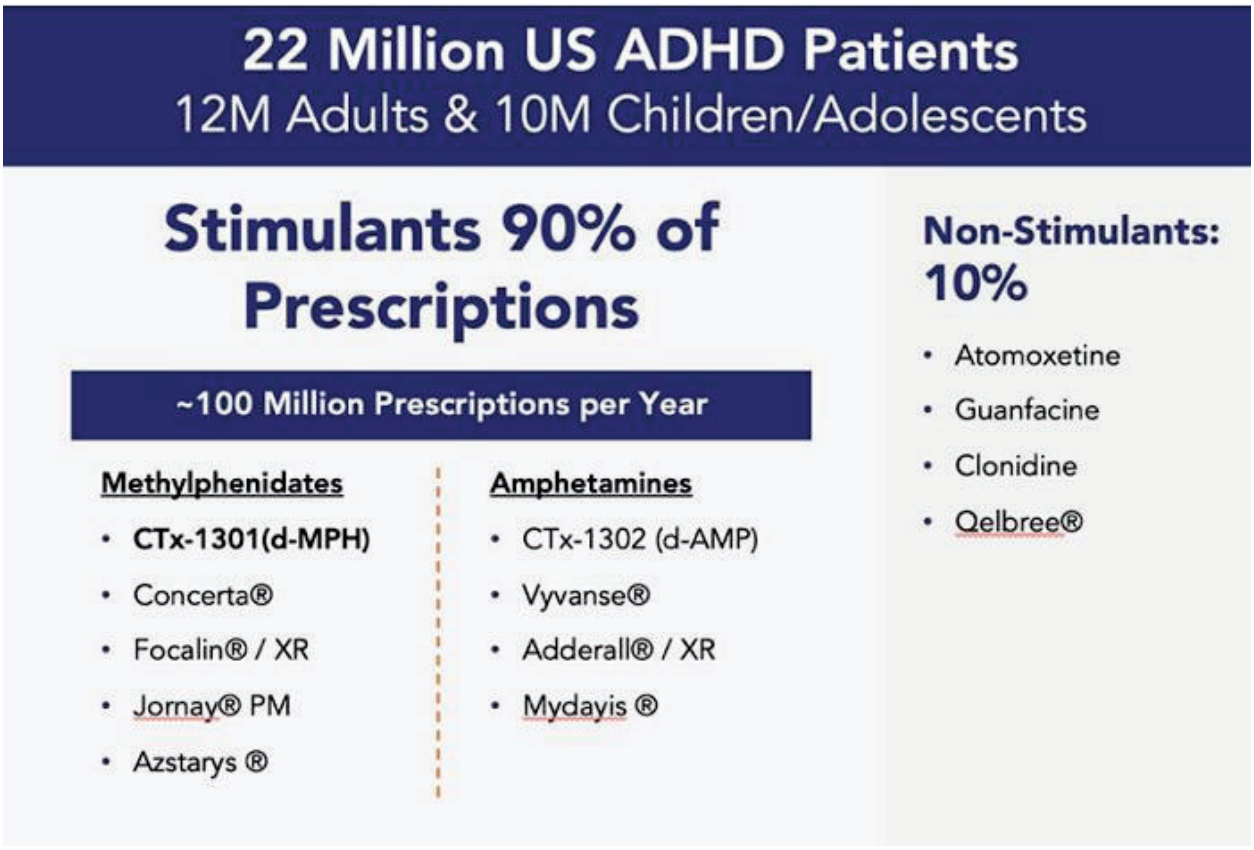
Inattentiveness: Inattentive children may quickly get bored with an activity if it's not something they really enjoy. Organizing and completing a task or learning something new is difficult for them. As students, they often forget to write down a school assignment or bring a book home. Completing homework can be huge challenge. At any age, an inattentive person may often be easily distracted, make careless mistakes, forget things, have trouble following instructions, or skip from one activity to another without finishing anything.

Adult ADHD patients typically suffer from restlessness, impulsivity, difficulty with time management, trouble regulating emotions and difficulty managing finances. Adults with ADHD report experiencing an internal sense of fidgetiness and restlessness and experience greater difficulty communicating with others. Upon entering the job market, many adults have difficulty gaining employment and are at increased risk of termination due to repeated tardiness or absenteeism. Additionally, adults with ADHD are more likely to exhibit a variety of comorbidities including drug and alcohol abuse, social anxiety and depression.

ADHD in both children and adults has an impact not only on the individual but on their families, friends and peers and because of its prevalence as one of the most commonly diagnosed behavioral disorders, a critical impact on society, the healthcare system and the economy at large. On a societal level, versus control groups, ADHD patients have historically experienced a higher rate of vehicle accidents, divorce, incarceration, and accidental death.

Although there is no single medical, physical, or genetic test for ADHD, qualified mental health care professionals and physicians are able to provide a diagnostic evaluation after gathering information from multiple sources including ADHD symptom checklists, standardized behavior rating scales, detailed histories of past and current functioning, and information obtained from close family members or significant others. Some practitioners will also conduct tests of cognitive ability and academic achievement in order to rule out a possible learning disability.

Stimulants are historically the most commonly prescribed class of medications for ADHD, accounting for approximately 90% of all ADHD medication prescriptions during the 12-months ended September 2025. Stimulants are Schedule II controlled substances and are believed to work by enhancing the effects of dopamine and norepinephrine neurotransmitters in the brain. Approximately 96 million stimulant prescriptions were written during the 12-months ended September 2025. In contrast, non-stimulant medications are typically deployed as second line or adjunctive therapies and accounted for approximately 10% of all ADHD medication prescriptions during that time. Currently, 92% of the ADHD extended-release stimulant market is dominated by four main medications: Vyvanse®, Adderall® XR, Concerta®, and Focalin® XR. These products were approved and became available between 2000 and 2007 and revolutionized ADHD treatment paradigm by finally providing a solution to avoid the late morning second dose of stimulant medication then required by ADHD patients. However, each product does not provide entire-active day efficacy with many patients requiring a booster dose of a short-acting stimulant medication.



Unfortunately, as designed, all four of the mostly commonly prescribed stimulant drugs deliver all the drug substance during the morning hours. As a result, most patients (up to 60%) still require additional medication to cover the remainder of their active day. Historically, a majority of ADHD patients have required an afternoon 'booster/recovery' dose due to lack of duration, slow onset of efficacy, and the crash or rebound effects in the early afternoon. Additionally, their PK-PD release profiles are such that they leave patients significantly impaired by crash and rebound effects even while on therapy.

Patients and practitioners report, that an ideal ADHD stimulant medication would provide ***all*** of the following characteristics: entire active-day duration; immediate onset of action (within 30 minutes); ability to minimize or avoid crash / rebound effects associated with rapid decline in medication blood levels; and elimination of the need for short-acting stimulant booster/recovery doses.

ADHD BRANDS	APPROVED	ATTRIBUTES[1]		UNMET NEEDS[1]			
		Onset	Duration (less onset)	Fast Onset of Action ≤ 30 min	Entire Active-Day Efficacy*	Minimize Crash/Rebound	Avoid Booster[1]
Vyvanse®	2007	1 ½ - 2 hours	8-9 hours	×	×	×	×
Adderall® XR	2001	1 ½ hours	7-8 hours	×	×	×	×
Concerta®	2000	2 hours	6-7 hours	×	×	×	×
Focalin® XR	2005	30 mins	7-8 hours	✓	×	×	×

92% of ALL Extended Release Stimulant Rx's[3]

60% use short-acting 'booster' dose every day![2]

- Entire-active day efficacy defined as less than or equal to a 30 min onset of action with true 12 hours of duration vs. baseline

Sources [1] Information based upon product Package Inserts, and Summary Basis of Approvals for the approved products in chart and Ann C. Childress, Nathalie Beltran, Carl Supnet & Margaret D. Weiss (2021) Reviewing the role of emerging therapies in the ADHD armamentarium, Expert Opinion on Emerging Drugs, 26:1, 1-16. [2] Outside the Box: Rethinking ADD/ADHD in Children and Adults A Practical Guide; First Edition, p. 185 Thomas E. Brown, PhD. [3] IQVIA, Stimulant Prescription Trends in the United States (2012–2023)

The chart above is based upon the Package Inserts and Summary Basis of Approvals for the approved products.

ADHD Market Leaders Do Not Provide "Built-In Booster"

Market Leaders Stop Delivery of Medication 4-5 Hours After Administration

ADHD BRANDS	ATTRIBUTES[1]		RELEASE PROFILES[1]		
	Onset	Duration (less onset)	DOSE 1 / STYLE / TIME	DOSE 2 / STYLE / TIME	DOSE 3 / STYLE /TIME
Vyvanse®	2 hours	12 hours	100% PRODRUG SUSTAINED RELEASE OVER 2 – 3 HOURS	0	0
Adderall® XR (and generics)	1 ½ hours	10 ½ hours	50% IMMEDIATE RELEASE	50% IMMEDIATE RELEASE AT HOUR 4	0
Concerta® (and generics)	2 hours	10 hours	22% IMMEDIATE RELEASE	78% SUSTAINED RELEASE OVER 4-5 HOURS	0
Focalin® XR (and generics)	30 mins	11½ hours	50% IMMEDIATE RELEASE	50% IMMEDIATE RELEASE AT HOUR 4	0

[1] Information based upon product Package Inserts, and Summary Basis of Approvals

The chart above is based upon the Package Inserts and Summary Basis of Approvals for the approved products.

In recent years, the FDA has approved additional stimulant medications that were designed to meet some of the remaining unmet needs. Chewables, liquids and oral disintegrating tablets have come to market as has one product with an evening dosing schedule intended to provide early morning onset. None of these products have been able to meet all of the unmet needs of ADHD patients and prescribers and consequently all have failed to gain traction as first-line agents. Furthermore, these recent stimulant medications, based on their market share, appear to offer little advantage over widely available generic products for healthcare practitioners and their patients. They have proven to be niche remedies occupying approximately 2.0% of the total ADHD prescriptions written in the United States in 2025. Thus, there is an unmet need for a true once-daily dose providing a fast onset of action, minimization or elimination of the crash/rebound, elimination of the booster/recovery dose, and most importantly, providing entire 'active-day' efficacy.

Recent Launches Lack Meaningful Clinical Innovation

Niche Delivery Platforms – Designed to Fail in ADHD

ADHD BRANDS	ATTRIBUTES[1]		UNMET NEEDS			
Product	Onset	Duration	Fast Acting (≤ 30 min)	Entire Active-Day Efficacy*	Avoid Crash/Rebound	Avoid Booster
Quillivant / Chew® XR	60 mins	8 hours	✗	✗	✗	✗
Mydayis®	2 or 4 hrs	16+ hours	✗	✗	✗	✗
Adzenys® ER/ODT	60 mins	8-9 hours	✗	✗	✗	✗
Cotempla® XR/ODT	60 mins	10-12 hours	✗	✗	✗	✗
Aptensio® XR	60 mins	9 hours	✗	✗	✗	✗
Evekeo® / ODT	60 mins	10 hours	✗	✗	✗	✗
Dynavel® XR Oral Susp.	60 min	13 hours	✗	✗	✗	✗
Zenzedi®	60 mins	4-5 hours	✗	✗	✗	✗
Jornay® PM (at night)	2-hour window	10-11 hours	✗	✗	✗	✗
Adhansia® XR – *Discontinued*	60 mins	12-13 hours	✗	✗	✗	✗
Azstarys® (summer 2021)	Failed Endpoint	Failed Endpoint	✗	✗	✗	✗

* Entire-active day efficacy defined as less than or equal to a 30 min onset of action with 14-16 hours of duration vs. placebo

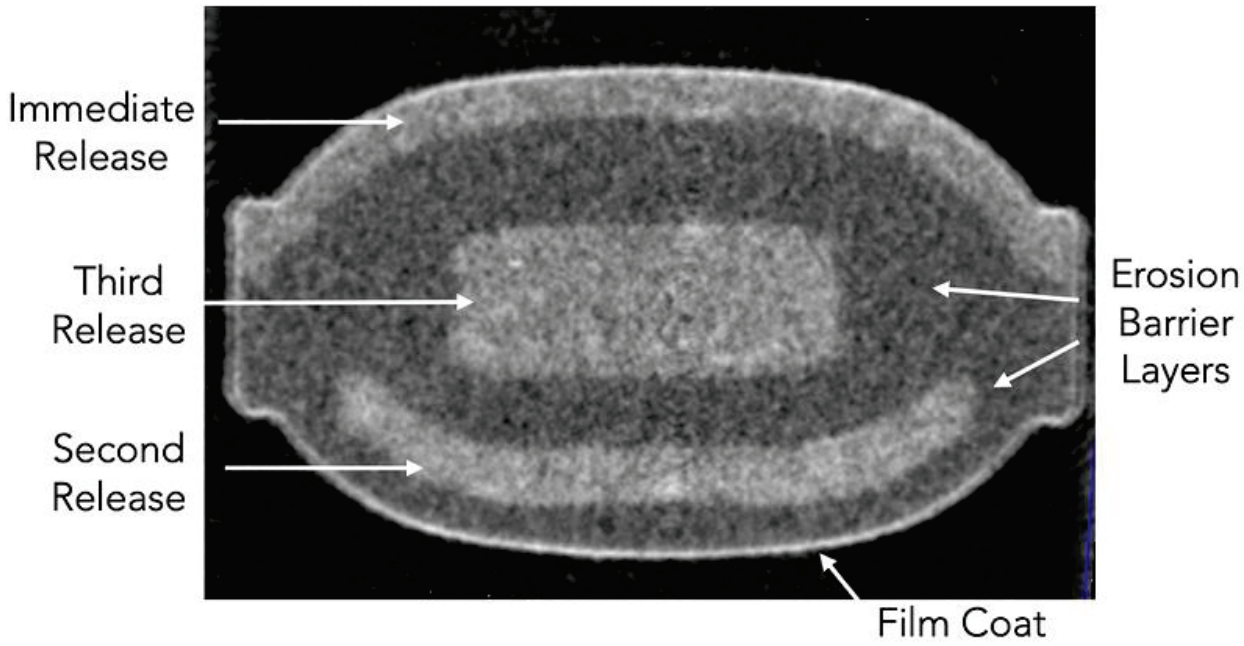
[1] Information based upon product Package Inserts and Summary Basis of Approvals and Ann C. Childress, Nathalie Beltran, Carl Sugnet & Margaret D. Weiss (2021) Reviewing the role of emerging therapies in the ADHD armamentarium, Expert Opinion on Emerging Drugs, 26:1, 1-16.

The chart above is based upon the Package Inserts and Summary Basis of Approvals for the approved products.

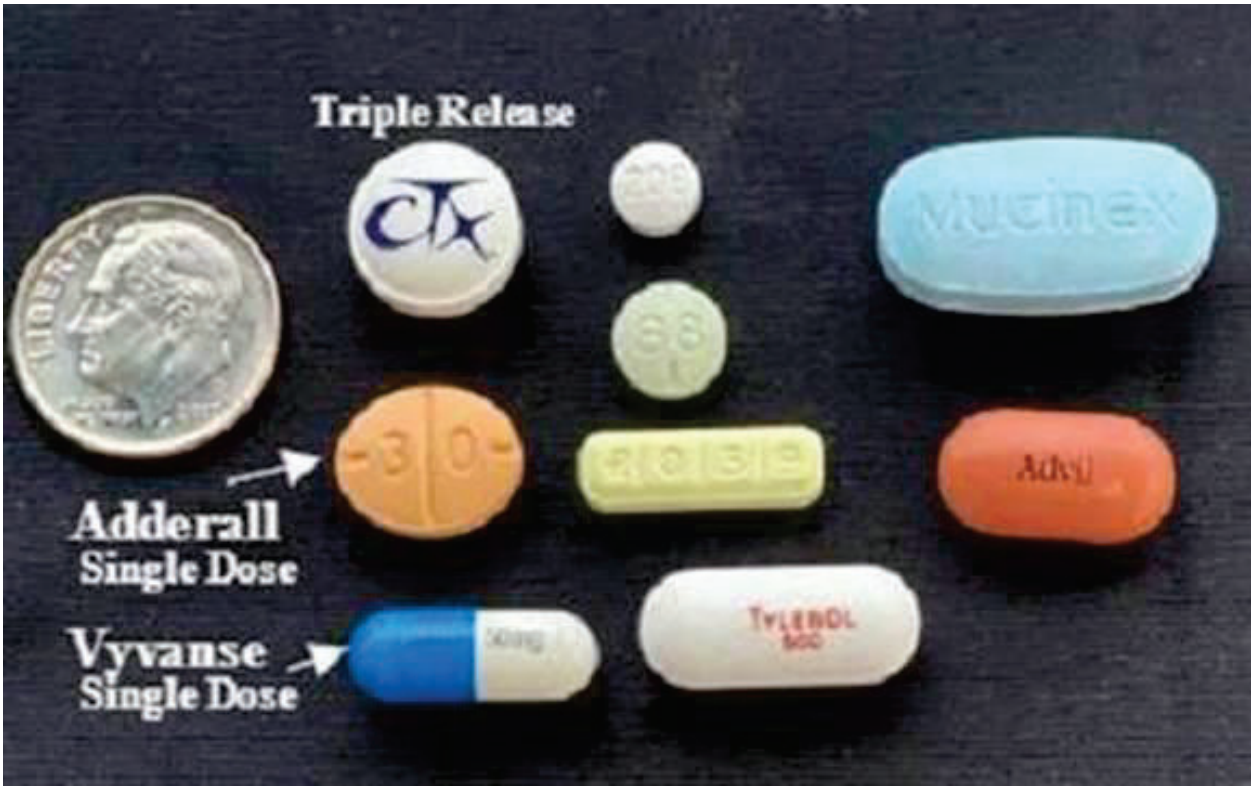
Our Solution: Our Proprietary Precision Timed Release Drug Delivery Platform Technology

We are developing medications capable of achieving true once-daily dosing using our internally developed PTR drug delivery platform technology. Our CTx-1301, CTx-1302 and CTx-2103 drug candidates contain three releases of active pharmaceutical ingredient combined into one small tablet dosage form (smaller than many comparable single dose ADHD products). Each release of API is separated with a proprietary EBL, a functional excipient that is designed to gradually erode throughout the day to provide controlled drug release at specific time intervals, allowing for a favorable target efficacious period.

Illustration of Our PTR Platform Film-Coated Tablet



Size Comparison of CTx-1301 Tablet versus Common ADHD and Other Medications



We believe our PTR technology affords our drug candidates the following advantages over currently available ADHD treatments:

Fast Onset. Many currently available therapies often take up to 60 minutes or longer to start working and thus can leave patients with long gaps between dosing and onset. In an effort to minimize this onset gap, patients will often wake up early to take their medication and attempt to go back to sleep until the medication takes effect. We have designed our drug candidates to be fast-acting so they can be taken in the morning when the patient starts their day, not predawn while they wait for onset.

Reduction of Need For Additional Stimulant Boosters. With entire active-day coverage, we believe our technology will reduce the need for patients to take afternoon booster doses when their currently prescribed therapies wear off. By reducing the need for a booster dose, we believe our candidates will cause less embarrassment for patients, especially child and adolescent patients who are often forced to take a second dose while at school surrounded by classmates and increase patient compliance especially in the ADHD population where patients are prone to forget to take the additional dose they need to get through their active day.

Lower Abuse Potential. We believe our fast onset and entire active-day solution for ADHD patients, if approved, will lower the incidence of short-acting stimulant drug abuse and diversion. We believe by eliminating the need for the short-acting stimulant booster dose, the potential for illicit sales and recreational use that often comes as a result of patients carrying short-acting Schedule II controlled substances to school or work for afternoon dosing will decrease.

Fewer Crash and Rebound Symptoms. Patients on currently available therapies may report adverse effects or a flare of ADHD symptoms as their medications wear off; these effects are termed "crash" and "rebound." Using our precise timing, ratio, and style of drug delivery, we believe our candidates provide a controlled descent of blood levels, mitigating this uncomfortable experience for patients.

Lower Cost. By providing entire active-day efficacy, our drug candidates eliminate the need for doctors to prescribe more than one medication lowering the overall cost of the condition to individual patients and within the healthcare system at large. Furthermore, generic medications in the stimulant ADHD category are not tremendously less expensive as they are in other categories of non-controlled medications. Generic stimulant medications cost anywhere from 55%-90% of the cost of their brand counterparts. We believe, if approved, our drug candidates will offer a much more cost-effective solution to patients.

Availability in Eight Dosage Strengths at Launch and Single-Enantiomer API Selection. Our CTx-1301 and CTx-1302 product candidates are both round film-coated tablets that we intend to provide in eight matching dosage strengths. We believe providing practitioners with the ability to properly titrate and optimize their patients' daily dosing needs is critical. By having eight dosage strengths, practitioners will not have to constantly switch their patients to other medications or supplement patients with more short-acting booster medications. In addition, we believe that eight dosage strengths will allow healthcare practitioners to appropriately treat the range of patients in their practice, from early childhood through adulthood. CTx-1301 contains Schedule II controlled substances. The API of CTx-1301 utilizes just one of the multiple enantiomers, which may result in improvements in potency, adverse events (AEs), and drug interactions profiles along with an enhanced therapeutic index.

Our Lead Candidate CTx-1301: Dexmethylphenidate for the Treatment of ADHD in 6 Years and Older

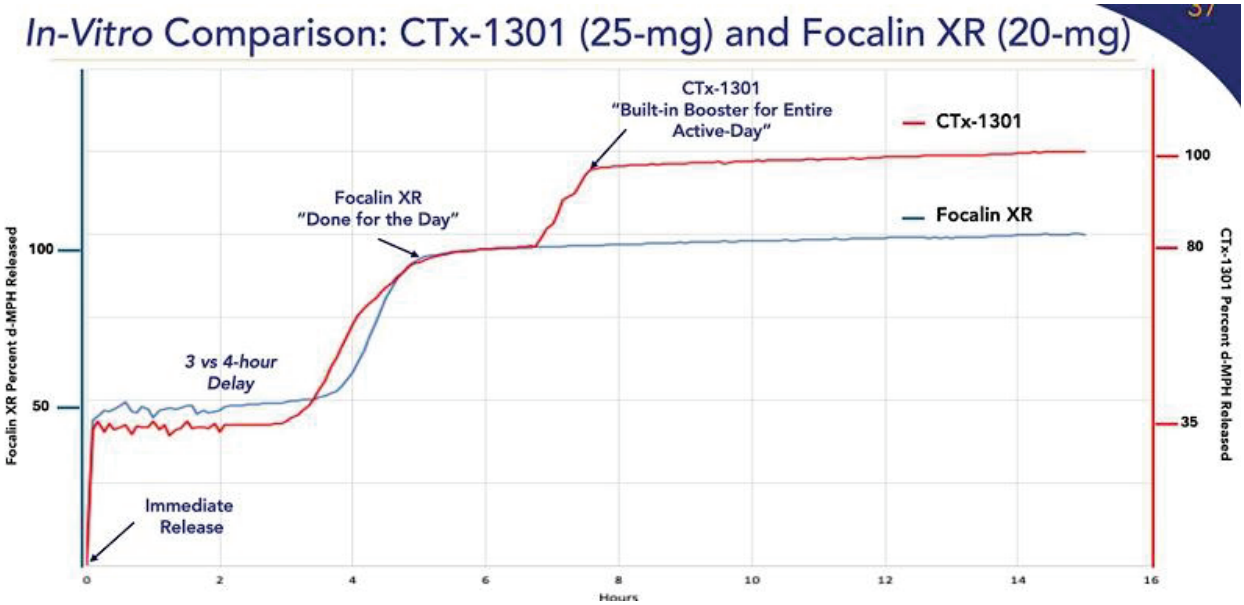
We believe our most advanced drug product candidate, CTx-1301, will be the first true once-daily dexmethylphenidate tablet for the treatment of ADHD, providing onset-of-action within 30 minutes and entire 'active-day' efficacy. CTx-1301 is a trimodal extended-release tablet, based on tablet-in-tablet technology, which provides three distinguishing releases of dexmethylphenidate hydrochloride at precise times, ratio, and modality of release. Our CTx-1301 release profile is as follows:

Release #1: An initial immediate-release, or IR, dose providing 35% of the total daily dose beginning within five to six minutes after administration and designed to achieve therapeutic efficacy within 30 minutes; and

Release #2: Three hours after the administration of the dosage form, the first delayed, sustained release (DR1) provides 45% of the total daily dose released over 90 minutes; and

Release #3: Seven hours after the administration of the dosage form, a second delayed, immediate release (DR2, the built-in-booster) provides 20% of the total daily dose released over approximately 30 minutes.

Release Comparison of CTx-1301 versus Focalin XR (Reference Listed Drug)



Our proprietary, trimodal release profile is engineered to provide patients with a rapid onset of relief from symptoms and to maintain that relief throughout the entire active day. Further, we believe CTx-1301 will continue to demonstrate a more favorable tolerability profile that results from this specialized three-release design and unique 35%-45%-20% release profile, compared to the currently available 50%-50% or 33%-33%-33% release profile that would be produced if a patient were to take three individual doses of dexmethylphenidate in the same milligram strengths. CTx-1301 delivers a release profile that cannot be replicated with commercially available (branded or generic) short and long-acting formulations and was precisely engineered and designed to meet the specific needs of ADHD patients and providers.

We expect CTx-1301 film-coated tablets to be available in eight dosage strengths ranging from 6.25mg to 50mg of dexmethylphenidate. All excipients are compendial and/or non-novel, well established for use in oral formulations, and are present in the drug product at levels well below their maximum potencies listed in FDA's inactive ingredient database ("IID").

Our CTx-1301 Clinical Development Program

The proposed clinical program for CTx-1301 consists of two Phase 1/2 clinical pharmacology studies and our Phase 3 Mastery clinical efficacy and safety trials.

Our Phase 1/2 Bioavailability Trial Results

In October 2020, we announced positive results from a Phase 1/2 comparative bioavailability study in ADHD subjects, under fasted conditions, and demonstrated similar bioavailability to our RLD, Focalin XR. Adjusted geometric mean ratios of primary exposure parameters (C_{max}, $AUC_{0\text{-}inf}$, and AUC_{last}) between CTx-1301 and Focalin XR were within the required 80% to 125% range, both at the high and the low doses, demonstrating a bridge to the RLD as well as dose proportionality. There were no unexpected adverse events, no serious adverse events, no deaths, and no other safety signals observed during this study.

Key Findings

Bridged to Focalin® XR

- Confirmed similar bioavailability to Focalin XR and confirmation of our ability to utilize the 505(b)2 pathway
- Demonstrated dose proportionality, allowing us to avoid the need to evaluate all individual strengths *in vivo*
- Eliminated any requirement for nonclinical studies and ability to utilize existing safety from the Focalin XR label, potentially resulting in a faster pathway to market

Demonstrated Plasma Levels versus Focalin® XR

- CTx-1301 blood levels demonstrated the potential for a fast onset, active-day duration, and favorable tolerability.
- Performed as designed, with its precise 20% 'built-in-booster' 3rd delivery confirming that if approved, CTx-1301 would eliminate patients need for short-acting stimulants and avoid the potential for non-ideal blood levels that could impact normal sleep and appetite

Demonstrated Controlled Descent of Plasma Levels versus Focalin® XR

- Precise 20% 3rd delivery stopped the mid-afternoon plummeting of blood levels, controlling the decline.

Demonstrated Significantly Lower Treatment Emergent Adverse Events

- Patients received 25% more medication via the PTR Platform in a precisely timed, unique ratio
- CTx-1301 patients experienced a 28.6% reduction of TEAE's related to study drug versus Focalin XR

Our comparative bioavailability data study versus Focalin XR is presented in Figure 1, Figure 2, and Figure 3

Figure 1: Comparative Bioavailability Study of CTx-1301 versus Focalin XR in Adult ADHD subjects under Fasted Conditions (low dose comparison)

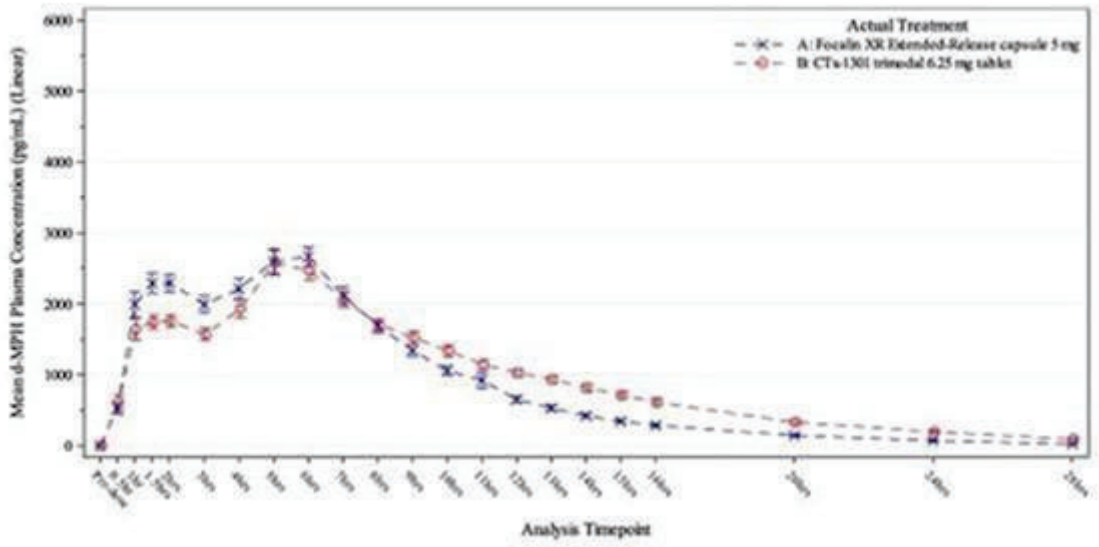


Figure 2: Comparative Bioavailability Study of CTx-1301 versus Focalin XR in Adult ADHD subjects under Fasted Conditions (high dose)

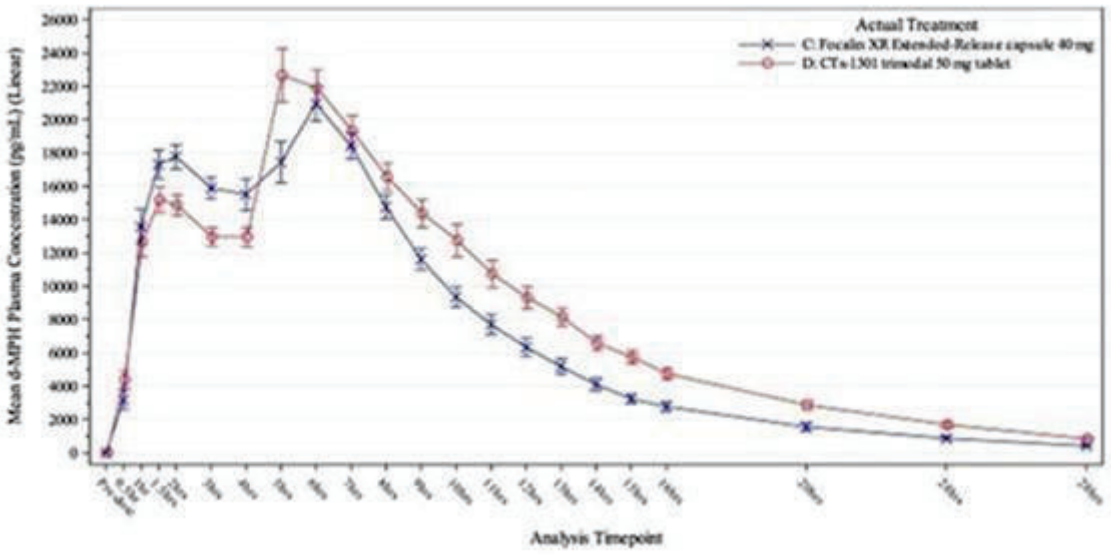
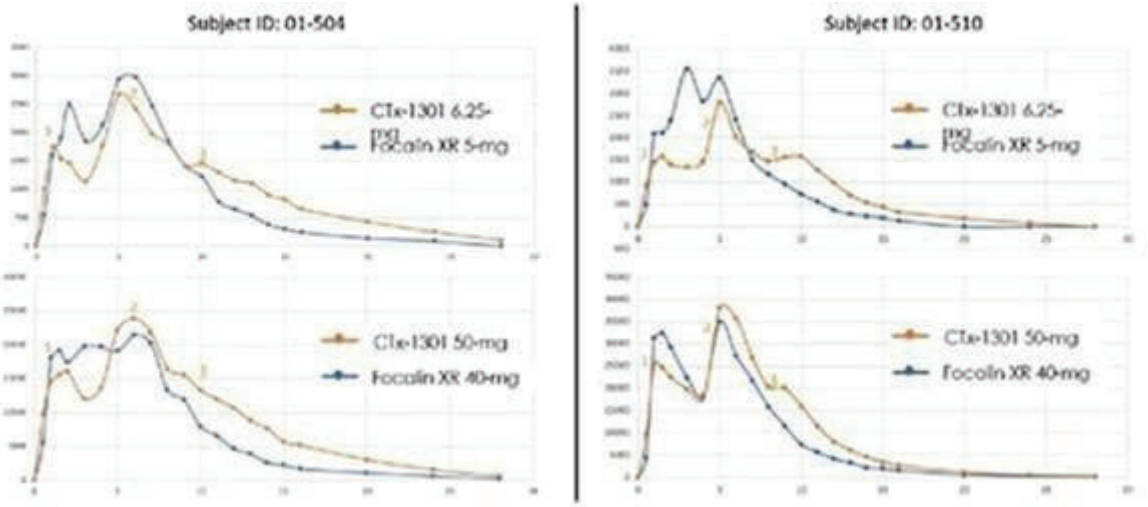


Figure 3: Comparative Bioavailability Study of CTx-1301 versus Focalin XR in individual Adult ADHD subjects under Fasted Conditions (low and high dose)



Our Two Additional Phase 1 Studies

We completed a Phase 1 Food Effect study in October 2022 utilizing a 25-mg dosage strength and a second Phase 1 Food Effect study in December 2024 utilizing our highest dosage strength of 50-mg. Primary endpoints demonstrated that each of these dosages of CTx-1301 can be taken with or without food. Analysis of the safety data from the 25mg and 50mg dose food effect studies revealed that no subjects experienced a serious treatment emergent adverse event ("TEAE"), a serious TEAE or a TEAE leading to death and there were no clinically relevant trends in TEAEs overall.

Fast-Fed Studies

CTx-1301-003

- *A Phase 1, open-label, randomized, single-dose, two-period, two-treatment (fed vs fasted), two-sequence, crossover study in 23 healthy adult subjects, 18-50 years of age, to assess the effect of food on the absorption and bioavailability of CTx-1301*. The objectives of this study were to assess the effect of food on the rate and extent of absorption and the overall bioavailability of a single dose of CTx-1301. Secondary objectives were to provide pharmacokinetic data on blood plasma levels of CTx-1301 in both a fasted and fed state, and to evaluate the safety of a single dose of CTx-1301 25 mg tablet. Exploratory objectives were to further explore the characteristics of CTx-1301 25 mg tablet within selected time intervals.

CTX-1301-013

- *A Phase I open-label, randomized, single-dose, two-period, two-treatment (Fed vs. Fasted), two-sequence, crossover study in healthy adult subjects to assess the effect of food on bioavailability of CTx-1301 (dexmethylphenidate).* The objectives of this study were to assess the effect of food on the rate and extent of the overall bioavailability of a single dose of CTx-1301 50 mg trimodal tablet. Secondary objectives were to provide pharmacokinetic data on blood plasma levels of d-MPH both in a fasted and fed state as well as to evaluate the safety of CTx-130150 mg trimodal tablet. Exploratory objectives to further explore the characteristics of CTx-1301 50 mg trimodal product within selected time intervals.

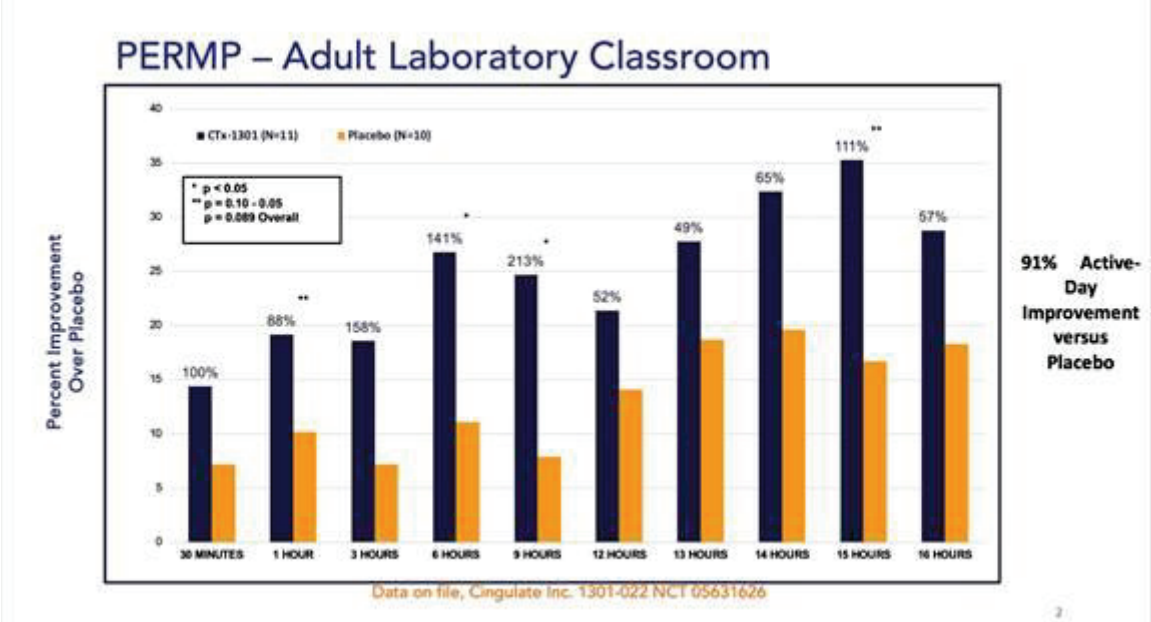
Our Phase 3 MASTERY Trials

A Phase 3 adult dose-optimization study to assess the efficacy and safety, along with onset and duration, of CTx-1301 in adults with ADHD was initiated in December 2022 and completed in June 2023. Results were presented at the 2023 Psych Congress and will be presented at the 2024 American Professional Society of ADHD and Related Disorders (APSARD) in January 2024. This Phase 3 CTx-1301study (NCT05631626) assessed efficacy and safety along with onset and duration of CTx-1301 in 21 adults (age range: 18-55 years) with ADHD in an adult laboratory classroom setting. It did not achieve statistical significance on the primary efficacy endpoint due to small sample size but CTx-1301 demonstrated a trend toward

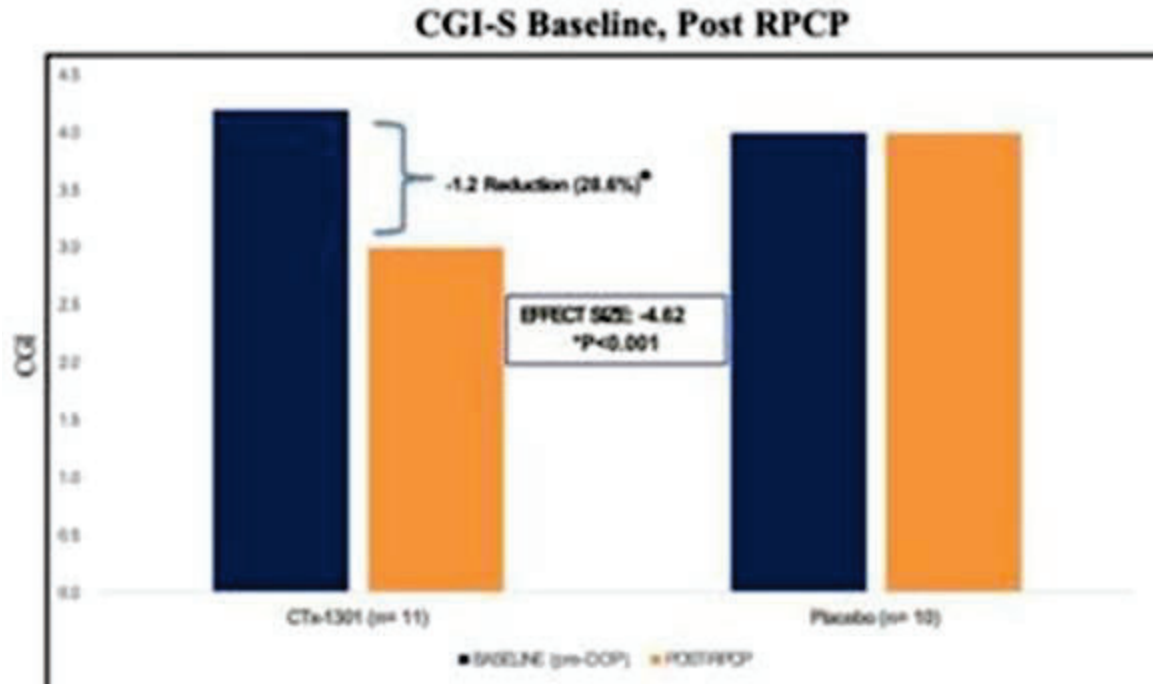
significance in improving PERMP scores compared to placebo. CGI-S scores with CTx-1301 compared to placebo also showed significant improvements that were indeed statistically significant for this secondary endpoint. The treatment effect size of CTx-1301 in this trial was notable – starting at 30 minutes and demonstrated the ability of CTx-1301 to improve upon ADHD symptoms in patients over an entire active day.

Key Findings

The PERMP is a skill-adjusted math test deployed in this Phase 3 study. The PERMP score is the sum of the number of math problems attempted plus the number of math problems answered correctly in a 10-minute session. The scores range from 0-800 with higher scores indicating better performance.

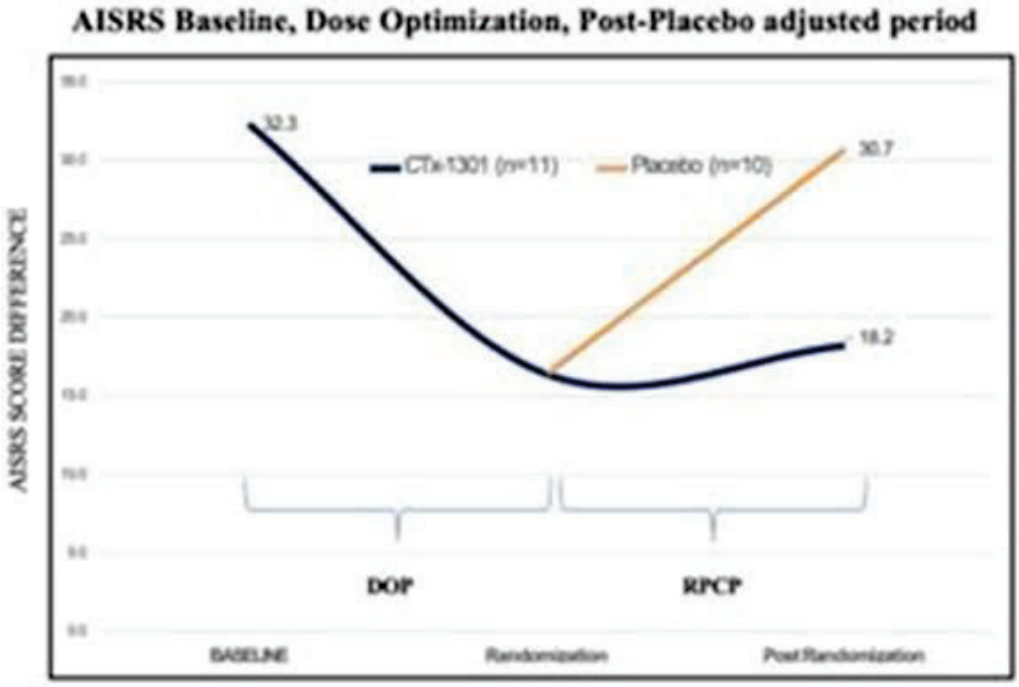


The CGI-S is a single-item scale that measures the severity of psychopathology from 1-7 and was measured during this Phase 3 study in adults.



* RPCP: Randomized Double-Blind Placebo Controlled Period

The AISRS, or ADHD Rating Scale is an 18-item scale based on Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) (American Psychiatric Association 2013) which evaluates the criteria of ADHD and rates symptoms on a 4-point scale and was also measured in this adult study. Each item is scored using a combination of severity and frequency ratings from zero (reflecting no symptoms or a frequency of never or rarely) to three (reflecting severe symptoms or a frequency of very often), so that the total AISRS-5 scores range from zero to 54.



These Phase 3 CTx-1301 diagnostic tools and ADHD evaluations including the AISRS-5, the CGI-S, and the PERMP are commonly used as study endpoints in support of an NDA filing.

Exploratory objectives were evaluated in the adult dose-optimization study to define and evaluate the unique benefits and satisfaction of optimized treatment with CTx-1301 against prior therapies using patient reported outcomes ("PROs"). The PRO evaluations included:

- Subjects required use of "booster" doses for entire active-day efficacy, avoidance of wear-off effect, crash/rebound, and abuse/diversion of short-acting stimulants.
- Compare overall treatment satisfaction of prior therapies versus CTx-1301.
- Compare adverse events of prior therapies versus CTx-1301.
- Evaluate importance of a true, once-daily treatment for ADHD.
- Evaluate the incidence of abuse and/or diversion of short-acting booster doses.
- Evaluate important differentiators for patients requiring ADHD treatment by providing a complete solution with entire active-day efficacy, fast onset of action, avoiding crash/rebound, and eliminating the required short-acting stimulant booster/recovery dose.

These exploratory measures will not only provide critical information for clinicians but also provide important data to payers and market access teams.

Our Phase 3 CTx-1301 clinical safety and efficacy studies also include two child and adolescent studies which were initiated in the third quarter of 2023:

CTx-1301-004

- *A Phase 3, dose-optimized, randomized, double-blind, placebo-controlled, single-center, parallel-group efficacy and safety laboratory classroom study in* children (6-12) with ADHD. The primary objective was to evaluate the efficacy of CTx-1301 compared to placebo in treating children with ADHD in a laboratory classroom study using the PERMP. Secondary objectives were to determine onset and duration of clinical effect of CTx-1301 and to determine safety and tolerability of CTx-1301 compared to placebo.

CTx-1301-005

- *A Phase 3, randomized, double-blind, placebo-controlled, multi-center, fixed-dose, parallel-group, efficacy and safety study in children and adolescent (6-17 y/o) with ADHD.* The primary objective was to evaluate the efficacy of a fixed dose of CTx-1301 compared to placebo using the ADHD-RS-5. Secondary objectives were to evaluate the efficacy of a fixed dose of CTx-1301 compared to placebo using the CGI-S, safety and tolerability of a fixed dose of CTx-1301, and PK levels after a single dose and at steady state.

Based on guidance received from the FDA regarding our clinical program for CTx-1301, it was determined that additional trials were not required for NDA submission. Therefore CTx-1301-005 was terminated early and all data has been submitted to FDA. Forty-five subjects were enrolled in the dose optimization phase in CTx-1301-004 and recruitment remains on hold. Safety information from the dose optimization phase was submitted to FDA.

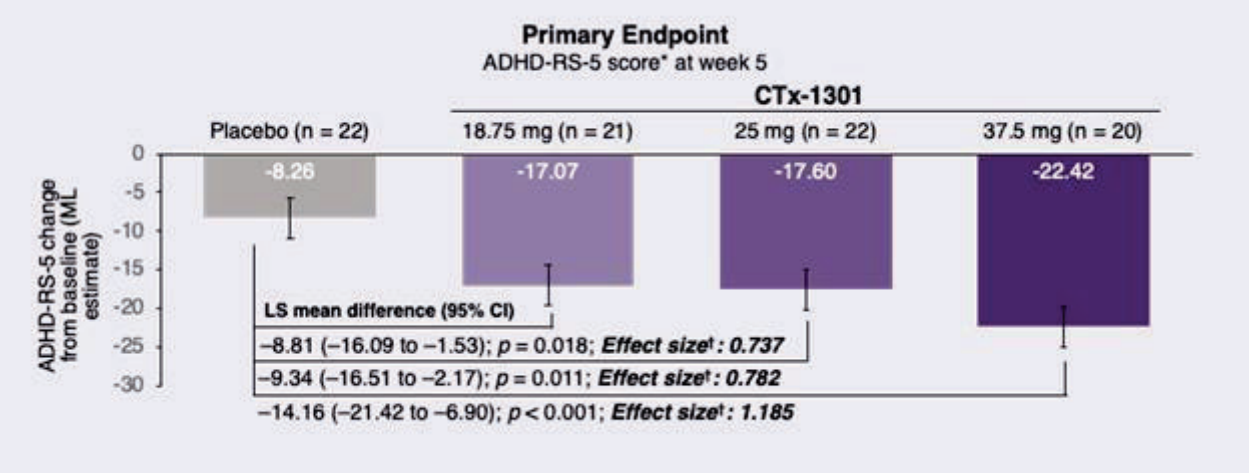
Additionally, based on this guidance, submitted the NDA for CTx-1301 on July 31, 2025 under the Section 505(b)(2) pathway with Focalin® XR as the reference listed drug, using its efficacy and safety data on file with the FDA as a basis for approval, together with bioavailability/bioequivalence data and efficacy/safety data from our CTx-1301 clinical program. The FDA accepted for review the NDA for CTx-1301 and assigned a PDUFA target action date of May 31, 2026. If we receive FDA approval for CTx-1301, we may conduct Phase 4 trials. However, there can be no assurance that approval of CTx-1301 will occur on or about the PDUFA date or that approval of CTx-1301 will occur at all. See "Risk Factors—We depend heavily on the success of CTx-1301. If we are unable to secure approval of CTx-1301, we will never be able to generate revenues from CTx-1301, and our ability to create stockholder value will be severely limited" on page 46.

Analysis of the safety data from the Phase 3 trials revealed that no subjects experienced a serious TEAE, a serious TEAE or a TEAE leading to death and there were no clinically relevant trends in TEAEs overall.

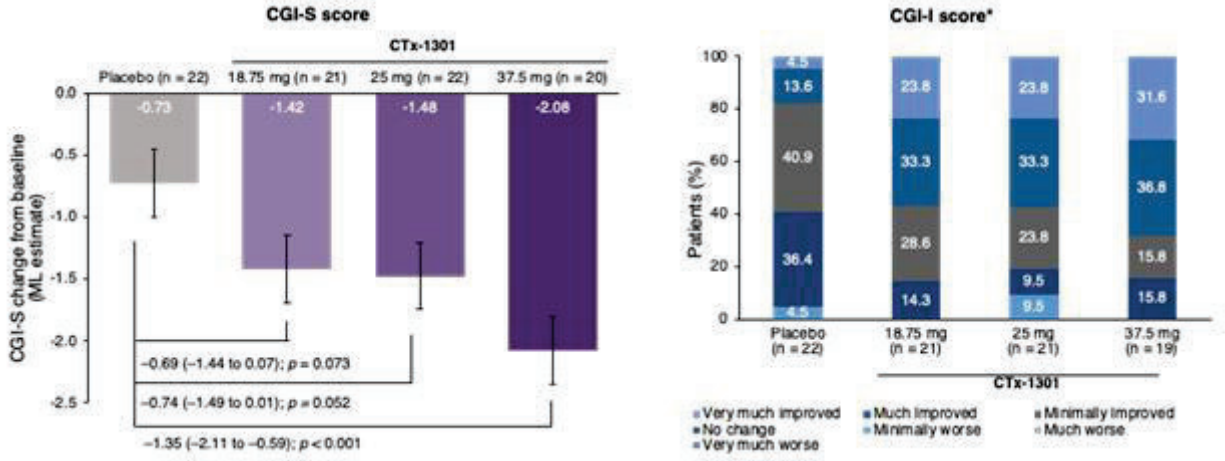
A Phase 3 fixed-dose study in children and adolescents to assess efficacy and safety (CTx-1301-005) was initiated in August 2023 and completed early in February 2024. Results were presented at the 2025 American Academy of Child and Adolescent Psychiatry (AACAP) annual meeting in Chicago. This Phase 3 study (NCT05286762) assessed safety and efficacy of CTx-1301 in 103 subjects (age range: 6-17) with ADHD. Due to the study terminating early, only 103 of the 385 planned subjects were enrolled. CTx-1301 demonstrated consistent dose-dependent efficacy in improving ADHD symptoms. The 37.5mg dose demonstrated the largest effect size and symptom reduction. CTx-1301 showed a favorable safety profile in all dosage strengths.

Key Findings

The ADHD-RS-5 is an 18-item scale based on Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) (American Psychiatric Association 2013). Total ADHD-RS-5 scores range from 0 to 54 with higher scores indicating higher symptom frequency.



The CGI-S is a scale that evaluates the severity of the psychopathology on a scale from 1 (not at all ill) to 7 (among the most severely ill). The CGI-I is a scale that is scored from 1 (very much improved) to 7 (very much worse).



Since the NDA was submitted in July 2025, at total of 13 Information Requests (IRs) have been received from FDA. As of this filing, all IRs have been responded to.

CTx-1302: Dextroamphetamine for the treatment of ADHD in 6 years and older

We believe our drug product candidate CTx-1302, will be the first true once-daily dextroamphetamine tablet for the treatment of ADHD, providing onset-of-action within 30 minutes and efficacy for the entire active day. CTx-1302 is a trimodal extended-release tablet, based on tablet-in-tablet technology, that provides three releases of dextroamphetamine at precise times, ratio, and modality of release. Our CTx-1302 release profile is as follows:

- Release #1: An initial immediate-release, or IR, dose providing 45% of the total daily dose begins within five to six minutes after administration is designed to achieve therapeutic efficacy within 30 minutes; and
- Release #2: Three hours after the administration of the dosage from, the DR1 provides 35% of the total daily dose released over 90 minutes; and
- Release #3: Seven hours after the administration of the dosage form, a DR2, the built-in-booster provides 20% of the total daily dose released over approximately 30 minutes.

We expect CTx-1302 tablets will be available in eight dosage strengths ranging from 6.25mg to 50mg of dextroamphetamine. All excipients are compendial and/or non-novel, well established for use in oral formulations, and are present in the drug product at levels well below their maximum potencies listed in FDA's IID.

Our CTx-1302 Clinical Development Program

Our proposed clinical program for CTx-1302 consists of Phase 1/2 clinical pharmacology studies and Phase 3 clinical efficacy and safety trials. We plan to initiate a Phase 1/2 bioavailability study in ADHD patients for CTx-1302 and, if the results from this study are successful, subsequently initiate pivotal Phase 3 clinical trials, , the timing of which is all dependent on additional capital resources. Our Phase 1/2 trials are expected to include approximately 100 patients and the Phase 3 clinical plan will include approximately 500 patients.

Our Planned Phase 1 Trials

Our proposed Phase 1 CTx-1302 clinical pharmacology studies include:

- *Phase 1/2 Comparative Bioavailability Study:* To evaluate and compare the pharmacokinetic profile of CTx-1302 to the RLD, Dexedrine Spansule in adults with ADHD (18+ y/o).
- *Phase 1 Food Effect Study:* To evaluate the pharmacokinetic profile of CTx-1302 under fed and fasted conditions in adults (18+ y/o).
- *Phase 1 Single-Dose, Fully-Replicate Crossover Study:* To evaluate the intra-subject variability of the in vivo pharmacokinetic profile of CTx-1302 to the RLD, Dexedrine Spansule in adults (18+ y/o).

Planned Phase 3 Trials

- *A Phase 3, fixed-dose, parallel-design, placebo-controlled, 5-week study in children and adolescent patients (6-17 y/o).* The primary efficacy endpoint is the ADHD-RS-5. The Clinical Global Improvement Severity Scale (CGI-S) will be evaluated as a secondary endpoint.
- *A Phase 3, analog workplace efficacy and safety study in adults (18+):* The primary efficacy endpoint is the PERMP. Time to onset and duration of effect will also be evaluated as key secondary endpoints.
- *A long-term dose-optimization safety study will evaluate safety of the pediatric population (6-17 y/o) for six months.* This study will collect and monitor any adverse events that occur during the timeframe of the study.

Important exploratory endpoints included in the analog Phase 3 protocols will define and evaluate the unique benefits and satisfaction of optimized treatment with CTx-1302 against prior therapies using PROs similar to those from the CTx-1301 Phase 3 plan.

We expect the 505(b)(2) NDA filing for CTx-1302 will use Dexedrine® Spansule® as a reference drug, using as a basis for approval that drug's efficacy and safety data on file at FDA, together with bioavailability/bioequivalence data and efficacy/safety data from our CTx-1302 clinical program.

If a complete Phase 3 safety and efficacy studies package will be required for CTx-1302 we can expect that similar diagnostic tools and ADHD evaluations including the ADHD-RS-5, the CGI-S, and the PERMP will be incorporated as in CTx-1301. However, based on our current knowledge about the clinical program for CTx-1301, we may again approach the FDA for their guidance on an alternate, more cost and time efficient approach for CTx-1302.

CTx-2103: Buspirone product candidate for the treatment of anxiety related disorders

We have embarked on a program to develop CTx-2103 (buspirone) for the treatment of anxiety, which is the most common mental health concern in the United States We believe CTx-2103 has the potential to be the first once-daily formulation of buspirone, one of the most widely prescribed agents in the anxiety market. CTx-2103 is a novel, extended-release tablet that contains the active pharmaceutical ingredient buspirone hydrochloride, a non-benzodiazepine medication, for which there is no evidence of the development or risk of dependency. However, due to its short half-life, buspirone is prescribed to be taken several times a day for management of anxiety, which can be challenging for patients and may lead to sub-optimal treatment outcomes. CTx-2103 will be designed as a once-daily, multi-dose tablet, which we believe will offer clear differentiation and compelling advantages over currently available treatment options.

Our CTx-2103 Clinical Development Program

In June 2022, we completed a human formulation study for CTx-2103. The first human subject study of CTx-2103 was a single-center, open-label, four-arm crossover study in 10 healthy subjects. Each participant received four different doses of buspirone at different assessment visits: one timed-release 10mg tablet releasing drug after a four-hour delay, one timed-release 10mg tablet releasing drug after an eight-hour delay, one triple-pulse 10mg tablet releasing drug at zero, four and eight hours, and one immediate release 10mg tablet of generic buspirone (the reference product, which is a commercially available formulation).

The primary objective was to evaluate the absorption of buspirone and the presence of metabolite 1-pyrimidinylpiperazine (1-PP) in blood plasma from time-delayed formulations and correlate this with scintigraphic time and site of release data. Secondary objectives of the study will compare the pharmacokinetic performance of the time delayed buspirone products with a commercially available formulation. Additionally, the study will evaluate the absorption of buspirone and the presence of metabolite 1-PP in blood plasma from a triple-release product.

Safety evaluations demonstrated that CTx-2103 is safe and well tolerated. No serious, severe, or clinically meaningful treatment-emergent adverse events ("TEAEs") occurred during this study. Most TEAEs were mild in severity and were consistent with events expected for buspirone. The evaluation of TEAEs, laboratory examinations, physical examinations, ECG recordings, and measurement of vital signs (blood pressure and pulse rate) revealed no safety concerns for buspirone.

Based on the pharmacokinetic profile seen in the data from the formulation study, CTx-2103 achieved a triple release of buspirone hydrochloride The positive results from this human formulation study provided the critical information needed for us to request a Pre-IND meeting with the FDA to discuss the design of our clinical and regulatory program for CTx-2103. The Pre-IND meeting occurred in the fourth quarter of 2023. We received input from the FDA regarding the regulatory pathway

for CTx-2103, and the design of clinical studies for filing of an IND. Based on the FDA's feedback, CTx-2103 may be able to seek and win approval under the 505(b)(2) pathway, which typically requires less time and resources than the 505(b)(1) full NDA pathway.

Commercialization

If we receive FDA approval for CTx-1301, we will utilize certain third parties to assist in commercialization. In March 2023, we entered into a joint commercialization agreement with Indegene for the go-to-market activities and launch of CTx-1301 in the United States, pending FDA approval. In May 2025, the joint commercialization agreement was replaced with the Commercialization Agreement. Upon FDA approval for CTx-1301, at Cingulate's direction, Indegene would provide commercialization services for CTx-1301 pursuant to statements of work that will set forth, among other things, the services to be performed by Indegene, the deliverables for such services and the fees to be paid by us. Key services that Indegene is expected to provide, include: (a) medical affairs; (b) pricing, reimbursement and market access; (c) commercial operations; and (d) marketing. See "Material Agreements –Commercialization Agreement with Indegene, Inc." below. Cingulate does not have or expect to build a large internal sales, marketing, or distribution infrastructure at this time. If we receive FDA approval for CTx-1301, we also intend to partner with IQVIA, pursuant to a Licensing and Services Master Agreement, in the commercialization of CTx-1301, including field sales and national accounts management.

In addition, we would expect to use multi-channel tactics, including non-personal strategies, to reach physicians, payers, patients and patient caregivers with the right frequency to help drive behavior. In addition to personal promotion, we intend to reach physicians through medical education, direct marketing, journal advertising and electronic health record communication. Advocacy groups, patients and caregivers are extremely active and vocal in the ADHD space. We expect that a direct-to-patient strategy would allow us to access this social group through focused education and advertising, as well as by employing appropriate social media listening and engagement to inform these patients and caregivers.

Manufacturing

Overview

We do not currently own or operate a manufacturing facility. Previously, we utilized Pharmaceutical Manufacturing Research Services, Inc. as our CDMO for the manufacture of our products used in pre-clinical research and clinical trials. In October 2022, we retained Societal CDMO, Inc. as our CDMO that has and will continue to manufacture all clinical, registration, and commercial batches of our lead candidate CTx-1301. In September 2024, Societal was acquired by CoreRx doing business as Bend Biosciences. In August 2025 we entered into a Commercial Supply Agreement with Bend Bioscience. Bend Bioscience has dedicated a specific manufacturing suite within its Gainesville, GA facility to manufacture our products, and the suite is outfitted with proprietary equipment owned by us.

Any third-party manufacturers, facilities, and all lots of drug substance and drug products used in our clinical trials are required to be in compliance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities where our products are produced must meet cGMP requirements and FDA satisfaction before any product is approved and we can manufacture commercial products. Any third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. In addition, our drug products are classified as Class II controlled substances which requires any future third-party manufacturers to be approved and regulated by the United States Federal Drug Enforcement Agency (the "DEA").

Drug Substance

We currently purchase the APIs used in CTx-1301 (Dexmethylphenidate); CTx-1302 (Dextroamphetamine) and CTx-2103 as well as excipients from third-party manufacturers based in the United States. We anticipate entering into commercial supply agreements with additional manufacturers in the future. The APIs for both CTx-1301 and CTx-1302 are controlled under United States federal law. Dexmethylphenidate, and dextroamphetamine are classified by the DEA as Schedule II controlled substances. As with all stimulate medications, there is a potential for abuse. Consequently, our procurements, manufacturing, shipping, dispensing and storing of our product candidates will be subject to regulation, as described in more detail under the "DEA Regulation" section included elsewhere in this annual report. The API for CTx-2103 (buspirone) is not as scheduled controlled substance therefore additional DEA regulations will not apply.

Intellectual Property

Proprietary protection

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, manufacturing and process discoveries and other know-how, to operate without infringing the proprietary rights of others, and to prevent others from infringing on our proprietary rights. We have been building and continue to build our intellectual property portfolio relating to our ADHD drug candidates, and our innovative proprietary PTR drug delivery platform technology, and our technology platform. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and certain foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also intend to rely on trade secrets, know-how, continuing technological innovation, and potential in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

Patent rights

We own or have licensed from BDD Pharma six patents and two patent applications in the United States and patents and patent applications in foreign countries and regions. In addition to the United States, we have patents issued or applications pending in Australia, Brazil, Canada, China, Egypt, Europe (with pending applications before the European Patent Office and patents validated with certain member states of the European Patent Organization), Hong Kong, Israel, India, Japan, Mexico, Russia, Saudi Arabia and South Korea. The patents and patent applications describe and claim certain features of our product candidates, our PTR drug delivery platform technology and our EBL, including claims to the product candidates, methods of making the product candidates and treatment methods using the product candidates

Patent life determination depends on the date of filing of the application and other factors as promulgated under the patent laws, such as patent term adjustments and extensions. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. The patents and, if granted, patent applications owned or licensed to us have expiry dates ranging from 2031 to 2043

Our owned and in-licensed patents and patent applications are summarized below.

Family/PCT Application	"Title"/(Type of Patent Protection)	Applicant/Owner	Pending Applications	Issued Patents	Patent Expiry
WO2011107750	"Delayed Prolonged Drug Delivery" (A press-coated tablet formulation for a delayed, followed by a prolonged release of an active agent)	DRUG DELIVERY INTERNATIONAL LTD		Germany, Great Britain, France, Japan, Switzerland, United States	March 2031
WO2011107749	"Pulsatile Drug Release" (A press-coated tablet formulation for a delayed, followed by a pulsed release of an active agent)	DRUG DELIVERY INTERNATIONAL LTD		Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Greece, Hungary, Ireland, Italy, Japan, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United States	March 2031

Family/PCT Application	"Title"/(Type of Patent Protection)	Applicant/Owner	Pending Applications	Issued Patents	Patent Expiry
WO2011107755	"Immediate Delayed Release" (A press-coated tablet formulation for a delayed, followed by a pulsed release of an active agent)	DRUG DELIVERY INTERNATIONAL LTD		Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Greece, Hungary, Ireland, Italy, Japan, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United States	March 2031
WO2016075496	"Pharmaceutical Processing" (A method for making a controlled release material)	DRUG DELIVERY INTERNATIONAL LTD	Europe	United States	November 2035
WO2016075495	"Compositions" (A press coated tablet for delayed release of an active ingredient)	DRUG DELIVERY INTERNATIONAL LTD	Egypt	Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Greece, Hong Kong Hungary, India, Ireland, Italy, Japan Mexico, Netherlands, Norway, Poland, Portugal, Romania, Russia, Saudi Arabia Slovakia, Slovenia South Korea, Spain, Sweden, Switzerland, Turkey, United States	November 2035
WO2016075497	"Tablet" (A sustained release tablet comprising a wax, a disintegrant and a therapeutic agent)	DRUG DELIVERY INTERNATIONAL LTD	Europe	United States	November 2035
WO2016138440	"Tripulse Release Stimulant Formulations"	CINGULATE THERAPEUTICS LLC	United States	Australia (2), Canada, Europe, Hong Kong, Israel	February 2036

Family/PCT Application	"Title"/(Type of Patent Protection)	Applicant/Owner	Pending Applications	Issued Patents	Patent Expiry
WO2022/240849	"Trimodal, Precision-Timed Pulsatile Release Tablet"	CINGULATE THERAPEUTICS LLC	Australia, Brazil, Canada, China, Israel, Hong Kong, India, Japan, Mexico, South Korea	Europe United States (Notice of Allowance)	May 2042
WO2023/158694	"Trimodal, Precision-Timed Release Tablet"	CINGULATE THERAPEUTICS LLC	Australia Brazil Canada China Europe Hong Kong Israel India Japan Korea United States		Feb 2043 (if issued)

Trade secret and other protection

In addition to patented intellectual property, we also rely on trade secrets and proprietary know-how to protect our technology and maintain our competitive position, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. The agreements generally provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of the individual's relationship with us except in limited circumstances. These agreements generally also provide that we shall own all inventions conceived by the individual in the course of rendering services to us.

Other intellectual property rights

We seek trademark protection in the United States when appropriate, including trade names that could be used with our potential products. We currently have registered trademarks for Cingulate, Cingulate Therapeutics, CTx as well as for the Cingulate Therapeutics logo. We claim to own common law trademark rights in Precision Timed Release and PTR for the good/services for which it is used.

From time to time, we may find it necessary or prudent to obtain licenses from third party intellectual property holders.

Competition

Our industry has been exemplified by advancing technologies, intense competition, and a strong emphasis on proprietary products. We may face competition from both pharmaceutical as well as generic drug companies as there are several short-acting and extended-release branded products with various formulations, some quite innovative as well as generic versions of these that have yet to satisfy the unmet medical need. We believe the key competitive factors that will affect the development and commercial success of our product candidates include oral administration, therapeutic efficacy which includes immediate onset and entire active day duration, safety and tolerability profiles, market access and pricing. Some competitors have substantially greater financial, technical and human resources than we do; however, we believe the level of branded competition is diminishing and will continue to decline with the loss of exclusivity for Vyvanse. In addition, our prospective competitors may also have more experience and expertise in obtaining marketing approvals from the FDA and foreign regulatory authorities. In addition to product development, testing, approval and promotion, other competitive factors in the pharmaceutical industry include consolidation, product quality and price, product technology, reputation, customer service and access to technical information. As a result, our prospective competitors may be able to develop competing or superior products and compete more aggressively and sustain their competitive advantage over a longer period of time than us. Our products may be rendered obsolete or may lack economic viability in the face of competition.

If approved, both CTx-1301 and CTx-1302 will compete against currently marketed, branded, and generic methylphenidate and amphetamine products for the treatment of ADHD. Some of these currently available products include Janssen's Concerta, Novartis' Focalin XR and Takeda's Adderall XR and Vyvanse, all of which have lost exclusivity.

In recent years the ADHD market has seen the entrance of many innovative but niche-focused ADHD products that have not commanded the market share of previous oral stimulants, in particular the extended-release oral stimulants. We are aware that we face competition from small biotechnology companies focused in ADHD with niche products including Aytu, Tris, Corium, Collegium, and Rhodes. However, we do not consider most of these companies to be significant competitors as their products are only capable of capturing small subsets of the overall market and do not employ substantial commercial efforts; whereas we believe our product candidates offer the potential to overcome longstanding unmet needs for the majority of ADHD patients. In addition, Cingulate, along with a potential commercialization or strategic partner, plans to employ appropriate resources to successfully commercialize its assets.

The FDA recently issued revised guidance for bioequivalence testing of generic extended-release methylphenidate. This new guidance makes it more difficult for new generic products to demonstrate bioequivalence to reference products. We believe this will limit generic competition in the methylphenidate market. It may be difficult for a generic product to show bioequivalence to a new branded, extended- release dexmethylphenidate drug with entire active day duration of effect, such as CTx-1301. Recently, generic products have been pressured by the availability of stimulant API and, as a result, there has been decreased production of generic ADHD medications. This is resulting in a decrease of generic commercial product availability, globally.

Government Regulation

Government authorities in the United States at the federal, state and local levels and in other countries regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and ultimately approved by the applicable regulatory authority.

U.S. Drug Development

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations. Drugs are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approval and maintaining subsequent compliance with applicable federal, state and local statutes and regulations requires the expenditure of substantial time, personnel, and financial resources. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, labeling, storage, packaging, recordkeeping, tracking, approval, import, export, distribution, advertising and promotion of pharmaceutical products. Failure to comply with the applicable United States regulatory requirements at any time during product development, the approval process, or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, voluntary product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution injunctions, fines, consent decrees, refusals of government contracts, restitution, disgorgement, or civil and criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Pharmaceutical product candidates must be approved by the FDA through the NDA process before they may be legally marketed and sold in the United States. Cingulate intends to submit our NDAs under the 505(b)(2) regulatory approval pathway. Development and approval of drugs generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practice ("GLP") regulations or other applicable regulations;
- Submission to the FDA of an investigational new drug application ("IND"), which must become effective before clinical trials involving humans may begin;
- Approval by an independent institutional review board ("IRB") or ethics committee at each clinical trial site before a trial may be initiated at that site;

- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, other good clinical practices ("GCPs") and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational product for each proposed indication;
- Compiling of information demonstrating that the product can be properly formulated, manufactured and stored;
- Submission of an NDA to the FDA for marketing approval, including payment of application user fees;
- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with cGMPs and assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- Possible FDA audit of the clinical trial sites to assure compliance with GCPs and the integrity of the clinical data submitted in support of the NDA; and
- FDA review and approval of the NDA, including satisfactory completion of an FDA advisory committee review of the product candidate, where appropriate or if applicable, prior to any commercial marketing or sale of the product in the United States.

Preclinical Studies

Before testing any drug product candidate in humans, it must undergo rigorous preclinical testing. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, 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. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin.

Preclinical studies include laboratory evaluation of product candidate chemistry and formulation, as well as in vitro and animal studies, to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety and toxicology studies. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after an IND for an investigational drug candidate is submitted to the FDA and human clinical trials have been initiated.

In the case of testing data to support a 505(b)(2) NDA, some or all of the necessary preclinical data may be referenced in literature or the FDA's previous findings of safety and efficacy for an RLD.

Clinical Trials

All clinical trials must be conducted under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Study subjects must sign an informed consent form before participating in a clinical trial. There are also requirements governing the reporting of on-going clinical trials and clinical trial results to public registries. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence. Clinical holds may also be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

In addition, an IRB representing each institution that is participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must thereafter conduct a continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to clinical trial subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific timeframes to the National Institutes of Health for public dissemination on the ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The National Institutes of Health's ("NIH") Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both NIH and FDA have signaled the government's willingness to begin enforcing those requirements against non-compliant clinical trial sponsors.

Clinical trials conducted to support an NDA are generally conducted in three sequential phases that may overlap or be combined.

- Phase 1 - clinical trials generally involve a relatively small number of healthy volunteers who are initially exposed to a single dose or multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution, and excretion in healthy volunteers or subjects with the target disease or condition. Changes to this general format that are suitable to a product candidate or a specific patient population may occur but usually are agreed to in advance with the FDA.
- Phase 2 - clinical trials typically involve studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3 - clinical trials are undertaken in larger subject populations to further evaluate dosage, clinical efficacy and safety in an expanded patient population, often at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing. These trials may be done globally to support global registrations so long as the global sites are also representative of the United States population and the conduct of the study at global sites comports with FDA regulations and guidance, such as compliance with GCPs.

By following the 505(b)(2) regulatory approval pathway, the applicant may reduce some of the burden of developing a drug by relying on investigations not conducted by the applicant and for which the applicant has not obtained a right of reference, such as prior investigations involving the RLD. In such cases, some clinical trials may not be required or may be otherwise limited; however, Phase 1 trials to establish bioavailability and pharmacokinetic characteristics of the product candidate and at least one Phase 3 pivotal trial are usually required to support a 505(b)(2) NDA.

Post-approval trials, sometimes referred to as Phase 4, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a new drug product, sponsors have the opportunity to meet with the FDA at certain points, including prior to submission of an IND, at the end of phase 2, and before submission of an NDA. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically meet with the agency before initiating Phase 3 clinical trials to present their plans for the pivotal trial that they believe will support approval of the new drug product.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the drug product and 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 product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

NDA and FDA Review Process

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with detailed descriptions of the product's chemistry, manufacturing, and controls, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently over $3.24 million for an NDA with clinical information, and the manufacturer and/or sponsor under an approved NDA is also subject to an annual program fee, currently approximately $394,000. These fees are typically increased annually. Fee waivers or reductions are available in certain circumstances. One such fee waiver is available for applicants that are small businesses, meaning the applicant (including any affiliates) employs fewer than 500 employees, does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and is submitting its first marketing application.

Section 505(b)(1) and Section 505(b)(2) of the FDCA are the provisions governing the type of NDAs that may be submitted under the FDCA. Section 505(b)(1) is the traditional pathway for new chemical entities when no other new drug containing the same active pharmaceutical ingredient or active moiety, which is the molecule or ion responsible for the action of the drug substance, has been approved by the FDA. As an alternate pathway to FDA approval for new or improved formulations of previously approved products, a company may file a Section 505(b)(2) NDA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing and may request additional information rather than accepting the applications. 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) VI, the agency seeks to review applications for standard review drug products within 10 months from the NDA filing date, and applications for priority review drugs within six months from the NDA filing date. The FDA may grant a priority review designation to drugs that are intended to treat a serious condition and that the agency determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process for both standard and priority reviews may be extended by FDA for three additional months to consider additional, late-submitted information, or information intended to clarify information already provided in the submission in response to FDA review questions.

Before approving an NDA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the product candidate to determine whether they comply with cGMPs, unless the facility has recently had an FDA inspection. 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 assure consistent production of the product to specifications. Additionally, the FDA may refer applications for novel drug products or drug 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 regarding whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers them carefully when making decisions. NDAs submitted under Section 505(b)(2) are typically not referred to an Advisory Panel for consideration unless new safety information is revealed in the review cycle.

As part of the NDA review process, the FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant. Additionally, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs and the IND protocol requirements and to assure the integrity of the clinical data submitted to the FDA. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

After the FDA evaluates an NDA, it will issue either an approval letter or a complete response letter (“CRL”). An approval letter authorizes the commercial marketing of the drug with prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and that the application will not be approved in its present form. A CRL generally describes the deficiencies in the NDA identified by the FDA and may require substantial additional clinical data or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. Additionally, the CRL may include recommended actions that the applicant might take to place the application in a condition for approval. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. If, or when, those deficiencies have been addressed to the FDA’s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter to the applicant. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA may decide that the NDA does not satisfy the regulatory criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than the sponsor interprets the same data.

There is no assurance that the FDA will approve a product candidate for marketing, and the sponsor may encounter significant difficulties or costs during the review process. Even if a product receives marketing 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, or it may condition approval on changes to the proposed labeling. The FDA also may condition approval on the development of adequate controls and specifications for manufacturing and a commitment to conduct post-marketing testing and surveillance to monitor the potential effects and efficacy. For example, the FDA may require Phase 4 trials designed to further assess a drug’s safety and efficacy.

The FDA may also place restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk evaluation and mitigation strategy ("REMS") plan in addition to the approved labeling, to help ensure that the benefits of the drug outweigh its risks. A REMS could include medication guides for patients, communication plans for health care professionals, and/or elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, restricted distribution requirements, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS plan. The FDA will not approve the NDA without an approved REMS, if required. Based on the required warnings included in the approved labeling of drug products containing the same drug substance as our product candidates (dexmethylphenidate and dextroamphetamine), we expect that as part of the NDA review and approval process, FDA will require at least some of our product candidates, in particular CTx-1301 and CTx-1302, to include black box warnings as part of their labeling.

Any of the above-mentioned limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products and therefore limit commercial success. Marketing approval may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

After NDA approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements, FDA notification, and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

Hatch-Waxman Act and New Drug Marketing Exclusivity

Under the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute and also enacted Section 505(b)(2) of the FDCA. To obtain approval of a generic drug, an applicant must submit an Abbreviated New Drug Applications ("ANDA"), to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the RLD. Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. In contrast, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously approved product is scientifically appropriate. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. The FDA may then approve the new product for all or some of the label indications for which the RLD has been approved, or for any new indication sought by the Section 505(b)(2) applicant, as applicable.

In seeking approval of an NDA or a supplement thereto, the NDA sponsor is required to list with the FDA each patent with claims that cover the sponsor's product or an approved method of using the product. Upon approval of an NDA, each of the patents listed in the application for the drug is published in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. When an ANDA applicant submits its application to the FDA, the applicant is required to certify to the FDA concerning any patents listed in the Orange Book for the RLD, except for patents covering methods of use for which the follow-on applicant is not seeking approval. To the extent a Section 505(b)(2) applicant is relying on studies conducted for an already approved product, such an applicant is also required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, any applicant who subsequently files an ANDA or 505(b)(2) NDA that references the drug listed in the Orange Book must certify to the FDA that with respect to each published patent, (i) the required patent information has not been filed by the original applicant of the RLD; (ii) the listed patent already has expired; (iii) the listed patent has not expired, but will expire on a specified date and approval is sought after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the new product. These are known as Paragraph I, II, III, and IV certifications, respectively.

If a Paragraph I or II certification is filed, the FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed, the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the ANDA or 505(b)(2) application.

A certification that the new product will not infringe the RLD's listed patents or that such patents are invalid is called a Paragraph IV certification. If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders for the RLD once the applicant's NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the follow-on applicant's ANDA or 505(b)(2) NDA will not be subject to the 30-month stay.

In addition, under the Hatch-Waxman Amendments, the FDA may not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the referenced RLD has expired. These market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of a NDA for a drug containing a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for a NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications for drugs containing the original active agent. Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent term extension. The allowable patent term extension is calculated as half of the drug's testing phase – the time between when the IND becomes effective and NDA submission – and all of the review phase – the time between NDA submission and approval, up to a maximum of five years. The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the Patent and Trademark Office (PTO) must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Pediatric Clinical Trials and Exclusivity

Under the Pediatric Research Equity Act ("PREA"), an NDA or certain types of supplements to an NDA must contain data to assess the safety and efficacy of the drug 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 pediatric data or full or partial waivers.

For purposes of satisfying the requirements of PREA, the appropriate age ranges to be studied may vary, depending on the pharmacology of the drug or biological product, the manifestations of the disease in various age groups, and the ability to measure the response to therapy. PREA requires pediatric assessments to be gathered "using appropriate formulations for

each age group for which the assessment is required" (section 505B(a)(2)(A) of the Act). Under PREA, applicants must submit requests for approval of the pediatric formulation used in their pediatric studies, and failure to submit such a request may render the product misbranded (section 505B(d) of the Act). FDA interprets the language "request for approval of a pediatric formulation" to mean that applicants must submit an application or supplemental application for any not previously approved formulation(s) used to conduct their pediatric studies.

The Food and Drug Administration Safety and Innovation Act, which was signed into law on July 9, 2012, amended the FDCA to require that a sponsor who is planning to submit an NDA for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("iPSP") within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 trial. The iPSP must include an outline of the pediatric trial(s) that the sponsor plans to conduct, including objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric trials along with supporting information. The FDA and the sponsor must reach an agreement on the iPSP, but the sponsor can submit amendments to an agreed-upon iPSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and other clinical development programs. We have submitted our iPSP, and it was accepted. We continue to be in discussions with the FDA regarding our PREA obligations.

The Best Pharmaceuticals for Children Act provides NDA holders a six-month extension of any exclusivity – patent or non-patent – for a drug if certain conditions are met, including satisfaction of a pediatric trial(s) agreed with FDA as a Pediatric Written Request. Conditions for pediatric exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric clinical trials, and the applicant agreeing to perform, and reporting on, the requested clinical trials within the statutory timeframe. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to the written request from the FDA for such data. Those data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. Although this is not a patent term extension, it effectively extends the regulatory period during which the FDA cannot approve another application.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Post-Approval Requirements

Following approval of a drug product, the manufacturer and the approved drug product are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA. Prescription drug promotional materials also must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the approved drug product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the applicant to develop additional data or conduct additional preclinical studies or clinical trials.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing

facilities for our product candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities' satisfaction before any product is approved and our commercial products can be manufactured. These manufacturers must comply with cGMPs that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs. The discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions including cessation of manufacturing activities. The discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including recalls and product seizures.

Further, changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented, or FDA notification. If there are any modifications to the drug, including changes to indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a supplemental NDA or new NDA, which may require the applicant to develop additional data or conduct additional pharmaceutical development/formulation studies, nonclinical studies or clinical trials.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; and
- mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws regulate the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Moreover, the Drug Supply Chain Security Act ("DSCSA") was enacted in 2013 with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that is expected to culminate in November 2023. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of prescription drug products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

DEA Regulation

The active ingredients in our current drug product candidates are listed by the DEA as controlled substances under the CSA. The CSA and its implementing regulations establish a closed chain of distribution for entities handling controlled substances and impose registration, record-keeping and reporting, security, storage, procurement, manufacturing, distribution, importation, exportation, labeling, packaging, and other requirements on such entities. The DEA requires individuals or entities that handle controlled substances to comply with these requirements to ensure legitimate use and prevent diversion of controlled substances to illicit channels of commerce.

The CSA categorizes controlled substances into one of five schedules, Schedule I, II, III, IV or V, depending on the potential for abuse and physical or psychological dependence. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. They may not be marketed or sold for dispensing to patients in the United States Pharmaceutical products having a currently accepted medical use and that are otherwise approved for marketing may be listed as Schedule II, III, IV, or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence. Schedule II substances (as well as substances defined as narcotics in any Schedule) are subject to the strictest requirements for registration, security, recordkeeping and reporting, and the distribution and dispensing of these substances are highly regulated. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist in most situations, unless they are electronically prescribed pursuant to DEA regulations, and may not be refilled. The active ingredients in our product candidates (dexmethylphenidate and dextroamphetamine) are Schedule II controlled substances and are under various restrictions. Consequently, the procurement, manufacturing, shipping, storage, sales and use of the products, if approved, will be subject to a high degree of regulation.

Facilities that manufacture, distribute, import or export controlled substances must register annually with the DEA. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized. Similarly, separate registrations are also required for separate facilities.

The DEA inspects manufacturers, distributors, importers, and exporters to review compliance with the CSA and DEA regulations, including security, record keeping and reporting prior to issuing a controlled substance registration and on a periodic basis. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled by the registrant, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations. Manufacturers and distributors must also submit regular reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Records must be maintained for the handling of all controlled substances, for example, a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of. All DEA registrants must also report any controlled substance thefts or significant losses and must obtain authorization to destroy or dispose of controlled substances. In addition to maintaining an importer and/or exporter registration, importers and exporters of controlled substances must obtain a permit for every import or export of a Schedule I or II substance and a narcotic substance in Schedule III, IV and V. For all other drugs in Schedule III, IV and V, importers and exporters must submit an import or export declaration.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. The DEA establishes annually an aggregate quota for how much of a controlled substance may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate number of opioids and stimulants that the DEA allows to be produced in the United States each year is allocated among individual companies, which must submit applications annually to the DEA for individual production and procurement quotas. We must receive an annual quota from the DEA in order to produce or procure our Schedule II substance for use in manufacturing of our product and product candidates. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA.

Failure to maintain compliance with applicable DEA requirements, particularly as manifested in loss or diversion or controlled substances, can result in administrative, civil or criminal enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could lead to criminal prosecution.

The various states and the District of Columbia also regulate controlled substances and impose similar licensing, recordkeeping, and reporting requirements on entities that handle controlled substances. Entities must independently comply with the various state requirements in addition to the federal controlled substance requirements.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States, sales of pharmaceutical products depend in significant part on the availability of coverage and adequate reimbursement by third-party payors, such as state and federal governmental authorities,

including those that administer the Medicare and Medicaid programs, managed care organizations and private insurers. Decisions regarding the extent of coverage and amount of reimbursement to be provided for each of our product candidates will be made on a plan-by-plan basis. The Medicare and Medicaid programs are often used as models by private payors and other governmental payors to develop their coverage and reimbursement policies for drugs. However, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Each third-party payor determines whether or not it will provide coverage for a drug, what amount it will pay providers for the drug, and on what tier of its formulary the drug will be placed. These decisions are influenced by the existence of multiple drug products within a therapeutic class and the net cost to the plan, including the amount of the prescription price, if any, rebated by the drug's manufacturer. Typically, generic versions of drugs are placed in a preferred tier. The position of a drug on the formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. As a result, coverage, reimbursement and placement determinations are complex and are often the subject of extensive negotiations between the payor and the owner of the drug.

Unless we enter into a strategic collaboration under which our collaborator assumes responsibility for seeking coverage and reimbursement for a given product, we will be responsible for negotiating coverage, reimbursement and placement decisions for our product candidates. Coverage, reimbursements and placement decisions for a new product are based on many factors including the coverage, reimbursement and placement of already marketed branded drugs for the same or similar indications, the safety and efficacy of the new product, availability of generics for similar indications, the clinical need for the new product and the cost-effectiveness of the product.

Within the Medicare program, CTx-1301, CTx-1302 and CTx-2103, which, if approved would likely be self-administered drugs, would likely be reimbursed under the expanded prescription drug benefit known as Medicare Part D. This program is a voluntary Medicare benefit administered by private plans that operate under contracts with the federal government. These plans develop formularies that determine which products are covered and what co-pay will apply to covered drugs. The plans have considerable discretion in establishing formularies and tiered co-pay structures, negotiating rebates with manufacturers and placing prior authorization and other restrictions on the utilization of specific products, subject to review by the Centers for Medicare and Medicaid Services ("CMS") for discriminatory practices. These Part D plans negotiate discounts with drug manufacturers, which are passed on, in whole or in part, to each of the plan's enrollees through reduced premiums.

If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicare Prescription Drug Improvement and Modernization Act of 2003 as well as the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 ("OBRA") and the Veterans Health Care Act of 1992, each as amended. Among other things, the OBRA requires drug manufacturers to pay rebates on prescription drugs to state Medicaid programs and empowers states to negotiate rebates on pharmaceutical prices, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

Third-party payors, including the United States government, continue to apply downward pressure on the reimbursement of pharmaceutical products. For example, the Inflation Reduction Act of 2022 reduces the US government reimbursement for some drugs. Also, the trend towards managed health care in the United States and the concurrent growth of organizations such as health maintenance organizations may result in lower reimbursement for pharmaceutical products. We expect that these trends will continue as these payors implement various proposals or regulatory policies. There are currently, and we expect that there will continue to be, a number of federal and state proposals to implement controls on reimbursement and pricing, directly and indirectly.

Other Healthcare Laws and Compliance Requirements

As we are commercializing our product candidates, if they are approved by the FDA or comparable foreign regulatory agencies for marketing, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by federal government and the states and foreign governments in the jurisdictions in which we conduct our business. Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any other product candidates for which we obtain marketing approval. Our arrangements with third-party payors and customers expose

us to broadly applicable fraud and abuse and other healthcare laws and regulations that constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval.

Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the federal Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- The federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalty laws, prohibit, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the United States government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the United States government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the United States government. Actions under these laws may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. The federal government uses these laws, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the United States, for example, in connection with the promotion of products for unapproved uses and other allegedly unlawful sales and marketing practices;
- The United States Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created new federal, civil and criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collective, "PPACA"), among other things, imposes reporting requirements on manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program to report, on an annual basis, to CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, chiropractors and, beginning in 2022 for payments and other transfers of value provided in the previous year, certain advanced non-physician health care practitioners), teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their respective implementing regulations impose specified 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," defined as independent contractors or agents of covered entities, which include certain healthcare providers, health plans, and healthcare clearinghouses, that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers;

- State laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act, as well as state and local laws that require the registration of pharmaceutical sales representatives; and
- State laws and foreign laws and regulations (particularly European Union laws regarding personal data relating to individuals based in Europe) that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

In November 2020, the United States Department of Health and Human Services ("DHHS") finalized significant changes to the regulations implementing the Anti-Kickback Statute, with the goal of offering the healthcare industry more flexibility and reducing the regulatory burden associated with those fraud and abuse laws, particularly with respect to value-based arrangements among industry participants.

Ensuring that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. It is possible that governmental authorities may conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. 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 civil, criminal and administrative penalties, including monetary damages, fines, disgorgement, imprisonment, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, reputational harm, diminished profits and future earnings, or additional reporting requirements if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with any of these laws, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Healthcare Reform and Potential Changes to Healthcare Laws

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our future products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Moreover, among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

By way of example, PPACA was enacted in March 2010 and has had a significant impact on the health care industry in the United States. PPACA expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to biopharmaceutical products, PPACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program.

As another example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020, incorporated extensive healthcare provisions and amendments to existing laws, including a requirement that all manufacturers of drugs and biological products covered under Medicare Part B report the product's average sales price to the DHHS beginning on January 1, 2022, subject to enforcement via civil money penalties.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA that affect health care expenditures. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, (the "CARES Act"), which was signed into law on March 27, 2020 and was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. The 2021 Consolidated Appropriations Act was subsequently signed into law on December 27, 2020 and extended the CARES Act suspension period to March 31, 2021. The most recently enacted pandemic-relief legislation, the American Rescue Plan Act of 2021, which was signed into law on March 11, 2021, also includes significant healthcare system reforms and programs intended to strengthen the insurance marketplace established under the PPACA, among others. In addition, other legislative changes that affect the pharmaceutical industry have been proposed and adopted in the United States since the ACA was enacted. For example, the Inflation Reduction Act of 2022 included, among other things, a provision that authorizes CMS to negotiate a "maximum fair price" for a limited number of high-cost, single-source drugs every year, and another provision that requires drug companies to pay rebates to Medicare if prices rise faster than inflation.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries 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 drug products. DHHS has solicited feedback on some of various measures intended to lower drug prices and reduce the out of pocket costs of drugs and implemented others under its existing authority. For example, in May 2019, DHHS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified a DHHS policy change that was effective January 1, 2019. Congress and the executive branch have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, making this area subject to ongoing uncertainty.

Individual states in the United States have also increasingly passed legislation and implemented 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 December 2020, the United States Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area.

The FDA's and other regulatory authorities' policies also may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. For example, in December 2016, the 21st Century Cures Act (the "Cures Act") was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and devices and to spur innovation, but its ultimate implementation is uncertain. In addition, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA's user fee programs and included additional drug and device provisions that build on the Cures Act. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once regulatory approval is obtained. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, including any future pharmaceutical products for which we secure marketing approval.

Data Privacy and the Protection of Personal Information

We are regulated by laws and regulations governing data privacy, security, and the protection of personal information, including health information, that are applicable to our business and associated data processing activities. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and

data protection issues globally which will continue to affect our business. In the United States, we may be subject to state data breach notification laws, state laws protecting the privacy and security of health and personal information and federal and state consumer protections laws which regulate the collection, use, disclosure and transmission of personal information. These laws may overlap and conflict with each other, and each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable data protection laws and regulations we could be subject to penalties or sanctions, including criminal penalties. Our current and future customers and research partners must comply with laws governing the privacy and security of health information, including HIPAA and state health information privacy laws. If we knowingly obtain health information that is protected under HIPAA, called "protected health information," without observing the correct protocols which may include execution of a business associate agreement, implementation of privacy or security measures, and other obligations, our customers or research collaborators may be subject to enforcement actions, and we may have direct liability for the unlawful receipt of protected health information or for aiding and abetting a HIPAA violation.

State laws protecting health and personal information are becoming increasingly stringent. For example, California has implemented the California Confidentiality of Medical Information Act, which imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. Washington has enacted the My Health My Data Act, which will (with certain exceptions) become effective on March 31, 2024, and Nevada's Consumer Health Privacy Law will enter into force on March 31, 2024. The development of general state privacy laws has been even more rapid. In 2020 California implemented the California Consumer Privacy Act of 2018 ("CCPA"). The CCPA reflects several key concepts included in the European Union General Data Protection Regulation ("GDPR"). The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. On January 1, 2023, the California Privacy Rights Act ("CPRA") entered into force and significantly modified the CCPA. This may result in further uncertainty, additional costs and expenses in an effort to comply, as well as additional potential for harm and liability for failure to comply. In addition to California, twelve other states have enacted state data privacy laws, and in five of these states – Colorado, Connecticut, Nevada, Utah and Virginia – these laws have entered into force in 2023. Other states in the U.S. are considering privacy laws similar to CCPA/CPRA and other state privacy laws.

When we do business and/or conduct clinical trials in the UK or the EEA (i.e., the EU plus Liechtenstein, Norway and Iceland), we are subject to the GDPR as well as the GDPR as saved into United Kingdom law by virtue of section 3 of the United Kingdom's European Union (Withdrawal) Act 2018 and the UK's Data Protection Act 2018 (the "UK GDPR"). The GDPR and UK GDPR apply to business colleagues, employees, service providers, trial participants and other individuals like investigators or CRO employees who are residents of the UK or EEA. Violations of the UK GDPR and/or the GDPR can carry hefty fines of up to EUR 20 million / £17.5 million or 4% of the total annual worldwide revenue in the preceding financial year, whichever is higher.

U.S. Foreign Corrupt Practices Act

In general, the Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, prohibits offering to pay, paying, promising to pay, or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business for or with, or in order to direct business to, any person. The prohibitions apply not only to payments made to "any foreign official," but also those made to "any foreign political party or official thereof," to "any candidate for foreign political office" or to any person, while knowing that all or a portion of the payment will be offered, given, or promised to anyone in any of the foregoing categories. "Foreign officials" under the FCPA include officers or employees of a department, agency, or instrumentality of a foreign government. The term "instrumentality" is broad and can include state-owned or state-controlled entities. Importantly, United States authorities deem most healthcare professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public healthcare and/or public education systems to be "foreign officials" under the FCPA. When we interact with foreign healthcare professionals and researchers in testing and marketing our products abroad, should any of our product candidates receive foreign regulatory approval in the future, we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection with marketing our products and services or securing required permits and approvals. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Material Agreements

Commercialization Agreement with Indegene, Inc.

In March 2023, we entered into a joint commercialization agreement with Indegene. In May 2025, the joint commercialization agreement was replaced with the Commercialization Agreement. The Commercialization Agreement governs the general terms under which Indegene would provide commercialization services for CTx-1301, if we receive FDA approval for CTx-1301, upon our request. Pursuant to the Commercialization Agreement, the parties will enter into statements of work that will set forth, among other things, the services to be performed by Indegene, the deliverables for such services, and the fees to be paid by us. Each statement of work will be governed by the terms of the Commercialization Agreement, unless expressly modified in such statement of work. We may elect to receive the following services from Indegene: (a) medical affairs; (b) pricing, reimbursement and market access; (c) commercial operations; and (d) marketing. The parties will negotiate in good faith any changes to the services provided by Indegene due to changes in circumstances or priorities established by us.

The term of the Commercialization Agreement is three years. Neither part can terminate the Commercialization Agreement for convenience during the initial twelve (12) months following the first commercial sale of CTx-1301 or eighteen (18) months from the effective date, whichever is earlier. Either party may terminate the Commercialization Agreement upon thirty (30) days prior, written notice for material, uncured breaches or immediately in the event of the other party's bankruptcy.

The Commercialization Agreement contains representations, warranties, confidentiality and indemnity obligations customary for agreements of this type.

Master Services Agreement with CoreRx, Inc. (dba Bend Bioscience)(fka Societal CDMO)

Effective August 27, 2025, we entered into a commercial supply agreement with CoreRx, Inc. doing business as Bend Bioscience (the "Manufacturing Agreement"). The Manufacturing Agreement governs the general terms under which Bend Bioscience, or one of its affiliates, will provide manufacturing services as specified by us at Bend Bioscience's Gainesville, Georgia manufacturing facility. Such services are performed under agreed statements of work. Under the terms of the Manufacturing Agreement, we have agreed to pay fees for Bend Bioscience's performance of services as provided in each applicable statement of work.

The Manufacturing Agreement terminates in August 2028 or such later date as required to complete a statement of work (the "Initial Term") and will renew automatically thereafter for successive one (1) year periods (a "Renewal Term") unless terminated by either Bend Bioscience with two (2) years prior written notice, or by us with one (1) year written notice. The term of each statement of work terminates upon completion of the services under such statement of work, unless terminated earlier. The Manufacturing Agreement or a statement of work may be terminated by either party for material, uncured breaches or in the event of the other party's bankruptcy.

The Manufacturing Agreement includes customary terms relating to, among others, indemnification, intellectual property protection, confidentiality, remedies and warranties.

Patent and Know-How License Agreement with BDD Pharma

We entered into a patent and know-how license agreement with BDD Pharma in August 2018, which we refer to as the BDD Pharma License Agreement. Pursuant to the BDD Pharma License Agreement, we have an exclusive license under technology, patents and know-how owned or controlled by BDD Pharma and relating to a barrier layer for controlled drug release in order to develop, manufacture, market, use, import, sell or otherwise supply and commercialize products that (i) deliver three distinct doses of dextroamphetamine, dexmethylphenidate or any methylphenidate based or any amphetamine based drug, (ii) have an extended release in vitro over a period of more than eight hours or (iii) are otherwise covered by the patents or are made, developed or used in accordance with the know-how. We also have the right to apply for marketing approvals and carry out clinical trials for the purpose of obtaining marketing approvals of such products. The rights granted to us are worldwide and exclusive in the field of the treatment of any disease or disorder in humans amenable to treatment with a methylphenidate-based or amphetamine-based drug or mixture or combination thereof. We have the right to sublicense the rights granted to us, subject to certain conditions.

BDD Pharma was entitled to a payment of $198,625 in connection with execution of the BDD Pharma License Agreement and has since been paid $500,000 in aggregate milestone payments relating to CTx-1301. We will be required to pay BDD Pharma $250,000 as a final milestone payment if CTx-1301 is approved by the FDA. We may be required to pay

BDD Pharma aggregate milestone payments of $750,000 for each additional product in connection with clinical trial and regulatory milestones relating to this license agreement, with different dose strengths of a product being considered the same product for purposes of milestone payments. We may be required to pay BDD Pharma low to mid-single digit royalties on aggregate net sales of products. We may also be required to pay BDD Pharma low to mid-single digit royalties on aggregate net receipts of products based on sales made by our sublicensees and non-royalty sublicensing consideration that we receive.

Unless terminated earlier, the term of the BDD Pharma License Agreement continues until the later of the expiration of the last-to-expire of all the patents licensed to us or the last-to-expire of all of our payment obligations. Our royalty payment obligations expire on a product-by-product and country-by-country basis upon the later of 10 years from the first commercial sale of a product in a country or expiration of the last-to-expire patent covering the manufacture, use or sale of the product in a country. Currently, the last-to expire patent licensed from BDD Pharma expires in November of 2035. Upon expiration of our royalty payment obligations, the licenses granted to us become fully-paid, irrevocable and perpetual.

We, or BDD Pharma, may terminate the BDD Pharma License Agreement if there is an uncured material breach by the other party or in connection with the other party's insolvency. BDD Pharma may terminate the BDD Pharma License Agreement immediately upon written notice if we, any sublicensee or related party or affiliate directly challenges, or assists a third party in challenging, the validity or enforcement of the patents owned by BDD Biopharma or the secret nature of the know-how.

Licensing and Services Master Agreement with IQVIA Inc.

In November 2025, we entered into a licensing and services master agreement with IQVIA Inc. Pursuant to the licensing and services master agreement, the parties will enter into statements of work that will set forth, among other things, the data to be purchased by us and the services to be performed by IQVIA, the deliverables for such services, and the fees to be paid by us. Each statement of work will be governed by the terms of the licensing and services master agreement, unless expressly modified in such statement of work. We may elect to receive the following services from IQVIA: (a) field sales; and (b) national account management team. The parties will negotiate in good faith any changes to the services provided by IQVIA due to changes in circumstances or priorities established by us.

The term of the field sales statement of work expires June 30, 2028 and we may terminate the field sales statement of work by providing sixty (60) days written notice. The national account team management statement of work expires December 31, 2028 and we have the right to terminate early.

Human Capital Resources

To achieve our goals, it is crucial that we attract and retain talented employees. To facilitate this, we strive to maintain a safe and rewarding workplace, with opportunities for our employees to grow and develop in their careers, supported by competitive pay, comprehensive benefits and health and wellness programs, and programs that build connections among our employees. Our compensation program includes the granting of stock options to attract, retain, and incentivize employees.

As of December 31, 2025, we employed fourteen (14) employees. Of these, five (5) are engaged in research and development and manufacturing activities, and nine (9) in commercial and general and administrative functions. All of our employees are located in the United States. We utilize outside consultants and independent contractors to supplement our full-time workforce. None of our employees are represented by a labor organization or are under a collective-bargaining arrangement. We consider our employee relations to be good.

Corporate Information

Cingulate Inc. is a Delaware corporation that was formed in May 2021 to serve as a holding company. CTx is a Delaware limited liability company that was formed in November 2012. In connection with the consummation of our initial public offering ("IPO"), on September 29, 2021, Cingulate Inc. acquired CTx through the merger of a wholly-owned acquisition subsidiary of Cingulate Inc. with and into CTx (the "Reorganization Merger"). As a result of the Reorganization Merger, CTx became a wholly-owned subsidiary of Cingulate Inc. Unless otherwise stated or the context otherwise requires, all information in this annual report reflects the consummation of the Reorganization Merger and the IPO.

Our primary executive offices are located at 1901 West 47th Place, Kansas City, Kansas 66205 and our telephone number is (913) 942-2300. Our website address is *www.cingulate.com*. The information contained in, or accessible through, our website does not constitute a part of this annual report. We have included our website address in this annual report solely as an inactive textual reference.

ITEM 1A. RISK FACTORS

Our future operating results could differ materially from the results described in this annual report due to the risks and uncertainties described below. You should consider carefully the following information about risks in evaluating our business. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and, in these circumstances, the market price of our securities would likely decline. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See "Cautionary Note Regarding Forward Looking Statements" for a discussion of some of the forward-looking statements that are qualified by these risk factors. Factors that could cause or contribute to such differences include those factors discussed below.

Summary of Risks

The following summarizes key risks and uncertainties that could materially adversely affect us. You should read this summary together with the more detailed description of each risk factor contained below.

- We are a biopharmaceutical company with a limited operating history and need additional capital to continue operations, including to advance and commercialize our product candidates.
- We have incurred a history of operating losses and expect to continue to incur substantial costs for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability.
- We need to raise significant additional capital to continue operations, including to complete the development and commercialization efforts for CTx-1301. If we are unable to raise additional capital, we could be required to seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us.
- The Note Purchase Agreement and Note issued in November 2025 contain restrictive covenants and adjustments in the event of a default that may limit our operating flexibility and affect our business operations and financial condition.
- If we fail to maintain compliance with the continued listing requirements of Nasdaq, our common stock and/or warrants may be delisted and the price of our common stock and/or warrants and our ability to access the capital markets could be negatively impacted.
- We are dependent primarily on the successful development and commercialization of our product candidates, CTx-1301 and CTx-1302 for the treatment of ADHD and CTx-2103 for the treatment of anxiety, which are in either product/early clinical development (CTx-2103), late development (CTx-1301) or planned for future product development (CTx-1302) and are not yet approved. We cannot give any assurance that we will receive regulatory approval for such product candidates or any other product candidates, which is necessary before they can be commercialized.
- Even if we obtain regulatory approval for one or more of our product candidates, such approval may be limited, and we will be subject to stringent, ongoing government regulation. The commercial success of our product candidates, if approved, depends partially upon attaining market acceptance by physicians, patients, third-party payors, and the medical community.
- Social issues around the abuse of opioids and stimulants, including law enforcement concerns over diversion and regulatory efforts to combat abuse, could decrease the potential market for our product candidates.
- Our business is subject to extensive regulatory requirements, and our product candidates that obtain approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.
- We rely on limited sources of supply for CTx-1301 and CTx-1302 as these are scheduled products, and any disruption in the chain of supply may impact production and sales of CTx-1301 and CTx-1302 and cause delays in developing and commercializing our product candidates.
- We rely on third parties to manufacture and package our product candidates and to conduct our clinical trials and our regulatory submissions for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the manufacture and delivery of our product candidates, completion of such trials and/or regulatory submissions.

- We will rely on third parties to commercialize our product candidates and we may rely on third parties to perform many essential services for any products that we commercialize, including distribution, customer service, accounts receivable management, cash collection and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize our product candidates will be significantly impacted and we may be subject to regulatory sanctions.
- If we are not able to maintain or establish collaborations, we may have to alter our development and commercialization plans.
- We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth.
- Our research and development is focused on discovering and developing product candidates, which may not make it to the market.
- We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.
- If our intellectual property related to our products or product candidates is not adequate, we may not be able to compete effectively in our market.
- An active trading market for our securities may not be sustained.

Risks Related to Our Financial Position and Need for Capital

We are a biopharmaceutical company with a limited operating history.

We are a biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We must complete clinical studies and receive regulatory approval before commercial sales of a product can commence. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Pharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially early-stage pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to, among other things:

- successfully implement or execute our business plan, and we cannot assure you that our business plan is sound;
- secure approval of CTx-1301 or any of our product candidates;
- successfully complete product development/formulation, and clinical trials for CTx-1301, CTx-1302, and/or CTx-2103 as well as for the marketing of any or all products;
- successfully manufacture or have manufactured clinical product and establish commercial drug supply in light of the manufacturing delays we experienced prior to October 2022 with respect to the clinical supply of CTx-1301 at our former contract manufacturing organization ("CDMO") and the Form 483 issued by the FDA to our current CDMO in February 2026 as a result of the FDA's pre-approval inspection;
- raise sufficient funds in the capital markets or otherwise to effectuate our business plan;
- secure adequate intellectual property protection for our products;
- attract and retain an experienced management and advisory team;
- secure acceptance of our drug candidates in the medical community and with third-party payors and consumers;
- launch commercial sales of our drug candidates, whether alone or in partnership with others;
- comply with post-marketing regulatory requirements; and
- utilize the funds that we do have and/or raise in the future to efficiently execute our business strategy.

If we cannot successfully execute any one of the foregoing, our business, financial condition, results of operations and future growth prospects would be materially and adversely affected.

We have incurred a history of operating losses and expect to continue to incur substantial costs for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability.

We have never generated revenue from operations and are currently operating at a loss and expect our operating costs will increase significantly as we incur costs related to formulation/manufacturing development, the clinical trials for our drug candidates and operating as a public company and, if we are successful in obtaining regulatory approval to market one or more of our product candidates, the marketing and commercialization of such approved product(s). We expect to incur expenses without corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize CTx-1301. We may never be able to obtain regulatory approval for the marketing of our drug candidates in any indication in the United States or internationally. Even if we obtain regulatory approval for CTx-1301, development expenses will continue to increase for any future assets. As we continue to develop CTx-1301, seek marketing approval and conduct pre-commercialization activities, we will continue to incur substantial costs.

We have incurred recurring losses since inception and had an accumulated deficit of approximately $132.4 million as of December 31, 2025. These conditions raise substantial doubt about our ability to continue as a going concern, meaning that we may be unable to continue operations for the foreseeable future or realize assets and discharge liabilities in the ordinary course of operations. If we are unable to obtain further funding, we may be unable to continue operations. Although we continue to pursue these plans, there can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

Even if we are successful in obtaining regulatory approval for CTx-1301 or one or more of our other drug candidates, our ability to generate revenue will still be dependent on a number of factors outside of our control, including, the size of the addressable market, the label for which approval is granted, the accepted price for the product, and/or the ability to get and maintain adequate coverage and reimbursement. See "If our drug candidates for which we obtain regulatory approval do not achieve broad acceptance from physicians, patients and third-party payors, we may be unable to generate significant revenues, if any" below.

We will continue to expend substantial cash resources for the foreseeable future for the clinical development of our product candidates and development of any other indications and product candidates we may choose to pursue, and, if we are successful in obtaining regulatory approval to market one or more of our product candidates, the marketing and commercialization of such approved product(s). These expenditures will include costs associated with manufacturing and clinical development, such as conducting clinical trials, manufacturing operations and product candidate supply, as well as marketing and selling any products approved for sale. Because the conduct and results of any clinical trial are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current and any future product candidates. If one or more of our product candidates are approved by the FDA, these expenditures will also include [__].

We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our securities and our ability to raise capital.

We depend heavily on the success of CTx-1301. If we are unable to secure approval of CTx-1301, we will never be able to generate revenues from CTx-1301, and our ability to create stockholder value will be severely limited.

Our most advanced product candidate currently is CTx-1301, for which we submitted a NDA with the FDA in July 2025. We do not currently generate revenues from any FDA approved drug products and our other product candidates are in the early stages of development. There is no guarantee that our clinical trials will be successful or that we will continue with clinical studies to support an approval from the FDA of any of our product candidates for any indication. We note that most drug candidates never reach the clinical development stage and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends heavily on the successful development, regulatory approval and commercialization of CTx-1301, which may never occur.

Completing the process of obtaining FDA approval of the pending NDA for CTx-1301 still involves substantial risk. We completed the NDA submission to the FDA in July 2025. On October 9, 2025, the NDA submission was accepted by the FDA and a PDUFA target action date of May 31, 2026 was assigned. To date, the FDA has made several information requests, primarily related to CMC, as it reviews our Precision Timed Release™ Platform, the first tri-modal, pulsatile capable tablet delivery system. We have been engaged with and responded to all information requests from the FDA received to date. In February 2026, the FDA conducted a pre-approval inspection of our CDMO's facility used to manufacture CTx-1301. This

facility was issued a Form 483 by the FDA at the conclusion of the inspection with three observations. Two observations were related to the facility, and one observation was specific to CTx-1301. Our CDMO is working on responses to these observations, with our input where relevant.

Our efforts (and those of our CDMO) to develop, make and win approval for CTx-1301 continue to be subject to inspection and approval by the FDA and other factors outside of our control, and there remains a risk that the required FDA approvals of CTx-1301 and/or our CDMO's facility used to manufacture CTx-1301 could be further delayed or not obtained. There can be no assurance that approval of CTx-1301 will occur on the previously expected timeline or that it will occur at all, which would significantly harm our business, results of operations and prospects.

We will need to raise significant additional capital to continue operations. If we are unable to raise capital, we could be required to seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us.

We will need to raise significant additional capital to continue to support our planned development and commercialization activities. We believe that our cash on hand will satisfy our capital needs late into the fourth quarter of 2026 under our current business plan. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available capital resources much faster than we currently expect or require more capital to fund our operations than we currently expect. The amount and timing of our future funding requirements will depend on many factors, including:

- the timing, rate of progress and cost of any clinical trials and other manufacturing/product development activities for our current and any future product candidates that we develop, in-license or acquire;
- the results of the clinical trials for our product candidates in the United States and any foreign countries;
- the timing of, and the costs involved in, FDA approval and any foreign regulatory approval of our product candidates, if at all;
- the number and characteristics of any additional future product candidates we develop or acquire;
- our ability to establish and maintain strategic partnerships, licensing, co-promotion or other arrangements and the terms and timing of such arrangements;
- the cost of commercialization activities if our current or any future product candidates are approved for sale, including manufacturing, marketing, sales and distribution costs;
- the degree and rate of market acceptance of any approved products;
- costs under our third-party manufacturing and supply arrangements for our current and any future product candidates and any products we commercialize;
- costs and timing of completion of any additional outsourced commercial manufacturing or supply arrangements that we may establish;
- the willingness of our third-party service providers to continue to provide services based on our limited liquidity and those service providers not requiring pre-payment for services;
- costs of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- costs associated with prosecuting or defending any litigation that we are or may become involved in and any damages payable by us that result from such litigation;
- costs associated with any product recall that could occur;
- costs of operating as a public company;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;
- costs associated with any acquisition or in-license of products and product candidates, technologies or businesses;
- personnel, facilities and equipment requirements; and
- continued compliance with the terms of the Note Purchase Agreement and Note issued by us in November 2025.

We cannot be certain that additional funding will be available on acceptable terms, or at all.

In November 2025, we issued the Note to Lender. Pursuant to the Note Purchase Agreement, while the Note is outstanding, we will not enter into any arrangement that prohibits us from entering into a variable rate transaction with Lender or its affiliates, or from issuing our securities to Lender or its affiliates. We are also prohibited from entering into a variable rate transaction while the Note is outstanding, subject to certain exceptions. Also, while the Note is outstanding, upon any issuance by us of any debt security with any economic term or condition more favorable to the holder of such security that was not provided to Lender pursuant to the Note, then, at Lender's option, such additional term shall become part of the Note. The Note also provides that following an event of default under the Note, Lender has the right to seek and receive injunctive relief from a court or an arbitrator prohibiting us from issuing any of our common stock or preferred stock to any party unless fifty percent of the gross proceeds received by us in connection with such issuance are simultaneously used to make a payment under the Note. Additionally, Lender has the right to seek and receive injunctive relief from a court or arbitrator to prevent the consummation of any fundamental transaction, as defined in the Note, unless it contains a closing condition that the Note is paid in full upon consummation of the transaction or lender has provided its written consent to such transaction.

In addition, future debt financing into which we may enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions.

If we are unable to raise additional capital when required or on acceptable terms or if we are unable to enter into strategic collaborations for our product candidates, we may be required to further restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our securityholders losing some or all of their investment in us. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

In addition, if we are unable to secure sufficient capital to fund our operations, we may have to enter into strategic collaborations that could require us to share commercial rights to our product candidates with third parties in ways that we currently do not intend or on terms that may not be favorable to us or our securityholders.

The note purchase agreement and note issued by us in November 2025 contain restrictive covenants and adjustments in the event we default on the Note that may limit our operating flexibility and impact our operations.

In November 2025, we entered into a Note Purchase Agreement with Avondale Capital, LLC, or Lender, pursuant to which we issued and sold to Lender an unsecured promissory note, or Note, in the amount of $6,570,000. The Note bears interest at a rate of 9% per annum and matures 18 months after its issuance date.

The Note provides for customary events of default, including, among other things, the event of nonpayment of principal, interest, fees or other amounts, a representation or warranty proving to have been incorrect when made, failure to perform or observe covenants within a specified cure period, a cross-default to certain our other indebtedness and material agreements, and the occurrence of a bankruptcy, insolvency or similar event. Upon the occurrence of an event of default that is deemed a "Major Trigger Event" as defined in the Note, Lender may increase the outstanding balance of the Note by 15%, and upon the occurrence of an event of default that is deemed a "Minor Trigger Event" as defined in the Note, Lender may increase the outstanding balance of the Note by 5%. Lender can exercise its right to increase the outstanding balance upon a Major or Minor Trigger Event three times each. Upon the occurrence of an event of default, Lender may declare all amounts owed under the Note immediately due and payable. In addition, upon the occurrence of an event of default, upon the election of Lender, interest shall begin accruing on the outstanding balance of the Note from the date of the event of default equal to the lesser of 22% per annum and the maximum rate allowable under law. There can be no assurance that we will be able to comply with the terms of the Note Purchase Agreement and Note, and if an event of default occurs, it may have significant detrimental effects on business operations and financial condition.

Pursuant to the Note Purchase Agreement, we are subject to certain restrictions on our ability to issue securities during the term of the Note. Specifically, we have agreed, among other things, to obtain Lender's consent prior to issuing any debt securities or certain equity securities where the pricing of such equity securities is tied to the public trading price of our common stock and to refrain from entering into any agreement or covenant that locks up, restricts or otherwise prohibits us from entering into a variable rate transaction with Lender or any of its affiliates, or from issuing common stock or other equity or debt securities to Lender or any of its affiliates. If we are unable to obtain Lender's consent prior to issuing such debt or certain equity securities, such issuance may be a breach of the Note Purchase Agreement, and we may be obligated to indemnify Lender for loss or damage arising as a result of any breach or alleged breach by us of the Note Purchase Agreement, which may affect our business operations and financial condition.

In addition, from time to time, beginning on May 7, 2026, Lender may redeem a portion of the Note, not to exceed an amount of $660,000 per month; provided, that, prior to our receipt of a "complete response letter" from the FDA, we may defer up to two redemptions for up to thirty (30) days each. If we exercise our deferral right, the outstanding balance of the Note will be increased by 1% of the outstanding balance on the date of the deferral. We were able to satisfy redemptions for the note we issued in December 2024 by exchanging shares of our common stock. Our failure to pay such redemptions with cash or in exchange for shares of our common stock, when due, may result in defaults under our agreements with the Lender. If we are in default with respect to our obligations under the Note, the Lender may consider the Note immediately due and payable and may elect to substantially increase the interest rate of the Note. We may not have the required funds to pay the required note redemptions and such redemptions, or penalties in connection therewith, may have an adverse effect on our cash flows, results of operations, and ability to pay our other debts as they come due.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest in our company may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

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, limit, reduce or terminate our product candidates' development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Changes in tax laws may materially adversely affect our business, financial condition, results of operations and cash flows.

We are subject to tax laws, regulations and policies of the jurisdictions in which we do business, which may include United States federal, state, and local governments and taxing authorities in foreign jurisdictions. Changes in tax laws, as well as other factors, could cause us to experience fluctuations in our tax obligations and otherwise adversely affect our tax positions and/or our tax liabilities. The income tax rules in the jurisdictions in which we operate are constantly under review by taxing authorities and other governmental bodies. Changes to tax laws (which changes may have retroactive application) could adversely affect us or our stockholders. We are unable to predict what tax proposals may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall effective tax rates in the future in jurisdictions where we have operations, and increase the complexity, burden, and cost of tax compliance.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations .

Our net operating loss carryforwards ("NOLs"), and certain other tax attributes could be unavailable to offset future income tax liabilities because of restrictions under U.S. tax law. Under the Tax Cuts and Jobs Act, or the TCJA, federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely. The carryforwards are limited to 80% of each subsequent year's net income.

In addition, Sections 382 and 383 of the Code, contain rules that limit the ability of a corporation that undergoes an "ownership change" (generally, any change in ownership of more than 50% of the corporation's stock over a three-year period) to utilize its pre-change NOLs and tax credit carryforwards to offset future taxable income. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a corporation and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of NOLs and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term, tax-exempt rate and the value of the corporation's stock immediately before the ownership change. As a result, following any such ownership change, we might be unable to offset our taxable income with losses, or our tax liability with credits, before such losses and credits expire, in which event we could incur larger federal and state income tax liabilities than we would have had we not experienced an ownership change.

The report of our independent registered public accounting firm for the fiscal years ended December 31, 2025 and 2024 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.

The report of our independent registered public accounting firm on our financial statements as of and for the years ended December 31, 2025 and December 31, 2024 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Since inception, we have experienced recurring operating losses and negative cash flows, and we expect to continue to generate operating losses and consume significant cash resources for the foreseeable future. Without additional financing, these conditions raise substantial doubt about our ability to continue as a going concern, meaning that we may be unable to continue operations for the foreseeable future or realize assets and discharge liabilities in the ordinary course of operations. If we are unable to obtain funding, we may be unable to continue operations. Although we continue to pursue these plans, there can be no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval

We are dependent primarily on the successful development and commercialization of our product candidates, CTx-1301 and CTx-1302 for the treatment of ADHD and CTx-2103 for the treatment of anxiety, which are either in product/early clinical development (CTx-2103), late development (CTx-1301) or planned for future product development (CTx-1302) and are not yet approved. We cannot give any assurance that we will receive regulatory approval for such product candidates or any other product candidates, which is necessary before they can be commercialized.

We have not completed development of and/or obtained regulatory approval for any of our product candidates. Development requires the commitment of substantial financial resources, extensive product candidate development, and clinical trials. This process takes years of effort without any assurance of ultimate success.

Our ability to generate revenue from our product candidates will depend heavily on their successful development, regulatory approval, and eventual commercialization. CTx-2103 and CTx-1302 are in the early stages of development, and we do not expect those product candidates to generate revenue for several years, if ever. The success of our product candidates will depend on many factors, including, but not limited to:

- successful completion of product development and requisite clinical trials;
- successful completion and achievement of endpoints in our clinical trials;
- demonstration that the risks involved with our product candidates are outweighed by the benefits;
- successful development of our manufacturing processes for our product candidates, including entering into and maintaining arrangements with third-party manufacturers;
- successful completion of an FDA preapproval inspection of the facilities used to manufacture our product candidates, as well as select clinical trial sites;
- receipt of timely marketing approvals from applicable regulatory authorities, including the determination by the DEA of the controlled substance schedule for a product candidate, taking into account the recommendation of the FDA;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidates and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including current good manufacturing practices, or cGMPs;
- launching commercial sales of product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our drug product candidates, if approved, by patients, the medical community and third-party payors;
- competing effectively with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- maintaining a continued acceptable safety and efficacy profile of the drug products following approval.

For example, in February 2026, the FDA conducted a pre-approval inspection of our CDMO’s facility used to manufacture CTx-1301. This facility was issued a Form 483 by the FDA at the conclusion of the inspection with three observations. Two observations were related to the facility and one observation was specific to CTx-1301.

If we are unable to achieve one or more of the above factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays and increased costs or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue operations. See "The commercial success of our product candidates, if approved, depends partially upon attaining market acceptance by physicians, patients, third-party payors, and the medical community" below for more information

Our product development efforts with respect to our product candidates may fail for many reasons, including but not limited to:

- the failure of the product candidate in clinical studies;
- adverse patient reactions to the product candidate or indications of other safety concerns;
- insufficient clinical trial data to support the effectiveness or superiority of the product candidate;
- the inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; and
- changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer attractive.

Premarket review of our product candidates by the FDA or other regulatory authorities is a lengthy and uncertain process and approval may be delayed, limited or denied, any of which would adversely affect our ability to generate operating revenues.

We are not permitted to market our drug product candidates in the United States until we receive the respective approval of a NDA from the FDA. The time required to obtain approval, if any, by the FDA is unpredictable, but typically takes multiple years following the commencement of clinical trials, and depends upon numerous factors, including the substantial discretion of the regulatory authorities and the type, complexity and novelty of the product candidates involved. We submitted a NDA for CTx-1301 to the FDA in July 2025. On October 9, 2025, the NDA submission was accepted by the FDA and a PDUFA target action date of May 31, 2026 was assigned. To date, the FDA has made several information requests, primarily related to CMC, as it reviews our Precision Timed Release™ Platform, the first tri-modal, pulsatile capable tablet delivery system. We have been engaged with and responded to all information requests from the FDA received to date. In February 2026, the FDA conducted a pre-approval inspection of our CDMO facility used to manufacture CTx-1301. This facility was issued a Form 483 by the FDA at the conclusion of the inspection with three observations. Two observations were related to the facility, and one observation was specific to CTx-1301. Our CDMO is working on responses to these observations, with our input where relevant.

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- could determine that we cannot rely on the 505(b)(2) regulatory approval pathway for a product candidate that we may identify and develop;
- could determine that the information provided by us as part of an IND or NDA is inadequate, contains clinical deficiencies or otherwise fails to demonstrate safety and effectiveness of any of our product candidates for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the safety risks outweigh clinical and other benefits of our product candidates;
- may require us to perform additional studies to demonstrate the safety, efficacy, pharmacokinetics, or other properties of our product candidates prior to approval, or require such studies as a condition of approval;
- may disagree with our clinical trial designs or our interpretation of data from product development manufacturing data, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that we inappropriately relied on a certain listed drug or drugs for our 505(b)(2) NDA or that approval of our applications for a product candidate is blocked by patent or non-patent exclusivity of the listed drug or drugs;

- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the supply of the API used in our product candidates;
- may identify deficiencies in our manufacturing processes or our proposed scale-up of the manufacturing processes or facilities for the production of our product candidates;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

Our efforts (and those of our contract manufacturer) to develop, make and win approval for CTx-1301 continue to be subject to inspection and approval by the FDA and other factors outside of our control, and there remains a risk that the required FDA approvals of CTx-1301 and/or the third party facilities used to manufacture CTx-1301 could be further delayed or not obtained. There can be no assurance that approval of CTx-1301 will occur on the previously expected timeline or that it will occur at all, which would significantly harm our business, results of operations and prospects.

We must ensure our CDMO complies with cGMP, and regulatory inspections or findings could interrupt supply and delay development.

We must ensure that our CDMO complies with cGMP regulations. Manufacturing deviations, documentation errors, or quality system gaps at CDMOs can lead to Form 483 observations, warning letters, or import alerts, jeopardizing clinical supply continuity. Pre-approval inspections assess readiness for commercial production and can reveal issues that require significant remediation time and investment. In February 2026, the FDA conducted a pre-approval inspection of our CDMO's facility used to manufacture CTx-1301. This facility was issued a Form 483 by the FDA at the conclusion of the inspection with three observations. Two observations were related to the facility and one observation was specific to CTx-1301. Our CDMO is working on responses to these observation, with our input where relevant. Changes to manufacturing processes or facilities can trigger comparability assessments or bridging studies, adding regulatory complexity. If a our CDMO loses licensure or fails to meet cGMP standards, transitioning to an alternate CDMO may be lengthy and costly, potentially delaying development and commercialization.

Disruptions at the FDA and other government agencies caused by funding shortages or otherwise could hinder their ability to hire and retain key leadership and other personnel, or otherwise review and process regulatory submissions in a timely manner, which could negatively impact our business.

The ability of the FDA to review and process regulatory submissions can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. For example, over the last several years, the U.S. government has shut down several times, including the most recent U.S. government shutdown which lasted from October 1, 2025 through November 12, 2025, and certain regulatory agencies, such as the FDA, have had to furlough FDA employees and suspend certain activities.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs or continues, or if the FDA or other regulatory authorities is prevented from conducting their regular inspections, reviews, or other regulatory activities, for any reason, 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.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is outcome uncertain. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of our product candidates.

It is impossible to predict when or if any of our product candidates will prove effective or safe in humans and will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete product/manufacturing development and then conduct clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of development. The outcome of early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical

trial do not necessarily predict final results. Interpretation of results from early, usually smaller, studies that suggest positive trends in some subjects, requires caution. Results from later stages of clinical trials enrolling more subjects may fail to show the desired safety and efficacy results or otherwise fail to be consistent with the results of earlier trials of the same product candidates. Later clinical trial results may not replicate earlier clinical trials for a variety of reasons, including differences in trial design, different trial endpoints, or lack of trial endpoints in studies, subject population, number of subjects, subject selection criteria, trial duration, drug dosage and formulation and lack of statistical power in the earlier studies. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in early and later stage clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including but not limited to:

- inability to generate satisfactory preclinical, toxicology or other in vivo or in vitro data capable of supporting the initiation or continuation of clinical trials;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site or amend clinical trial protocols as needed;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and contract research organizations, or CROs;
- inability, delay or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance in cases where that is required, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- failure of patients to complete a trial or return for post-treatment follow-up;
- inability to monitor patients adequately during or after treatment;
- clinical sites and investigators deviating from trial protocols, failing to conduct the trial in accordance with regulatory requirements or dropping out of a trial;
- our third-party contractors may fail to comply with regulatory requirements or trial protocols, or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate, including if we are not able to pursue the 505(b)(2) NDA pathway for approval of our product candidates;
- failure to initiate or delay of or inability to complete a clinical trial as a result of a clinical hold imposed by the FDA or comparable regulatory authority due to observed safety findings or other reasons;
- regulatory authorities may not agree with our trial design or implementation;
- inability to manufacture sufficient quantities of a drug candidate of acceptable quality for use in clinical trials; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval but without the claims necessary for us to successfully commercialize our product candidates;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing, surveillance, or other requirements; or
- have the product removed from the market after obtaining marketing approval.

Our development costs may also increase if we experience delays in testing, clinical trials, manufacturing or obtaining marketing approvals. For example, our development costs increased for CTx-1301 due to rescheduling of the Phase 3 fixed-dose study as a result of manufacturing delays prior to October 2022 for the final dosage strengths needed for that study. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. In late 2023, we announced a change in the clinical development plan for CTx-1301 based on feedback from the FDA, and accordingly stopped enrollment in two Phase 3 trials of CTx-1301 Significant product manufacturing or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

Moreover, in February 2026, the FDA conducted a pre-approval inspection of our CDMO's facility used to manufacture CTx-1301. This facility was issued a Form 483 by the FDA at the conclusion of the inspection with three observations. Two observations were related to the facility and one observation was specific to CTx-1301. Our CDMO is working on responses to these observation, with our input where relevant.

Obtaining regulatory approval for clinical trials of CTx-1301 and CTx-1302 in children and adolescents may require additional studies and/or longer duration of studies since the requirements for regulatory approval for the pediatric populations are more stringent.

Pediatric drug development may require additional studies to determine safe dosing and long-term safety. These additional studies may require investment of significant additional resources beyond those required for regulatory approval of the drugs in adults. Although, we have stopped enrollment in the pivotal Phase 3 fixed-dose pediatric and adolescent safety and efficacy study of CTx-1301 and the Phase 3 pediatric dose-optimization onset and duration study of CTx-1301 based on feedback from the FDA, we may have to restart and complete these and other trials in order to obtain regulatory approval. Approval of CTx-1301 may be delayed due to these additional requirements and this may have an adverse effect on the commercial prospects of CTx-1301, as well as delay our ability to generate product revenue, possibly materially. We cannot guarantee that we will receive regulatory approval to commercialize our product candidates in the pediatric populations or the adult population. See "—We depend heavily on the success of CTx-1301. If we are unable to secure approval of CTx-1301, we will never be able to generate revenues from CTx-1301, and our ability to create stockholder value will be severely limited" above for more information about the risks related to FDA approval of CTx-1301.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through nonclinical testing and early to late-stage clinical trials towards potential approval and commercialization, various aspects of the development program, such as manufacturing methods and formulation, may be altered along the way in an effort to optimize processes and results. Such changes may not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials, or they may alter the safety or risk profile of the product candidate that could involve further FDA or other regulatory agency inquiries. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the performance of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

Our product candidates CTx-1301 and CTx-1302 contain controlled substances, the manufacture, use, sale, importation, exportation, prescribing and distribution of which are subject to regulation by the DEA.

Before we can commercialize our product candidates, the DEA will need to determine the controlled substance schedule, taking into account the recommendation of the FDA. This may be a lengthy process that could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible. Our CTx-1301 and CTx-1302 product candidates, if approved, will be regulated as "controlled substances" as defined in the CSA and the implementing regulations of the DEA, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are applicable to us, our contract manufacturers and distributors, as well as prescribers and dispensers of our product candidates.

The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in the manufacturing and packaging, in order to prevent loss and diversion into illicit channels of commerce. A number of states and foreign countries also independently regulate these drugs as controlled substances.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. An approved pharmaceutical product may be listed as Schedule II, III, IV or V, depending on the potential for abuse and physical or psychological dependence, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Schedule II drugs are those that meet the following characteristics:

- the drug has a high potential for abuse, misuse and addiction; and
- the drug has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

The active pharmaceutical ingredients in CTx-1301 and CTx-1302 (dexmethylphenidate and dextroamphetamine) are currently listed as Schedule II products. We expect that some of our future product candidates may also be listed by the DEA as Schedule II controlled substances under the CSA. Consequently, the manufacturing, shipping, storing, selling and using of the products, if approved, will be subject to a high degree of regulation. Schedule II drugs are subject to the strictest requirements for registration, security, recordkeeping and reporting, and the distribution, prescribing and dispensing of these drugs are highly regulated.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule.

In addition, a DEA quota system controls and limits the availability and production of controlled substances, and our products may be subject to the DEA's production and procurement quota scheme. The DEA establishes an aggregate quota for how much of a controlled substance may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. Manufacturers of controlled substances are required to apply for quotas on an annual basis. If we or our contract manufacturers or suppliers do not obtain a sufficient quota from DEA, we may not be able to obtain sufficient quantities of these controlled substances in order to complete our clinical trials or meet commercial demand, if our product candidates are approved for marketing.

Because of their restrictive nature, these laws and regulations could limit commercialization of our product candidates containing controlled substances. Failure to comply with these laws and regulations could also result in withdrawal of our DEA registrations, disruption in manufacturing and distribution activities, consent decrees, criminal and civil penalties and state actions, among other consequences.

If we experience delays or difficulties in the enrollment of subjects in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. We cannot predict how successful we will be at enrolling subjects in future clinical trials. If we are not successful at enrolling subjects in one clinical trial, it may affect when we are able to initiate our next clinical trial, which could result in significant delays in our efforts to pursue regulatory approval of and commercialize our product candidates. In addition, some of our competitors have ongoing clinical trials to treat the same indications as our product candidates, and subjects who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors. Subject enrollment is affected by other factors including, but not limited to:

- the size and nature of the subject population specified in the trial protocol;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the fact that the product candidate may be a controlled substance;
- severe or unexpected drug-related adverse events experienced by subjects in a clinical trial;
- the availability of drugs approved to treat the diseases or conditions under study;
- the extent of efforts to facilitate timely enrollment in clinical trials;

- the patient referral practices of physicians;
- the ability to obtain and maintain subject informed consent;
- the ability to retain subjects in the clinical trial and their return for follow-up;
- the clinical trial design, including required tests, procedures and follow-up;
- the ability to monitor subjects adequately during and after treatment;
- delays in adding new investigators and clinical sites;
- withdrawal of clinical trial sites from clinical trials;
- the presence of other drug candidates in clinical development for the same indication; and
- the proximity and availability of clinical trial sites for prospective subjects.

Our inability to enroll a sufficient number of subjects 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 development costs for our product candidates, which could cause our value to decline and limit our ability to obtain additional financing.

Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some or all of our product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate thorough, lengthy, complex and expensive product development and clinical trials that our product candidates are both safe and effective for use in each target indication, and failures can occur at any stage of development. Clinical trials often fail to demonstrate safety and efficacy of the product candidate studied for the target indication.

As with many pharmaceutical products, treatment with our product candidates may produce undesirable side effects or adverse reactions or events. Although our product candidates contain active pharmaceutical ingredients that have already been approved, meaning that the side effects arising from the use of the active pharmaceutical ingredient or class of drug in our product candidates are generally known, our product candidates still may cause undesirable side effects.

If our product candidates are associated with serious side effects in clinical trials or have characteristics that are unexpected, we may need to limit development to more narrow uses or subpopulations in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an institutional review board may also require that we suspend, discontinue, or limit our clinical trials based on safety information to limit potential serious harm to enrolled subjects. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates.

Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, or result in significant negative consequences following marketing approval, if any.

If any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including, but not limited to:

- the FDA may require additional clinical testing or clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the product;
- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients, or we may be required to implement a REMS to ensure that the benefits of the product outweigh the risks;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is distributed or administered;
- we may need to voluntarily recall our products;
- we could be sued and held liable for harm caused to individuals exposed to or taking our product candidates; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate and could substantially increase the costs of commercializing our products and product candidates.

If the FDA does not conclude that our product candidates are sufficiently bioequivalent, or have comparable bioavailability, to approved reference drugs, or if the FDA does not allow us to pursue the 505(b)(2) NDA pathway as anticipated, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and the FDA may not ultimately approve our product candidates.

Section 505(b)(2) of the FDCA permits the filing of an NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) of the FDCA, for the purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. The FDA may also require the applicant to perform additional clinical trials or measurements to support any deviation from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The FDA may require an applicant's product label to have all or some of the limitations, contraindications, warnings or precautions included in the reference product's label, including a black box warning, or may require the label to have additional limitations, contraindications, warnings or precautions. A key element of our strategy is to seek FDA approval for our current product candidates, CTx-1301, CTx-1302, and CTx-2103, through the 505(b)(2) NDA pathway. Based on guidance received from the FDA, we submitted the NDA for CTx-1301 in July 2025 under the Section 505(b)(2) pathway with Focalin® XR as the reference listed drug, using its efficacy and safety data on file with the FDA as a basis for approval, together with bioavailability/bioequivalence data and efficacy/safety data from our CTx-1301 clinical program. If the FDA determines that our product candidates do not meet the requirements of Section 505(b)(2), or if we cannot demonstrate bioequivalence or comparable bioavailability of our product candidates to approved products, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval applicable to a traditional NDA submitted pursuant to Section 505(b)(1). Moreover, even if the FDA does allow us to pursue the 505(b)(2) NDA pathway, depending on the product candidate, we may still need to conduct additional clinical trials, including clinical trials to assess product safety or efficacy. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates, and complications and risks associated with our product candidates, would likely substantially increase.

Moreover, an inability to pursue the 505(b)(2) NDA pathway could result in new competitive products reaching the market more quickly than our product candidates, which could hurt our competitive position and our business prospects. Even if we are allowed to pursue the 505(b)(2) NDA pathway, we cannot assure that our product candidates will receive the requisite approvals for commercialization on a timely basis, if at all. Other companies may achieve product approval of similar products before we do, which would delay our ability to obtain product approval, and expose us to greater competition.

In addition, notwithstanding the approval of a number of products by the FDA under 505(b)(2) over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of 505(b)(2) of the FDCA to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation of 505(b)(2) is successfully challenged in court it could delay or even prevent the FDA from approving any 505(b)(2) NDA that we submit in the future. Moreover, the FDA has adopted an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if it does not rely on the previously-approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA's interpretation, the approval of one or more of our product candidates may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with our product candidates, even if our 505(b)(2) application does not identify the previously-approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

Even if our product candidates are approved under 505(b)(2) regulatory pathway, the approval may be subject to limitations on the indicated uses for which the products may be marketed, including more limited subject populations than we request, may require that contraindications, warnings or precautions be included in the product labeling, including a black box warning, may be subject to other conditions of approval, or may contain requirements for costly post-marketing clinical trials, testing and surveillance to monitor the safety or efficacy of the products, or other post-market requirements, such as a REMS. The FDA also may not approve a product candidate with a label that includes the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Even if we obtain and maintain regulatory approval of our product candidates in one jurisdiction, such approval does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate within the United States comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as investigations conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Moreover, the acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, any foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction.

We may be unable to successfully complete Phase 3 clinical trials for our product candidates.

The conduct of a Phase 3 clinical trial is a complicated process. Although members of our management team have conducted Phase 3 clinical trials in the past while employed at other companies, we as a company had not conducted a Phase 3 clinical trial prior to the clinical trials for CTx-1301. Failure to include the correct treatment regimen, complete, or delays in, our Phase 3 clinical trials, could prevent us from or delay us in commencing future clinical trials, obtaining regulatory approval of and commercializing our product candidates, which would adversely impact our financial performance. In addition, some of our competitors are currently conducting clinical trials for product candidates that treat the same indications as CTx-1301, and patients who are otherwise eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- factors we may not be able to control, such as potential pandemics that may limit subjects, principal investigators or staff or clinical site availability.

In May 2024, we announced a change in the clinical development plan for CTx-1301 based on feedback from FDA, and accordingly stopped enrollment in two Phase 3 trials of CTx-1301. We may need to restart these trials and/or start new trials in order to win regulatory approval of CTx-1301. We may find it difficult or impossible to restart or start such clinical trials.

Even if we obtain regulatory approval for our product candidates, such approval may be limited, and we will be subject to stringent, ongoing government regulation.

Even if regulatory authorities approve our product candidates for commercialization, the FDA could approve less than the full scope of indications or labeling claims that we seek or may otherwise require special warnings or other restrictions on their use or marketing. Regulatory authorities may limit the segments of the target population to which we or others may market our product candidates. The advantages of our product candidates may not be agreed to by the FDA or other regulatory authorities or such authorities may otherwise object to the inclusion of related claims in product labeling or advertising and, as a result our product candidates may not have our expected competitive advantages when compared to other similar products. In particular, the FDA may limit labeling claims based upon the duration of efficacy of our products. In addition, any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance.

If we obtain regulatory approval for any of our product candidates, activities such as the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and record keeping for the products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs. The FDA or comparable regulatory authorities may also impose requirements for costly post-marketing nonclinical studies or clinical trials (often called "Phase 4 trials") and post-marketing surveillance to monitor the safety or efficacy of the product. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, production problems or issues with the facility where the product is manufactured or processed, such as product contamination or significant not-compliance with applicable cGMPs, a regulator may impose restrictions on that product, the manufacturing facility or us. Accordingly, we and our CDMOs will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA submission to the FDA or any other type of domestic or foreign marketing application. If we or our third-party providers, including our CDMOs fail to comply fully with applicable regulations, then we may be required to initiate a recall or withdrawal of our products.

In addition, later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in the following, among other things:

- restrictions on the manufacturing of the product, the approved manufacturers or the manufacturing process;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- withdrawal of the product from the market;
- product recalls;
- warning or untitled letters from the FDA or comparable notice of violations from foreign regulatory authorities;
- refusal of the FDA or other applicable regulatory authority to approve pending applications or supplements to approved applications;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- suspension of any of our ongoing clinical trials;
- product seizure or detention or refusal to permit the import or export of products; and
- consent decrees, injunctions or the imposition of civil or criminal penalties.

In addition, the FDA's or other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are otherwise not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay marketing approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Our employees, independent contractors, principal investigators, consultants, vendors, CROs, CDMOs and any partners with which we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, CROs, CDMOs, and any partners with which we may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or other regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws; data privacy laws and regulations; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse impact on our business, financial condition, results of operations and prospects including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, loss of eligibility to obtain marketing approvals from the FDA, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with any of these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our operating results.

We may be required to modify our business practices, pay fines and significant expenses or experience other losses due to governmental investigations or other enforcement activities.

We may become subject to litigation or governmental investigations in the United States and/or foreign jurisdictions that may arise from the conduct of our business. Like many companies in our industry, we may from time to time receive inquiries and subpoenas and other types of information requests from government authorities and we may be subject to claims and other actions related to our business activities.

While the ultimate outcome of investigations and legal proceedings are difficult to predict, adverse resolutions or settlements of those matters could result in, among other things:

- significant damage awards, fines, penalties or other payments, and administrative remedies, such as exclusion and/or debarment from government programs, or other rulings that preclude us from operating our business in a certain manner;
- changes to our business operations to avoid risks associated with such litigation or investigations;
- product recalls;
- reputational damage and decreased demand for our products; and
- expenditure of significant time and resources that would otherwise be available for operating our business.

While we maintain insurance for certain risks, the amount of our insurance coverage may not be adequate to cover the total amount of all adverse resolutions and settlements of claims and liabilities. It also is not possible to obtain insurance to protect against all potential risks and liabilities.

We or our current and prospective partners may be subject to product recalls in the future that could harm our brand and reputation and could negatively affect our business.

We or our current and prospective partners may be subject to product recalls, withdrawals or seizures if any of our product candidates, if approved for marketing, fail to meet specifications or are believed to cause injury or illness or if we are alleged to have violated governmental regulations including those related to the manufacture, labeling, promotion, sale or

distribution. Any recall, withdrawal or seizure in the future could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our approved products. In addition, a recall, withdrawal or seizure of any of our approved products would require significant management attention, would likely result in substantial and unexpected expenditures and would harm our business, financial condition and operating results.

We will need to obtain FDA approval of any proposed names for our product candidates that gain marketing approval, and any failure or delay associated with such naming approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the United States Patent and Trademark Office ("USPTO"). The FDA typically conducts a review of proposed product names, including an evaluation of whether proposed names may be confused with other product names. The FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates, which could result in further evaluation of proposed names with the potential for additional delays and costs.

Government initiatives such as the Make America Healthy Again Commission could affect the development and approval of our product candidates

Government initiatives and regulatory policies can significantly affect our ability to develop, obtain approval for, and commercialize prescription drug candidates. The Trump Administration, through its recently established Make America Healthy Again Commission, has signaled its intent to reevaluate the regulatory landscape surrounding treatments for certain conditions, including ADHD and anxiety. As part of its mandate, the Make America Healthy Again Commission may propose new guidelines and policy recommendations that could impact the approval, labeling, marketing, and prescription of drugs intended to treat these conditions.

Potential changes introduced or recommended by the Commission may include:

- increased scrutiny of the efficacy and long-term safety of prescription medications, leading to more stringent clinical trial requirements, extended approval timelines, or the abandonment of the utilization of prescription medication to treat ADHD and anxiety;
- restrictions on the prescription and distribution of medications targeting ADHD and anxiety, potentially reducing market access and limiting patient eligibility; and/or
- greater emphasis on non-pharmacological treatments, such as behavioral therapies and lifestyle interventions, which could diminish the perceived necessity of pharmaceutical options.

If the Make America Health Again Commission's recommendations result in stricter regulatory policies, we could face substantial delays, increased costs, or the inability to obtain approval for our product candidates. If potential new restrictions limit or prevent the approval and eventual prescription of our product candidates CTx-1301 and CTx-1302, which are intended for the treatment of ADHD, or CTx-2301, which is intended for the treatment of anxiety, the inability to bring our product candidates to market could materially and adversely affect our business.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize our product candidates in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize our other product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain market access and appropriate reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;

- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

A pandemic, epidemic, or outbreak of an infectious disease could cause a disruption to the development of our product candidates.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. The extent to which a pandemic, epidemic or outbreak of an infectious disease impacts our operations or those of our third-party partners, including our development studies or clinical trial operations, will depend on future occurrences, which are highly uncertain and cannot be predicted with confidence, including the duration of any outbreak and the actions to contain or treat its impact, among others. Although the majority of our operations are conducted in the United States, the spread of an infectious disease globally could adversely impact our product candidate development or clinical trial operations in the United States and abroad. Any negative impact infectious diseases have on patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Some factors that may delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, in the event of a pandemic, epidemic or outbreak of an infectious disease include:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling or retaining participants in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to a pandemic, epidemic or infectious disease, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial participant visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will acquire an infectious disease while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruptions in preclinical studies due to restricted or limited operations at our research and development facilities;
- the potential negative effect on the operations of our third-party manufacturers;
- delays in necessary interactions with local regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of employees;
- limitations in employee resources at third-party CROs that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA or other regulatory authorities to accept data from clinical trials in affected geographies; and
- delays in FDA pre-approval inspections, which are a prerequisite for approval.

Risks Related to Commercialization

The commercial success of our product candidates, if approved, depends partially upon attaining market acceptance by physicians, patients, third-party payors, and the medical community.

Our ability to generate product revenue will depend significantly on our ability to successfully obtain final marketing approval for and commercialize our product candidates.

Even if any of our product candidates obtain regulatory approval, they may not gain sufficient market acceptance among physicians, patients, third-party payors, and the healthcare community. Failure to achieve market acceptance would limit our ability to generate revenue and would affect our results of operations. The degree of market acceptance of our product candidates will depend on many factors, including:

- the efficacy and potential advantages of our product candidates and compared to alternative treatments or competitive products;
- the effectiveness of our third-party collaborators' efforts to educate physicians and patients about the potential benefits and advantages of our product candidates;
- the willingness of the healthcare community and patients to adopt new technologies;
- the size of the market for such drug candidate, based on the size of the patient populations we are targeting, in the territories for which we gain regulatory approval and have commercial rights;
- the prevalence and severity of any side effects;
- the safety of the drug candidate as demonstrated through broad commercial distribution;
- the ability to offer our product candidates for sale at competitive prices;
- cost-effectiveness of our product candidates relative to competing products;
- the ability to manufacture our product candidates in sufficient quantities and yields;
- perceptions of physicians, patients and the healthcare community, including third-party payors, regarding the safety, efficacy and potential benefits of our product candidates compared to competing products or therapies;
- the timing of any such marketing approval in relation to other product approvals;
- any restrictions on concomitant use of other medications;
- support from patient advocacy groups;
- relative convenience and ease of administration compared to alternative treatments; and
- the availability of adequate coverage and reimbursement from governmental health programs and third-party payors and pricing relative to other competing products and therapies.

If our drug candidates are approved but fail to achieve an adequate level of acceptance by key market participants, we will not be able to generate significant revenues, and we may not become or remain profitable, which may require us to seek additional financing.

Our ability to negotiate, secure and maintain third-party coverage and reimbursement for our product candidates may be affected by political, economic and regulatory developments in the United States and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of any product candidate of ours that receives marketing approval in the future.

Recently enacted and future policies and legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the reimbursement made for any product candidate for which we receive marketing approval.

Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. In the United. States, for example, the PPACA was enacted in 2010 to expand healthcare coverage and made significant changes to drug reimbursement. Other legislative changes that affect the pharmaceutical industry have been proposed and adopted in the United States since PPACA was enacted. For example, the Inflation Reduction Act of 2022 included, among other things, a provision that authorizes CMS to negotiate a "maximum fair price" for a limited number of

high-cost, single-source drugs every year, and another provision that requires drug companies to pay rebates to Medicare if prices rise faster than inflation. Complying with any new legislation could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, many states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, in 2017, California's governor signed a prescription drug price transparency state bill into law, requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs that exceed a specified threshold. Both Congress and state legislatures are considering various bills that would reform drug purchasing and price negotiations, allow greater use of utilization management tools to limit Medicare Part D coverage, facilitate the import of lower-priced drugs from outside the United States and encourage the use of generic drugs. Such initiatives and legislation may cause added pricing pressures on our products.

Changes to the Medicaid program at the federal or state level could also have a material adverse effect on our business. Proposals that could impact coverage and reimbursement of our products, including giving states more flexibility to manage drugs covered under the Medicaid program and permitting the re-importation of prescription medications from Canada or other countries, could have a material adverse effect by limiting our products' use and coverage. Furthermore, state Medicaid programs could request additional supplemental rebates on our products as a result of an increase in the federal base Medicaid rebate. To the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, they could use the enactment of these increased rebates to exert pricing pressure on our products, and the adverse effects may be magnified by their adoption of lower payment schedules.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services. Moreover, recent U.S. federal administrations have indicated that lowering prescription drug prices is a priority, but we do not yet know what steps the administration will take or whether such steps will be successful.

Other proposed regulatory actions affecting manufacturers could have a material adverse effect on our business. It is difficult to predict the impact, if any, of any such proposed legislative and regulatory actions or resulting state actions on the use and reimbursement of our products in the United States, but our results of operations may be adversely affected.

Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives could harm our business in the future.

There is increasing pressure on pharmaceutical companies to reduce healthcare costs. In the United States, these pressures come from a variety of sources, such as managed care groups and institutional and government purchasers. Increased purchasing power of entities that negotiate on behalf of federal healthcare programs and private sector beneficiaries could increase pricing pressures in the future. Such pressures may also increase the risk of litigation or investigation by the government regarding pricing calculations. The pharmaceutical industry will likely face greater regulation and political and legal actions in the future.

Adverse pricing limitations may hinder our ability to recoup our investment in one or more future product candidates, even if our future product candidates obtain regulatory approval. Adverse pricing limitations prior to approval will also adversely affect us by reducing our commercial potential. Our ability to commercialize any potential products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments becomes available from third-party payors, including government health administration authorities, private health insurers and other organizations. Third-party payors decide which medications they will pay for and establish reimbursement levels. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical products, will apply to companion diagnostics.

A significant trend in the United States healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize in the future and, if reimbursement is available, what the level of reimbursement will be. Reimbursement

may impact the demand for, or the price of, any product for which we obtain marketing approval in the future. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Accordingly, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Our inability to promptly obtain coverage and adequate reimbursement from third-party payors for approved products could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize potential products and our overall financial condition.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we focus on development programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may face significant competition from other pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

We expect to have competitors both in the United States and internationally, including major multinational pharmaceutical companies. For example, amphetamine XR (mixed-amphetamine salts) is currently marketed in the United States by Shire under the brand name Adderall XR, and methylphenidate is marketed in the United States by Janssen under the brand name Concerta, and by Novartis under the brand names Focalin XR and Ritalin LA. Further, makers of branded drugs could also enhance their own formulations in a manner that competes with our enhancements of these drugs. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than our PTR platform, or any product candidate that we are currently developing or that we may develop. In addition, our competitors may file citizens petitions with the FDA in an attempt to persuade the FDA that our products, or clinical trials that support their approval, contain deficiencies or that new regulatory requirements be placed on the product candidate or drug class of the product candidate. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our future pharmaceutical products may face direct competition from generic and other follow-on drug products. Any of our product candidates that may achieve regulatory approval in the future may face competition from generic products earlier or more aggressively than anticipated, depending upon how well such approved products perform in the United States prescription drug market. Our ability to compete also may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Generic products are expected to become available over the coming years. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive generic products, if any have been approved by then.

In addition to creating the 505(b)(2) NDA pathway, the Hatch-Waxman Amendments to the FDCA authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to approved ANDAs. An ANDA relies on the preclinical and clinical testing conducted for a previously approved reference listed drug ("RLD") and must demonstrate to the FDA that it is "bioequivalent" to the RLD. The FDA is prohibited by statute from approving an ANDA when certain marketing or data exclusivity protections apply to the RLD. If any such competitor or third party is able to demonstrate bioequivalence without infringing our patents, then this competitor or third party may then be able to introduce a competing generic product onto the market.

We believe that our ability to successfully compete will depend on, but is not limited to:

- the efficacy and safety of our product and product candidates, including as relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- the ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our product and product candidates that receive regulatory approval, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to protect intellectual property rights related to our product and product candidates;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of our product and product candidates that receive regulatory approval; and
- acceptance of any of our products and product candidates that receive regulatory approval by physicians and other healthcare providers.

If our competitors market products that are more effective, safer or less expensive than our product, if any, or that reach the market sooner than our products, if any, we may enter the market too late in the cycle and may not achieve commercial success, or we may have to reduce our price, which would impact our ability to generate revenue and obtain profitability.

In addition, successful commercialization will also depend on whether we can adequately protect against and effectively respond to any claims by holders of patents and other intellectual property rights that our products infringe their rights, whether any unanticipated adverse effects or unfavorable publicity develops in respect of our products, as well as the emergence of new or existing products as competition, which may be proven to be more clinically effective and cost-effective. If we are unable to successfully complete these tasks, we may not be able to commercialize in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business.

We cannot predict the interest of potential follow-on competitors or how quickly others may seek to come to market with competing products, whether approved as a direct ANDA competitor or as a 505(b)(2) NDA referencing one of our future drug products. If the FDA approves generic versions of our drug candidates in the future, should they be approved for commercial marketing, such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval, which could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments in those product candidates.

Social issues around the abuse of opioids and stimulants, including law enforcement concerns over diversion and regulatory efforts to combat abuse, could decrease the potential market for our product candidates.

Media stories regarding prescription drug abuse and the diversion of opioids, stimulants, and other controlled substances are commonplace. Law enforcement and regulatory agencies may apply policies that seek to limit the availability of opioids and stimulants. Such efforts may inhibit our ability to commercialize our product candidates. Aggressive enforcement and unfavorable publicity regarding opioid drugs, the limitations of abuse-deterrent formulations, public inquiries and investigations into prescription drug abuse, litigation or regulatory activity, sales, marketing, distribution or storage of our products could harm our reputation. Such negative publicity could reduce the potential size of the market for our product candidates and decrease the revenue we are able to generate from their sale, if approved.

Additionally, current and future efforts by Congress, state legislatures, the FDA, DEA and other regulatory bodies to combat abuse of opioids and stimulants may negatively impact the market for our product candidates. It is possible that lawmakers or the FDA will announce new legislation or regulatory initiatives at any time that may increase the regulatory burden or decrease the commercial opportunity for our product candidates.

Risks Related to Our Dependence on Third Parties

We rely on third-parties, many of whom are our single source for services, products and/or supplies, over whom we have limited control. Should the cost, delivery and/or quality of services, products or supplies provided by these third-parties vary to our disadvantage, our business operations could suffer significant harm.

We are a research and development company and have limited experience in commercial manufacturing. To conduct late-stage clinical trials, as well as manufacture and commercialize our drug candidates, we engage a CDMO and suppliers in the U.S. to manufacture our drug candidates on a large scale at a competitive cost and in accordance with cGMP and regulatory requirements, as applicable. We also rely on third parties for filling, labeling and storage for studies inside and outside the U.S.

Moreover, while we will try to obtain multiple sources whenever possible, similar to other clinical stage pharmaceutical companies, all stages of our manufacturing process are currently completed by a single CDMO, which could expose us to a number of risks related to our supply chain if and when we become a commercial stage company, including delivery failure and drug shortages. To date, we have no qualified alternative sources. Any manufacturing failures or compliance issues experienced by our CDMO could cause delays in our clinical studies or commercialization of our drug candidates.

Any change to our manufacturing process, facilities or suppliers could require that we amend our NDA as the NDA we submitted for CTx-1301 included our proposed manufacturing process for CTx-1301. Also, because of our proprietary processes for manufacturing our product candidates, we cannot immediately transfer manufacturing activities for our drug products to an alternate supplier, and a change of manufacturing facilities would be time- consuming and could be a costly endeavor. For example, in October 2022, we announced a new CDMO. The CTx-1301 fixed-dose study was delayed while the manufacturing process with the new CDMO was established to manufacture the final dosage strengths needed for the fixed-dose study.

In February 2026, the FDA conducted a pre-approval inspection of our CDMO's facility used to manufacture CTx-1301. This facility was issued a Form 483 by the FDA at the conclusion of the inspection with three observations. Two observations were related to the facility and one observation was specific to CTx-1301. Our CDMO is working on responses to these observations, with our input where relevant.

Identifying an appropriately qualified source of alternative supply for any one or more of the component substances for our product candidates or product could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates. Any alternative vendor would also need to be qualified through an NDA supplement and may need to undergo an FDA inspection before the supplement can be approved, which could result in further delay, including delays related to additional clinical trials. Potential changes in manufacturing facilities would also require us to supplement our NDA filings to include the change of manufacturing site.

In order for us to establish our own commercial manufacturing facility, we would require substantial additional funds and we would need to acquire a manufacturing facility, make facility modifications, hire and retain significant additional personnel and comply with extensive cGMP regulations applicable to such a facility. The commercial manufacturing facility would also need to be licensed for the production of our drug candidates by the FDA and meet other regulatory standards. We therefore work with our CDMO under established manufacturing arrangements that comply with the FDA's requirements and other regulatory standards, although there is no assurance that the manufacturing will be successful.

Use of third-party manufacturing facilities limits our control over and ability to monitor the manufacturing process. As a result, we may not be able to detect a variety of problems that may arise and may face additional costs in the process of interfacing with and monitoring the progress of our CDMO. If our CDMO fails to meet our manufacturing needs in an acceptable manner or fail to comply with regulatory requirements, we would face delays and additional costs while we develop internal manufacturing capabilities or find alternate sources. It may not be possible to have multiple manufacturers ready to supply us with needed material at all or without incurring significant costs. Our dependence upon third-party manufacturing facilities for the manufacture of our products may adversely affect our profit margins and our ability to develop, manufacture, sell and deliver products on a timely and competitive basis. Any manufacturing failures, supply chain delays or compliance issues could cause delays in our clinical studies for our drug candidates, FDA approval of our product candidates, and, if approved, commercialization of our product candidates.

Prior to approval of CTx-1301 or any product candidate, the FDA must review and approve validation studies for both drug substance and drug product. In February 2026, the FDA conducted a pre-approval inspection of our CDMO's facility used to manufacture CTx-1301. This facility was issued a Form 483 by the FDA at the conclusion of the inspection with three observations. Two observations were related to the facility, and one observation was specific to CTx-1301. Our efforts continue to be subject to inspection and approval by the FDA and other factors outside of our control, and there remains a risk that the required FDA approvals of CTx-1301 and/or our CDMO's facility used to manufacture CTx-1301 could be further delayed or not obtained.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and APIs on a timely basis and at commercially reasonable prices, including if our suppliers did not receive adequate DEA quotas for the supply of certain scheduled components, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, commercialization of our product candidates, and clinical trials of future potential product candidates, may be delayed or we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected.

If we fail to produce our product or product candidates in the volumes that are required on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face regulatory penalties and delays in the development, approval and/or commercialization of our product candidates.

We currently depend on third-party suppliers for the supply of the APIs and excipients for our product candidates. Any shortages in the availability of raw materials could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs. Any such delays could trigger penalties, which would have a negative impact on our business. If our raw material manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain FDA approval and market our product and product candidates would be jeopardized. In addition, any delay or interruption in the supply of clinical trial supplies could delay or prohibit the completion of our bioequivalence and/or clinical trials, increase the costs associated with conducting our bioequivalence and/or clinical trials and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate a trial.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Pharmaceutical companies may encounter difficulties in manufacturing scale up of production. These problems include manufacturing difficulties relating to production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. We may also need to purchase additional equipment, some of which can take several months or more to procure, setup and validate, and increase our software and computing capacity to meet increased demand. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, or slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products and could damage our reputation and the prospects for our business.

Manufacturers of pharmaceutical products need to comply with cGMP requirements enforced by the FDA through the agency's facility inspection programs. The cGMP requirements include, among other things, quality control, quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production,

suspension or delay in product approval, product seizure or voluntary recall, or withdrawal of product approval. If the safety of any of our products or product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain, or to maintain once obtained, regulatory approval for such product candidate or successfully commercialize such products or product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical developments, regulatory submissions, approvals or commercialization of our products or product candidates, entail higher costs or result in our being unable to effectively commercialize our product candidates.

We rely and expect to continue to rely completely on third parties to formulate and manufacture our preclinical, clinical trial and commercial drug supplies. The development and commercialization of any of our drug candidates could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of such drug supplies or fail to do so at acceptable quality levels, including in accordance with applicable regulatory requirements or contractual obligations, and our operations could be harmed as a result.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally, such as our own manufacturing facilities, to manufacture our preclinical and clinical drug supplies for our clinical trials and preclinical studies or commercial quantities of any drug candidates that may obtain regulatory approval. We procure bulk drug substance from a sole source, third-party supplier and have contracted with a CDMO to produce our drug candidates at its facilities, and we anticipate that we will continue to do so for the foreseeable future. Therefore, we lack the resources and expertise to formulate or manufacture our own drug candidates, and our reliance on third parties increases the risk that we will not have sufficient quantities of bulk drug substances or our product candidates, in such quantities at an acceptable cost, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts. For example, we experienced delays in the manufacturing and delivery of clinical supply for the CTx-1301 fixed-dose study due to operational resource issues at our former CDMO. The manufacture of the clinical supply was further delayed while our new CDMO established its manufacturing process for CTx-1301.

We have entered into an agreement with a CDMO and intend for that CDMO to manufacture all clinical, registration and commercial batches of our drug candidate, CTx-1301. We intend to establish or continue those relationships for the supply of our drug candidates; however, there can be no assurance that we will be able to retain those relationships on commercially reasonable terms, if at all. If we are unable to maintain those relationships, we could experience delays in our development efforts as we locate and qualify new CDMOs. If any of our current drug candidates or any drug candidates we may develop or acquire in the future receives regulatory approval, we will rely on one or more CDMOs to manufacture the commercial supply of such drugs.

Even if we are able to maintain our existing third-party relationships or establish any such agreements with other third-party manufacturers, reliance on third-party manufacturers entails additional risks, including, but not limited to:

- reliance on the third party for FDA and DEA regulatory compliance and quality assurance;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- disruption and costs associated with changing suppliers, including additional regulatory filings;
- the possible breach, termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; and
- the reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms.

Each of these risks could delay our clinical trials, the approval, if any, of our drug candidates or the commercialization of our drug candidates, could result in higher costs or could deprive us of potential product revenues. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

While we are ultimately responsible for the manufacture of our product candidates, we do not manufacture our products ourselves and are dependent on our CDMO for compliance with cGMPs. Our agreement with our CDMO requires it to perform according to certain cGMP requirements such as those relating to quality control, quality assurance and qualified personnel, but we cannot control the conduct of our CDMO to implement and maintain these standards. If our CDMO cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we would be prevented from obtaining regulatory approval for our drug candidates unless and until we engage a substitute CDMO that can comply with such requirements, which we may not be able to do. Any such failure by our CDMO would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved.

Further, if our product candidates are approved, our suppliers will be subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to our product candidates, and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements, as well as market disruption related to any necessary recalls or other corrective actions.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our CDMO, to comply with applicable regulations could result in sanctions being imposed on us, including warning letters, clinical holds or termination of clinical trials, fines, injunctions, restitution, disgorgement, civil penalties, delays, suspension or withdrawal of approvals or other permits, FDA refusal to approve pending applications, product detentions, FDA consent decrees placing significant restrictions on or suspending manufacturing and distribution operations, debarment, refusal to allow import or export, product detentions, adverse publicity, dear-health-care-provider letters or other warnings, license revocation, seizures or recalls of product candidates, operating restrictions, refusal of government contracts or future orders under existing contracts and civil and criminal liability, including False Claims Act liability, exclusion from participation in federal health care programs, and corporate integrity agreements among other consequences, any of which could significantly and adversely affect supplies of our products.

Failure by our CDMO to comply with DEA regulations related to controlled substances may cause their license to be revoked and production of our products and product candidates may be interrupted or stopped. This would impact our ability to develop, obtain marketing approval for or market our product candidates, if approved.

Our product candidates and any drugs that we may develop may compete with other product candidates and drugs for access to manufacturing facilities, and we may be unable to obtain access to these facilities on favorable terms.

There are a limited number of manufacturers that operate under cGMP regulations and possess a DEA license to procure, hold and work with controlled substances. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second contract manufacturer. If our current CDMO cannot perform as agreed, we may be required to replace such manufacturer and we may incur added costs and delays in identifying and qualifying any such replacement. For example, we experienced delays in the manufacturing and delivery of clinical supply for the CTx-1301 fixed-dose study due to operational resource issues at our former CDMO prior to October 2022. The manufacture of the clinical supply was further delayed while our new CDMO established its manufacturing process for CTx-1301.

We expect to rely on third parties to conduct our clinical trials and our regulatory submissions for our product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials and/or regulatory submissions.

We expect to engage CROs for our planned clinical trials and our regulatory submissions of our product candidates. We expect to rely on CROs, as well as other third parties, such as clinical data management organizations, regulatory strategists, medical institutions and clinical investigators, to conduct our planned clinical trials, prepare the appropriate regulatory submissions for our product candidates, and assist with ensuring compliance with applicable regulatory requirements. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our drug development activities would be delayed.

Our reliance on these third parties for clinical development activities may reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and

reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. We also are required to register specified ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. In addition, we must conduct our clinical trials with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Failure to comply with the applicable requirements related to clinical investigations by us, our CROs or clinical trial sites can also result in clinical holds and termination of clinical trials, debarment, FDA refusal to approve applications based on the clinical data, warning letters, withdrawal of marketing approval if the product has already been approved, fines and other monetary penalties, delays, adverse publicity and civil and criminal sanctions, among other consequences.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA we submit by the FDA. Any such delay or rejection could prevent us from commercializing our product candidates. Further, our arrangements with principal investigators are also subject to scrutiny under other health care regulatory laws, such as the federal Anti-Kickback Statute.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure or noncompliance with applicable regulatory requirements, including those of the FDA or DEA, on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

If the third parties with whom we contract do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, we may need to conduct additional trials, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be adversely affected.

We depend on collaborations with third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

If we receive FDA approval for CTx-1301, we intend to partner with Indegene, pursuant to the Commercialization Agreement, in the commercialization of CTx-1301, including marketing, market access and pricing, commercial operations and an unparalleled omnichannel, on a fee for service basis. We also intend to partner with IQVIA, pursuant to a Licensing and Services Master Agreement, in the commercialization of CTx-1301, including field sales and national accounts management. Use of third-parties for these commercial functions limits our control over and ability to monitor the process. As a result, we may not be able to detect a variety of problems that may arise and may face additional costs in the process of interfacing with and monitoring the progress of Indegene and/or IQVIA. If Indegene or IQVIA fails to meet our needs in an acceptable manner or fails to comply with regulatory requirements, we would face delays and additional costs while we develop internal capabilities or find an alternate third-party.

Potential partners and collaborators for other product candidates include co-commercialization partners, as well as regional, national and international large and mid-size pharmaceutical companies. We may have limited control over the amount and timing of resources that our current and any future collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Pursuant to the Commercialization Agreement, we and Indegene will enter into statements of work that will set forth, among other things, the services to be performed by

Indegene, the deliverables for such services and the fees to be paid by us. We may be unable to negotiate the terms of the statements of work, including the services to be performed by Indegene and IQVIA or the fees payable by us, on terms acceptable to us, or at all. If we are unable to do so, we would have to seek other collaborations for the commercialization of CTx-1301, which may delay commercialization.

Our current collaborations pose, and any future collaborations involving our product candidates would pose the following risks, including but not limited to:

- 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;
- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- we may be subject to termination fees if we terminate a collaboration; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Our agreements with Indegene and IQVIA, and any future collaboration agreements, may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

If we are not able to maintain or establish partnerships or collaborations, we may have to alter our development and commercialization plans.

The development of our product candidates and clinical programs and the potential commercialization will require substantial additional capital. For some of our product candidates, we may need to be able to maintain and further collaborate with co-commercial partners or pharmaceutical companies for the development and/or commercialization of those product candidates.

If we receive FDA approval for CTx-1301, we intend to partner with Indegene, pursuant to the Commercialization Agreement, in the commercialization of CTx-1301, including marketing, market access and pricing, commercial operations and an unparalleled omnichannel, on a fee for service basis. We also intend to partner with IQVIA, pursuant to a Licensing and Services Master Agreement, in the commercialization of CTx-1301, including field sales and national accounts management.

Use of third-parties for these commercial functions limits our control over and ability to monitor the process. As a result, we may not be able to detect a variety of problems that may arise and may face additional costs in the process of interfacing with and monitoring the progress of Indegene and/or IQVIA. If Indegene or IQVIA fails to meet our needs in an acceptable manner or fails to comply with regulatory requirements, we would face delays and additional costs while we develop internal capabilities or find an alternate third-party. If CTx-1301 is approved, there can be no assurance that Indegene or IQVIA will be successful in assisting with our commercialization efforts for CTx-1301.

We face significant competition in seeking appropriate partners and collaborators. Whether we reach additional definitive agreements for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of product candidates, reduce or delay one or more of our development programs, delay potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Additionally, pursuant to our agreements with Indegene and IQVIA, we would enter into statements of work that would set forth, among other things, the services to be performed by Indegene and IQVIA, the deliverables for such services and the fees to be paid by us. We may be unable to negotiate the terms of the statements of work, including the services to be performed by Indegene or the fees payable by us, on terms acceptable to us, or at all. If we are unable to do so, we may have to seek other collaborations for the commercialization of CTx-1301, which may delay commercialization.

We rely on third parties to perform many essential services for any products that we commercialize, including distribution, customer service, accounts receivable management, cash collection and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize CTx-1301 and other product candidates will be significantly impacted and we may be subject to regulatory sanctions.

If we receive FDA approval for CTx-1301, we intend to partner with Indegene, pursuant to the Commercialization Agreement, in the commercialization of CTx-1301, including marketing, market access and pricing, commercial operations and an unparalleled omnichannel, on a fee for service basis. We also intend to partner with IQVIA, pursuant to a Licensing and Services Master Agreement, in the commercialization of CTx-1301, including field sales and national accounts management. We would substantially rely on Indegene and IQVIA and will substantially rely on any future third-party providers to perform services for us. We may retain additional third-party service providers to perform a variety of functions related to the sale and distribution of any or all of our products, including CTx-1301, CTx-1302, and CTx-2103, if approved, key aspects of which will be out of our direct control. These service providers may provide key services related to distribution, customer service, accounts receivable management and cash collection.

If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, our ability to deliver product to meet commercial demand may be significantly impaired. In addition, we may engage third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient or if they fail to comply with various requirements, we could be subject to regulatory sanctions.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for our product candidates, if approved, their commercial success may be severely hindered.

Successful sales of our product and any product candidates that receive regulatory approval depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs.

Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our product candidates will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third party coverage and reimbursement for our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Third-party payors may not adequately cover or reimburse consumers for the purchase of our products.

Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of governments and third-party payors to contain or reduce the costs of healthcare through various means. In certain foreign markets, the pricing of prescription pharmaceuticals is subject to governmental control. In the United States, there has been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services may take in response to any drug pricing reform proposals or legislation. Such reforms may make it difficult to complete the development and testing of our products, and therefore may limit our ability to generate revenues from sales and achieve profitability. Further, to the extent that such reforms may affect our business and collaborators, our ability to commercialize our products may be harmed.

In the United States and elsewhere, sales of prescription pharmaceutical products still depend in large part on the availability of reimbursement to the consumer from third-party payors, such as governmental and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products. The market for CTx-1301, CTx-1302, and/or CTx-2103 will depend significantly on whether third-party payors provide coverage and reimbursement. Industry competition to be eligible for reimbursement often leads to downward pricing pressures on pharmaceutical products. Also, third-party payors may refuse to reimburse for a particular branded drug or product when a less costly generic equivalent or other alternative is available. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We would be required to provide scientific and clinical support for the use of our products to each third-party payor separately with no assurance that approval would be obtained. This process could delay the market acceptance of our products and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing a product candidate to market, we cannot be certain that it would be considered cost effective or that coverage and adequate reimbursement to patients would be available. Patients may be unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of its cost.

In addition, in many foreign countries, particularly countries within the European Union, the pricing of prescription drugs is subject to government control. In some jurisdictions outside the United States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which

their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Moreover, pricing negotiations with governmental authorities in these countries can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in countries outside of the United States, we may be required to conduct additional clinical trials that specifically compares the cost-effectiveness of our products to other available therapies. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be foreign products imported that compete with our product candidates, which could negatively impact our profitability.

We believe our product candidates will need to be priced competitively with current therapies to be eligible for full reimbursement in the United States and international markets. If we are unable to obtain coverage of, and adequate payment levels for our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe it and patients may decline to purchase it. This in turn could affect our ability to successfully commercialize any or all of our products and harm our business.

If we are unable to support demand for our product candidates, including ensuring that we have adequate capacity to meet increased demand, or we are unable to successfully manage the evolution of our drug delivery technology platform, our business could suffer.

As our volume grows, we will need to extend our platform to support product production at a larger scale within expected turnaround times. We may need additional certified laboratory scientists and technical and manufacturing personnel to process higher volumes of our product candidates, if approved. We may also need to purchase additional equipment, some of which can take several months or more to procure, setup and validate. There is no assurance that any of these increases in scale, expansion of personnel, equipment, or process enhancements will be successfully implemented, or that we will have adequate space in our facilities to accommodate such required expansion.

Our relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

For our products and any product candidates that obtain regulatory approval and are marketed in the United States, if any, our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to health information privacy and security regulation by United States. federal and state governments and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate including:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, 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; actions may be brought by the government or a whistleblower and may include an assertion that a claim for payment by federal health care programs for items and services which results from a violation of the federal Anti-Kickback Statue constitutes a false or fraudulent claim for purposes of the False Claims Act;
- HIPAA that imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, or 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 health care benefits, items or services; similar to the United States federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; HIPAA, as amended by HITECH and their respective implementing regulations, which imposes certain obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- The Physician Payments Sunshine Act, enacted as part of the PPACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. 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 civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our product candidates.

We face an inherent risk of product liability claims as a result of the clinical testing of our product candidates despite obtaining appropriate informed consents from our clinical trial participants. We will face an even greater risk if we obtain marketing approval for and commercially sell our product candidates. For example, we may be sued if any product that we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- reduced resources for our management to pursue our business strategy;
- decreased demand for our product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend resulting litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products manufactured and distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

Our product liability insurance coverage may not be adequate to cover any and all liabilities that we may incur.

We currently have $10.0 million in product liability insurance coverage in the aggregate, which may not be adequate to cover any and all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business. In addition, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims, which could prevent or inhibit the commercial production and sale of our products.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations produce hazardous waste products. We expect to contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Managing Our Growth, Our Employees, and Our Operations

We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth.

Our management, personnel, systems, and facilities currently in place may not be adequate to support our business plan and near-term future growth. We will need to further expand our manufacturing team, clinical team, managerial, operational, financial, and other resources to support our planned research, development and commercialization activities.

To manage our operations, growth and various projects effectively requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- develop a marketing, sales and distribution capability;
- manage our commercialization activities for our product candidates effectively and in a cost-effective manner;
- establish and maintain relationships with development and commercialization partners;
- manage our clinical trials effectively;
- manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for our current product candidates to commercial levels; and
- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to product development and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. We rely on consultants for certain functions of our business and will need to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our

existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively manage our growth and expand our organization by hiring new employees and expanding our use of consultants, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and/or sell our product candidates, we may be unable to generate any revenue.

We do not currently have an organization for the sale, marketing or distribution of our product candidates. The establishment and development of our own sales force in the United States to market our product candidates would be expensive and time consuming and could delay any product launch. We cannot be certain that we would be able to successfully develop this capacity, and even if we do, the cost of establishing and maintaining such an organization may exceed the benefit of doing so.

There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, effectively manage a geographically dispersed sales and marketing team and successfully negotiate with managed care and third-party payors. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products.

If we receive FDA approval for CTx-1301, we intend to partner with Indegene, pursuant to the Commercialization Agreement, in the commercialization of CTx-1301, including marketing market access and pricing, commercial operations and an unparalleled omnichannel, on a fee for service basis. We also intend to partner with IQVIA, pursuant to a Licensing and Services Master Agreement, in the commercialization of CTx-1301, including field sales and national accounts management.

We also may enter into additional strategic partnerships with third parties to commercialize our product candidates.

Pursuant to our agreements with Indegene and IQVIA, we would enter into statements of work that would set forth, among other things, the services to be performed by Indegene and IQVIA, the deliverables for such services and the fees to be paid by us. We may be unable to negotiate the terms of the statements of work, including the services to be performed by Indegene or IQVIA or the fees payable by us, on terms acceptable to us, or at all. If we are unable to do so, we would have to seek other collaborations for the commercialization of CTx-1301, which may delay commercialization. We may also have difficulty establishing relationships with third parties on terms that are acceptable to us, or in all of the regions where we wish to commercialize our products, or at all. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations and/or ingrained distribution channels. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. In December 2023, two executive officers, including our Chief Financial Officer, and two clinical operations employees resigned. On January 25, 2024, we appointed Ms. Callahan as our Senior Vice President and Chief Financial Officer. In August 2025, the employment of our Chief Operating Officer was terminated. Also in August 2025, our Chairman and Chief Executive Officer was placed on administrative leave, and in connection with that action, our Chief Financial Officer was appointed to serve as interim Chief Executive Officer and a current member of our Board was appointed to serve as Executive Chairman of the Board. In December 2025, our Chief Executive Officer was reinstated. During 2025 and the first quarter of 2026, we hired our Chief Legal Officer and Chief Commercial Officer, as well as several other officers and employees in connection with pre-commercialization efforts for CTx-1301.

In December 2023, four independent members of our Board resigned resulting in our Board consisting of two non-independent directors, one of whom is our Chief Executive Officer. On December 26, 2023, we received a letter from the Staff indicating that, based upon the resignation of three members of our Board on December 12, 2023 and December 13, 2023, we no longer comply with the independent director, audit committee, compensation committee and independent director oversight of director nominations requirements as set forth in Nasdaq Listing Rule 5605 (the "Independent Director Rule"). On February 12, 2024, our Board appointed three independent directors to the Board and subsequently regained compliance with the Independent Director Rule. There can be no assurance that we will be able to retain key management personnel and members of our Board or attract replacements in the event of their departure from the Company.

We maintain "key man" insurance policies on the lives of specific individuals but not on the lives of all critical employees. In order to retain valuable employees at our company, in addition to salary and cash incentives, we may provide stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract offers from other companies.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

Our research and development is focused on discovering and developing product candidates but these product candidates may not make it to the market.

Our development research and clinical development efforts to date have resulted in product candidates, CTx-1301, CTx-1302, for the treatment of ADHD, and CTx-2103, for the treatment of anxiety. As part of our growth strategy, we intend to identify, develop and market additional product candidates. We are exploring various therapeutic opportunities for our pipeline and proprietary technologies. We may spend several years completing our development of any particular current or future internal product candidates, and failure can occur at any stage. We may not be able to develop drugs that are bioequivalent, safe and effective and/or that have commercially significant improvements over already approved drugs. The product candidates to which we allocate our resources may not end up being successful. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising product candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- higher than expected acquisition and integration costs; and
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and other regulatory authorities.

If we do not successfully develop and commercialize product candidates based upon our Precision Timed Release platform technology, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our operations to date have been primarily limited to formulating and developing our product candidates and undertaking clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- delays in the commencement, enrollment and the timing of clinical testing for our product candidates;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review and approval of product candidates in clinical development;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on FDA guidelines and requirements, and the quantity of production;
- our ability to obtain additional funding to develop our product candidates;
- our ability to comply with the terms of the Note Purchase Agreement and Note issued in November 2025;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;
- our dependency on third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish or outsource an effective sales, marketing and distribution infrastructure in a timely manner;
- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive approval and commercialize our product candidates outside of the United States;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- costs related to and outcomes of potential litigation or other disputes;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

Our operating results and liquidity needs could be negatively affected by market fluctuations and economic downturn.

Our operating results and liquidity could be negatively affected by economic conditions generally, both in the United States and elsewhere around the world. The market for discretionary medical products and procedures may be particularly vulnerable to unfavorable economic conditions. Some patients may consider certain of our product candidates to be discretionary, and if full reimbursement for such products is not available, demand for these products may be tied to the

discretionary spending levels of our targeted patient populations. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen, and the markets continue to remain volatile, our operating results and liquidity could be adversely affected by those factors in many ways, including weakening demand for certain of our products and making it more difficult for us to raise funds if necessary, and our stock price may decline. Additionally, although we plan to market our products primarily in the United States, our partners have extensive global operations, indirectly exposing us to risk.

Our business and operations would suffer in the event of failures in our internal computer systems.

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities, development programs and our business operations. For example, the loss of manufacturing records or clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization and development of our products and product candidates could be delayed.

We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors, from attacks by malicious third parties, or from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. The rapid evolution and increased adoption of artificial intelligence ("AI") technologies may also heighten our cybersecurity risks by making cyber-attacks more difficult to detect, contain, and mitigate. Attackers are also increasingly sophisticated and using techniques and tools, including AI, that can circumvent security controls, evade detection and remove forensic evidence. As a result, we may be unable to detect, investigate, remediate or recover from future attacks or incidents, or to avoid a material adverse impact to our systems, information, or business. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations or cash flow.

The regulatory framework for use of AI technologies in our business is rapidly evolving and any failure or perceived failure by us or our employees, representatives, contractors, consultants, CDMO, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

The regulatory framework for AI technologies is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of AI technologies. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations.

It is possible that new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability, directly or indirectly, to use AI technologies for our business, or require us to change the way we use AI technologies in a manner that negatively affects the performance of our products, services, and business and the way in which we use AI technologies. We may need to expand resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CDMO, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Risks Related to Our Intellectual Property

If our intellectual property related to our products or product candidates is not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products, product candidates and technology. Any disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Due to legal standards relating to patentability, validity, enforceability and scope of claim, patents covering pharmaceutical and biotechnology inventions involve complex legal, scientific and factual questions. Formulation of drug products such as ours with complex release profiles is an area of intense research, publishing and patenting, which limits the scope of any new patent applications. As a result, our ability to obtain, maintain and enforce patents is uncertain and any rights under any existing patents, or any patents we might obtain or license, may not provide us with sufficient protection for our products and product candidates to afford a commercial advantage against competitive products or processes. The patent applications that we own may fail to result in issued patents in the United States or in foreign countries. Even if patents do successfully issue, third parties may challenge their patentability, validity (e.g., by discovering previously unidentified prior art, or a patent-barring event such as a prior public disclosure, use, sale or offer for sale of the invention), enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. For example, United States patents may be challenged by third parties via *inter partes* review, post grant review, derivation or interference proceedings at the USPTO, and European patents may be challenged via an opposition proceeding at the European Patent Office. Furthermore, if we were to assert our patent rights against a competitor, the competitor could challenge the validity and/or enforceability of the asserted patent rights. Although a granted United States patent is entitled to a statutory presumption of validity, its issuance is not conclusive as to its validity or its enforceability, and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products.

If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our products and product candidates is successfully challenged, we may face unexpected competition that could have a material adverse impact on our business. Even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. For example, a third party may develop a competitive product that provides therapeutic benefits similar to our products or product candidates but is sufficiently different to fall outside the scope of our patent protection.

Furthermore, if we encounter delays in our clinical trials or entry onto the market in a particular jurisdiction, the period of time during which we could market a particular product under patent protection would be reduced.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we or one of our future collaborators were to initiate legal proceedings against a third party to enforce a patent covering a product or our technology,

the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description, non-enablement or a patent-barring event, such as a public disclosure, use or sale of the invention more than a year before the filing date of the application. Grounds for an unenforceability assertion could, for example, be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution, or that a third party challenging one of our patents would not assert that a patent-barring event had occurred. If a plaintiff or a defendant were to prevail on a legal assertion of invalidity and/or unenforceability against one or more of our patents, we would lose at least part, and perhaps all, of the patent protection for one or more of our products or product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in reexamination, *inter partes* review, or interference proceedings challenging our patent rights. Patents based on applications that we file in the future may also be subject to derivation and/or post-grant review proceedings. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights and allow third parties to commercialize our technology or products and compete directly with us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We may not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, even where we do elect to pursue patent rights outside the United States, we may not be able to obtain relevant claims and/or we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may possibly export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from competing with us.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many 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. This could make it difficult for us to stop the infringement of our patents, if obtained, 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.

Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we have, and may in the future, choose not to seek patent protection in certain countries. Furthermore, while we intend to protect our intellectual property rights in certain markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell their approved products and our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our products and product candidates may give rise to claims of infringement of the patent rights of others. There may, for example, be issued patents of third parties of which we are currently unaware, that may be infringed by our products or product candidates, which could prevent us from being able to commercialize our products or product candidates, respectively. Because patent applications can take many years to issue, there may be currently pending applications which may later result in issued patents that our products or product candidates may infringe.

The pharmaceutical industry is rife with patent litigation between patent holders and producers of follow-on drug products. The possibility of blocking FDA approval of a competitor's product for up to 30 months provides added incentive to litigate over Orange Book patents, but suits involving non-Orange Book patents are also common in the ADHD space. There have been multiple patent litigations involving nearly all of the medications for treatment of ADHD. This trend may continue and, as a result, we may become party to legal matters and claims arising in the ordinary course of business.

We may be exposed to, or threatened with, future litigation by third parties alleging that our products or product candidates infringe their intellectual property rights. If one of our products or product candidates is found to infringe the intellectual property rights of a third party, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to commercialize the applicable approved products and product candidates unless we obtain a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our approved products, pending a trial on the merits, which may not occur for several years.

There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. If a third-party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- third parties bringing claims against us may have more resources than us to litigate claims against us;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling our product or any product candidate approved in the future, if any, unless the third party licenses its rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, fees or grant cross-licenses to our intellectual property rights; and
- redesigning any of our products and product candidates so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Our drug development strategy relies heavily upon the 505(b)(2) regulatory approval pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications routinely result in third-party claims of intellectual property infringement, the defense of which would be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.

Our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory approval pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidate CTx-1301, we certified to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. If we certify to the FDA that a patent is invalid or not infringed, or a Paragraph IV certification, a notice of the Paragraph IV certification must also be sent to the patent owner once our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us asserting infringement of the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our NDA will not be subject to the 30-month stay. However, even if the third party does not sue within the 45-day time limit, thereby invoking the 30-month stay, it may still challenge our right to market our product upon FDA approval; therefore, some risk of an infringement suit remains even after the expiry of the 45-day limit. We have not received a complaint asserting patent infringement.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Some of our employees were previously employed at other companies, including actual or potential competitors. We may also engage advisors and consultants who are concurrently employed at other organizations or who perform services for other entities. Although we try to ensure that our employees, advisors and consultants 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 our employees, advisors, or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party's former employer or in violation of an agreement with or legal obligation in favor of another party. Litigation may be necessary to defend against these claims.

In addition, while we generally require our employees, consultants, advisors and contractors who may be involved in the 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 develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Similarly, we may be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person's obligations to a third party, such as an employer or former employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or 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 prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Our decision to seek approval of CTx-1301 and our other product candidates under 505(b)(2) may increase the risk that patent infringement suits are filed against us, which would delay the FDA's approval of such product candidates.

In connection with any NDA that we file under the 505(b)(2) regulatory pathway, if there are patents that claim the approved drug contained in our product candidates and referenced in our 505(b)(2) NDA, we must certify to the FDA and notify the patent holder that any patents listed for the approved drug in the FDA's Orange Book publication are invalid, unenforceable or will not be infringed by the manufacture, use or sale of our drug. If a patent infringement lawsuit is filed against us within 45 days of its receipt of notice of our certification, the FDA is automatically prevented from approving our 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a court decision in the infringement case that is favorable to us, or such shorter or longer period as may be ordered by a court. Such actions are routinely filed by patent owners. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and patent litigation before our product candidates may be commercialized. We may not be successful in defending any patent infringement claim. Even if we are found not to infringe, or a plaintiff's patent claims are found invalid or unenforceable, defending any such infringement claim would be expensive and time-consuming, and would delay launch of our products or our other product candidates and distract management from their normal responsibilities. We have not received a complaint asserting patent infringement.

Risks Related to the Securities Markets and Ownership of Our Securities

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our securities from Nasdaq, and the price of our common stock and/or warrants and our ability to access the capital markets could be negatively impacted.

Our common stock and warrants are currently listed for trading on The Nasdaq Capital Market. We must satisfy the continued listing requirements of Nasdaq to maintain the listing of our securities on The Nasdaq Capital Market.

On May 16, 2023, we received a notice from the Listing Qualifications Staff (Staff) of Nasdaq stating that we no longer complied with the minimum stockholders' equity requirement of $2.5 million under the Nasdaq Listing Rule 5550(b)(1) (Minimum Stockholders' Equity Rule) for continued listing. We submitted a plan of compliance to Nasdaq on June 30, 2023. On July 28, 2023, Nasdaq notified us that it had granted an extension until November 13, 2023 to regain compliance with the Minimum Stockholders' Equity Rule, conditioned upon achievement of certain milestones included in the plan of compliance previously submitted to Nasdaq, including a plan to raise additional capital. On November 14, 2023, we received a letter from Nasdaq indicating that, based upon our non-compliance with the Minimum Stockholders' Equity Rule, the Staff had determined to delist our securities from Nasdaq, subject to our request for a hearing before the Nasdaq Hearings Panel (Panel).

On December 26, 2023, we received an additional letter from the Staff indicating that, based upon the resignation of three members of our board of directors on December 12, 2023 and December 13, 2023, we no longer compiled with the independent director, audit committee, compensation committee and independent director oversight of director nominations requirements as set forth in Nasdaq Listing Rule 5605. We timely requested a hearing before the Panel, which was held on February 13, 2024. On February 22, 2024, the Panel notified us that (i) as a result of the appointment of three independent board members on February 12, 2024, we had regained compliance with the board composition requirements of Nasdaq set forth in Nasdaq Listing Rule 5605 and (ii) it granted our request for an exception to evidence continued compliance with the Minimum Stockholders' Equity Rule through May 13, 2024. On May 21, 2024, we were formally notified that the Panel determined that we had regained compliance with the Minimum Stockholders' Equity Rule. Pursuant to Nasdaq Listing Rule 5815(d)(4)(A), we were subject to a discretionary panel monitor through May 21, 2025 (Panel Monitor). If, within that one-year monitoring period, we failed to maintain compliance with any Nasdaq continued listing requirement, the Staff would issue a Delist Determination Letter and we would have an opportunity to request a new hearing with the initial Panel or a newly convened Panel if the initial Panel is unavailable. Notwithstanding Nasdaq Listing Rule 5810(c)(2), we would not be permitted to provide the Staff with a plan of compliance with respect to any deficiency that arose during the one-year monitoring period, and the Staff would not be permitted to grant additional time for us to regain compliance with respect to any deficiency.

On July 28, 2023, we received a notice from Nasdaq indicating that we were not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq (Minimum Bid Price Rule). We were provided a compliance period of 180 calendar days from the date of the notice, or until January 24, 2024, to regain compliance

with the Minimum Bid Price Rule, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). On November 30, 2023, we effected a reverse stock split of our common stock, and on December 15, 2023, we received notice from Nasdaq that we had regained compliance with the Minimum Bid Price Rule.

On June 17, 2024, we received a notice from Nasdaq indicating that, based upon our non-compliance with the Minimum Bid Price Rule, the Staff had determined to delist our securities from Nasdaq unless we timely requested a hearing before the Panel. Because we were subject to the Panel Monitor, the Staff did not grant additional time for the Company to regain compliance with the Minimum Bid Price Rule. We timely requested a hearing before the Panel, which was held on July 25, 2024. Our request for a hearing stayed any suspension or delisting action by the Staff. At such hearing we requested an extension within which to evidence compliance with the Minimum Bid Price Rule. On August 2, 2024, we received a notice from Nasdaq stating that the Panel determined to grant our request for an exception through August 23, 2024 to demonstrate compliance with the Minimum Bid Price Rule. Accordingly, the Panel granted our request for continued listing on Nasdaq, subject to: 1) on or before August 9, 2024, the Company effecting a reverse stock split at a ratio of between 1-for-3 and 1-for-15; and 2) on or before August 23, 2024, the Company demonstrating compliance with the Minimum Bid Price Rule by evidencing a closing bid price of $1.00 or more per share for a minimum of ten consecutive trading sessions. On August 9, 2024, we completed a one-for-twelve reverse stock split in an effort to evidence compliance with the Minimum Bid Price Rule. On September 9, 2024, we were formally notified that the Panel determined the Company has regained compliance with the Minimum Bid Price Rule.

In the event that our closing bid price again falls below $1.00 per share for more than 30 consecutive business days, we will no longer be in compliance with the Minimum Bid Price Rule. We must also maintain either (i) minimum stockholders' equity of $2.5 million pursuant to the Minimum Stockholders' Equity Rule or (ii) a market value of listed securities of at least $35 million pursuant to Nasdaq Listing Rule 5550(b)(2) (Minimum Market Value Rule). As of December 31, 2025, our stockholders' equity was $2.5 million and as of March 13, 2026, the market value of our common stock was approximately $101 million based on a closing price of our common stock on that date of $8.69 per share. There can be no assurance that we will continue to maintain compliance with the Minimum Bid Price Rule, the Minium Stockholders' Equity Rule, the Minimum Market Value Rule or the other Nasdaq listing requirements.

We must satisfy Nasdaq's continued listing requirements or risk delisting, which could have a material adverse effect on our business. If our common stock and warrants are delisted from Nasdaq, it could materially reduce the liquidity of our common stock and warrants and result in a corresponding material reduction in the price of our common stock and warrants as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. If our common stock and warrants are delisted, it could be more difficult to buy or sell our common stock and warrants or to obtain accurate quotations, and the price of our common stock and warrants could suffer a material decline. Delisting could also impair our ability to raise capital on acceptable terms, if at all.

An active trading market for our common stock or warrants may not be sustained.

An active trading market for our common stock or warrants may not be sustained. The lack of an active market for our common stock or warrants may impair investors' ability to sell their common stock or warrants at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares of common stock or warrants and may impair our ability to raise capital to continue to fund operations by selling securities and may impair our ability to acquire additional intellectual property assets by using our securities as consideration.

The prices of our securities may be volatile, which could subject us to securities class action litigation and our stockholders could incur substantial losses.

The market price for our common stock and warrants may be volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- actual or anticipated changes in the pace of our corporate achievements or our growth rate relative to our competitors;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;

- share price and volume fluctuations attributable to inconsistent trading volume levels of our common stock or warrants;
- additions or departures of key management or other personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock or warrants by us, our insiders or our other stockholders; and
- general economic, market or political conditions in the United States or elsewhere.

In particular, the market prices of clinical-stage companies like ours have been highly volatile due to factors, including, but not limited to:

- any delay or failure in a clinical trial for our product candidates or to receive approval from the FDA and other regulatory agents;
- developments or disputes concerning our product's intellectual property rights;
- our or our competitors' technological innovations;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies or patents;
- failure to complete significant transactions or collaborate with vendors in manufacturing our product; and
- proposals for legislation that would place restrictions on the price of medical therapies.

These and other market and industry factors may cause the market price and demand for our common stock and warrants to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock or warrants and may otherwise negatively affect the liquidity of our common stock and warrants. In addition, the stock market in general, and Nasdaq and emerging growth companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a security has been volatile, holders of that security have instituted securities class action litigation against the company that issued the security. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

We are an "emerging growth company," and will be able take advantage of reduced disclosure requirements applicable to "emerging growth companies," which could make our securities less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and, for as long as we continue to be an "emerging growth company," we intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We can be an "emerging growth company" for up to five years from our initial public offering, which occurred in December 2021, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.235 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period.

We intend to take advantage of these reporting exemptions described above until we are no longer an "emerging growth company." Under the JOBS Act, "emerging growth companies" can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

We cannot predict if investors will find our securities less attractive if we choose to rely on these exemptions. If some investors find our securities less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our securities and the price of our common stock and warrants may be more volatile.

If we are not able to maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be adversely affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

Management identified a material weakness during its assessment of internal controls over financial reporting as of December 31, 2023 as a result of the fact that as of December 31, 2023, we did not have any independent directors. Effective February 12, 2024, our Board appointed Bryan Lawrence as a Class III director, and each of Jeffrey S. Ervin, and John A. Roberts, as a Class II director. The Board has affirmatively determined that each the newly appointed directors (i) is independent under the rules of Nasdaq and (ii) meets the heightened standards of independence for compensation and audit committee membership under the applicable rules of the U.S. Securities and Exchange Commission ("SEC") and Nasdaq. The Board had also determined that Mr. Roberts qualifies as an "audit committee financial expert" under the criteria set forth in Item 407(d)(5) of Regulation S-K. The Board appointed each of the new directors to serve on the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee of the Board. As a result of the foregoing, the material weakness was deemed remediated as of the date of the filing of our Annual Report on Form 10-K for fiscal year 2023.

Although the material weakness described above has been remediated, we can give no assurance that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our financial statements.

As a public company, we are obligated to develop and maintain proper and effective controls over financial reporting. If we fail to maintain proper and effective internal controls over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our securities.

Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and provide a management report on internal control over financial reporting. When we lose our status as an "emerging growth company," as defined in the JOBS Act, and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. We anticipate that we will no longer be an emerging growth company after December 31, 2026. However, for so long as we remain an emerging growth company, we intend to take advantage of an exemption available to emerging growth companies from these auditor attestation requirements. The rules governing the standards that must be met for 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 will need to upgrade our systems including information technology; 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 or warrants may decline.

As described in the prior risk factor, management identified a material weakness during its assessment of internal controls over financial reporting as of December 31, 2023, which was remediated as of the date of the filing of our Annual Report on Form 10-K for fiscal year 2023. We cannot assure you that there will not be additional material weaknesses or significant deficiencies in our internal control over financial reporting in the future. 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, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock or warrants 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 or significant deficiencies 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.

We will incur significantly increased costs as a result of and devote substantial management time to operating as a public company.

As public company, we will incur significant legal, accounting and other expenses. For example, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and are required to comply with the applicable requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC, including the establishment and maintenance of effective disclosure and financial controls, changes in corporate governance practices and required filing of annual, quarterly and current reports with respect to our business and operating results. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. In addition, our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. We will also need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and may need to establish an internal audit function. We also expect that operating as a public company will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. This could also make it more difficult for us to attract and retain qualified people to serve on our Board, our board committees or as executive officers. In addition, after we no longer qualify as an "emerging growth company," as defined under the JOBS ACT we expect to incur additional management time and cost to comply with the more stringent reporting requirements applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We anticipate that we will no longer be an emerging growth company after December 31, 2026. We are just beginning the process of compiling the system and processing documentation needed to comply with such requirements. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. In that regard, we currently do not have an internal audit function, and we will need to hire or contract for additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs.

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

The trading market for our common stock and warrants will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently have limited research coverage by securities and industry analysts. If we fail to maintain adequate coverage by securities or industry analysts, the trading price for our stock could be negatively impacted. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Future sales of our common stock, warrants, or securities convertible into our common stock may depress our stock price.

The price of our common stock or warrants could decline as a result of sales of a large number of shares of our common stock or warrants or the perception that these sales could occur. These sales, or the possibility that these sales may occur, including pursuant to an at-the-market offering or the 2025 LP Purchase Agreement, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

In addition, in the future, we may issue additional shares of common stock, warrants or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuances could result in substantial dilution to our existing stockholders and could cause the price of our common stock or warrants to decline.

Anti-takeover provisions contained in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our amended and restated certificate of incorporation, bylaws and Delaware law contain provisions which could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our Board. Our corporate governance documents include provisions:

- classifying our Board into three classes;

- authorizing "blank check" preferred stock, which could be issued by our Board without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock;
- limiting the liability of, and providing indemnification to, our directors and officers;
- limiting the ability of our stockholders to call and bring business before special meetings;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our Board;
- controlling the procedures for the conduct and scheduling of Board and stockholder meetings; and
- providing our Board with the express power to postpone previously scheduled annual meetings and to cancel previously scheduled special meetings.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents some stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock.

Any provision of our amended and restated certificate of incorporation, bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock or warrants and could also affect the price that some investors are willing to pay for our common stock and warrants.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock and warrants after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that shares of our common stock or warrants will appreciate in value or even maintain the price at which stockholders have purchased their shares or warrants.

Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated certificate of incorporation requires that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for each of the following:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim for breach of any fiduciary duty owed by any director, officer or other employee of ours to the Company or our stockholders;
- any action asserting a claim against us or any director or officer of ours arising pursuant to, or a claim against us or any of our directors or officers, with respect to the interpretation or application of any provision of, the DGCL, our certificate of incorporation or bylaws; or
- any action asserting a claim governed by the internal affairs doctrine;

provided, that, if and only if the Court of Chancery of the State of Delaware dismisses any of the foregoing actions for lack of subject matter jurisdiction, any such action or actions may be brought in another state court sitting in the State of Delaware.

The exclusive forum provision is limited to the extent permitted by law, and it will not apply to claims arising under the Exchange Act or for any other federal securities laws which provide for exclusive federal jurisdiction.

Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than in the federal district courts of the United States of America. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation.

Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, this provision may limit or discourage 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 may result in increased costs for investors to bring a claim. Alternatively, if a court were to find the choice of forum provision contained 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.

We note that there is uncertainty as to whether a court would enforce the provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

Like many of our peer companies, we recognize the significance of cybersecurity threats to our clients and operations. Our business strategy, results of operations, and financial condition have not, to date, been affected by risks from cybersecurity threats. During the reporting period, we have not experienced any material cyber incidents, nor have we experienced a series of immaterial incidents, which would require disclosure.

In the ordinary course of our business, we use, store and process data including data of our employees, partners, collaborators, and vendors. To effectively prevent, detect, and respond to cybersecurity threats, we maintain a cyber risk management program, which is comprised of a wide array of architecture and processes. The cyber risk management program falls under the responsibility of our Chief Financial Officer who, in turn, manages our outsourced experts in IT and cyber security. Under the guidance of our Chief Financial Officer, we task reputable third-party IT experts that utilize a wide variety of software to secure the environment.

We have implemented a cybersecurity risk management program that is designed to identify, assess, and mitigate risks from cybersecurity threats to this data and our systems. We deploy a wide range of security tools across the environment including multifactor authentication, data encryption, cloud-based backups, endpoint monitoring, and dark web monitoring. As a result, we have not identified any material cybersecurity risks and are continuously hardening our environment. Additionally, our program includes regular cybersecurity testing for all employees.

Governance

Our board of directors is responsible for the oversight of cybersecurity risk management. The Chief Financial Officer reports to the board of directors. The Chief Financial Officer provides updates to the board of directors on our cybersecurity risk management program, including any critical cybersecurity risks, ongoing cybersecurity initiatives and strategies, and applicable regulatory requirements and industry standards on a regular basis. The Chief Financial Officer also notifies the board of directors of any cybersecurity incidents (suspected or actual) and provides updates on the incidents as well as cybersecurity risk mitigation activities as appropriate.

ITEM 2. PROPERTIES

Our corporate headquarters is located in Kansas City, Kansas, where we lease approximately 14,205 square feet of office space. Our lease expires in May 2030, with an option to extend. We executed a sub-lease of a portion of our Kansas City office space through September 1, 2027. Our manufacturing activities take place at Core Rx, Inc. (dba Bend Bioscience), our CDMO in Gainesville, Georgia. We believe our current offices, laboratories, and manufacturing spaces are sufficient to meet our needs. We may seek to negotiate new leases or evaluate additional or alternate space to accommodate operations. We believe that appropriate alternative space is readily available on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

See Part II-*Item 8, Notes to Consolidated Financial Statements* and *Note 6 – Contingencies*, of this annual report.

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 trades on the NASDAQ Capital Market under the symbol "CING."

Holders of Record

As of March 9, 2026, we had 209 holders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

Except with respect to the stock dividend that was effective on September 20, 2021 for the purpose of establishing the correct number of shares outstanding based upon our valuation prior to our IPO, we have never declared or paid any dividends on our common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our Board.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this annual report. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this annual report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company using our proprietary PTR™ drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. With an initial focus on the treatment of ADHD and anxiety, we are identifying and evaluating additional therapeutic areas where our PTR technology may be employed to develop future product candidates. Our PTR platform incorporates a proprietary EBL designed to allow for the release of drug substance at specific, pre-defined time intervals, unlocking the potential for once-daily, multi-dose tablets. We believe there remains a significant, unmet need within the current treatment paradigm for true once-daily ADHD stimulant medications with lasting duration to better serve the needs of patients throughout their entire active-day.

Since inception in 2012, our operations have focused on developing our product candidates, primarily CTx-1301, organizing and staffing our company, business planning, raising capital and establishing our intellectual property portfolio. We do not have any product candidates approved for sale and have not generated any revenue. We have funded our operations through public and private capital raised. Cumulative capital raised from these sources, including debt financing, was approximately $128.7 million as of December 31, 2025.

We have incurred significant losses since our inception. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and commercialization of one or more of our product candidates. Our net losses were $22.4 million and $16.6 million for the years ended December 31, 2025 and 2024, respectively. See "Results of Operations" below for an explanation of the fluctuations in our net losses. As of December 31, 2025, we had an accumulated deficit of $132.4 million.

We expect to continue to incur significant expenses and operating losses in the near term as we:

- seek regulatory approval for CTx-1301;
- continue research and development activities for our existing and new product candidates, primarily for CTx-1301;
- continue manufacturing activities, primarily for CTx-1301;
- advance commercialization efforts for CTx-1301; and
- operate as a public company.

We believe our cash will satisfy our capital needs late into the fourth quarter of 2026 under our current business plan, which primarily includes activities related to us seeking regulatory approval for CTx-1301 and pre-commercialization efforts for CTx-1301. We will also need additional capital to advance our other programs. See "Liquidity and Capital Resources" below.

Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates. Our most advanced product candidate currently is CTx-1301, for which we submitted a NDA with the FDA in July 2025. On [DATE], the NDA submission was accepted by the FDA and a PDUFA target action date of May 31, 2026 was assigned. However, completing the process of obtaining FDA approval of the pending NDA for CTx-1301 still involves substantial risk. See "Risk Factors—We depend heavily on the success of CTx-1301. If we are unable to secure approval of CTx-1301, we will never be able to generate revenues from CTx-1301, and our ability to create stockholder value will be severely limited" for more information about the risks related to regulatory approval of CTx-1301.

2024 Reverse Stock Split

On August 9, 2024, we completed a one-for-twelve reverse stock split (the "2024 Reverse Stock Split"), which reduced the number of shares of our common stock that were issued and outstanding immediately prior to the effectiveness of the 2024 Reverse Stock Split. The number of shares of our authorized common stock was not affected by the 2024 Reverse Stock Split and the par value of our common stock remained unchanged at $0.0001 per share. No fractional shares were issued in connection with the 2024 Reverse Stock Split. All share and per share amounts in this report have been adjusted to reflect the 2024 Reverse Stock Split.

Securities Issuances

ATM Agreement

We entered into the At the Market Offering Agreement ("ATM Agreement") with HCW, as sales agent, in January 2023 as amended in May 2023, pursuant to which we could offer and sell, from time to time through HCW, shares of our common stock for aggregate proceeds of up to $32.34 million (upon the terms and subject to the conditions and limitations set forth in the ATM Agreement). On March 16, 2026, we terminated the ATM Agreement, effective March 23, 2026.

During 2025, we sold 785,784 shares of common stock under the ATM Agreement, for net proceeds of $3,574,574, after deducting $122,576 of compensation to HCW and other administration fees. Subsequent to December 31, 2025, we sold 210,158 shares of common stock under the ATM Agreement, for net proceeds of $1,304,011, after deducting $43,300 of compensation to HCW and other administration fees.

Equity Line of Credit

In April 2023, we entered into a purchase agreement (the "Original LP Purchase Agreement") with Lincoln Park Capital Fund LLC ("Lincoln Park"). Pursuant to the Original LP Purchase Agreement, Lincoln Park agreed to purchase from us up to an aggregate of $12.0 million of common stock. During 2025, we sold 897,415 shares of common stock under the Original LP Purchase Agreement, for net proceeds of $3,513,236. As of June 30, 2025, we sold to Lincoln Park the maximum dollar value worth of common stock pursuant to the Original LP Purchase Agreement, and the Original LP Purchase Agreement thereupon expired in accordance with its terms.

On July 21, 2025, we entered into a second purchase agreement with Lincoln Park (the "2025 LP Purchase Agreement"), pursuant to which Lincoln Park has agreed to purchase from us up to an aggregate of $25.0 million of common stock (subject to certain limitations and satisfaction of the conditions set forth in the 2025 LP Purchase Agreement) from time to time and at the Company's sole discretion over the 36-month term of the 2025 LP Purchase Agreement. Pursuant to the terms of the 2025 LP Purchase Agreement, we issued 120,424 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of common stock under the 2025 LP Purchase Agreement. During 2025, we sold 852,948 shares of common stock to Lincoln Park, under the 2025 LP Purchase Agreement, for net proceeds of $3,238,007. Subsequent to December 31, 2025, we sold 1,526,628 shares of common stock to Lincoln Park, under the 2025 LP Purchase Agreement, for net proceeds of $8,506,791. As of March 18, 2026, we had approximately $13.3 million of availability under the 2025 LP Purchase Agreement.

Private Placement

On January 27, 2026, we entered into a securities purchase agreement (the "Purchase Agreement") with several purchasers, including a lead investor (the "Lead Investor") and certain of our officers, directors and other affiliates, for the private placement (the "Private Placement") of: (i) 2,147,472 shares of our common stock, (ii) 954 shares of Series A convertible preferred stock with a stated value of $1,000 (the "Stated Value") and a conversion price equal to a $5.04 per share of common stock (the "Preferred Stock") and (iii) a warrant (the "Warrant") to purchase 1,869,415 shares of common stock (the "Warrant Shares") for aggregate gross proceeds of approximately $12.0 million, at a price per share of $5.14 per share of common stock (including $0.10 per Warrant Share). The Warrant Shares have an exercise price of $5.04 per share of common stock, subject to adjustment as provided in the Warrant. The shares of Common Stock, the shares of Preferred Stock, and the Warrant Shares are referred to collectively as the Securities.

The closing of the Private Placement occurred on February 6 and 13, 2026. At a special meeting of stockholders scheduled for March 24, 2026, stockholders are being asked to approve the issuance of common stock upon conversion of the Preferred Stock and the exercise of the Warrant. Upon stockholder approval (i) each outstanding share of the Preferred Stock, without any further action by us or the holder, will automatically convert into shares of common stock determined by dividing the Stated Value plus all unpaid accrued and accumulated preferential dividends on such share by the $5.04 conversion price and (ii) the Warrant will be exercisable.

Falcon Creek Capital Advisor LLC ("Falcon Creek"), on behalf of the Lead Investor that it manages, may designate up to two (2) directors (each a "Falcon Creek Director") to serve on our board of directors (the "Board"), who will be designated as follows: (i) one Falcon Creek Director was designated on February 13, 2026 and (ii) Falcon Creek will have the right to designate the second Falcon Creek Director upon stockholder approval; provided, that (1) one Falcon Creek Director shall be required to resign from the Board if the Lead Investor no longer beneficially owns at least 15% of our outstanding common stock and (2) the remaining Falcon Creek Director shall be required to resign from the Board if the Lead Investor no longer beneficially owns at least 5% of our outstanding common stock.

Except as provided in the Purchase Agreement, during the period commencing on and including the date of the Purchase Agreement and continuing through and including the 180th day following the date of the Purchase Agreement (such period being referred to as the "Lock-up Period"), each purchaser will not, without our prior written consent, sell, offer to sell, contract to sell or lend any Securities. The Purchase Agreement also provides that during the Lock-up Period, the purchasers will not (i) effect any short sale, or establish or increase any "put equivalent position" or liquidate or decrease any "call equivalent position" of any Securities; (ii) pledge, hypothecate or grant any security interest in any Securities; (iii) in any other way transfer or dispose of any Securities; (iv) enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of any Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise; (v) grant any proxies or powers of attorney with respect to any Securities, deposit any Securities into a voting trust, or enter into a voting agreement or similar arrangement or commitment with respect to any Securities; or (vi) publicly announce the intention to do any of the foregoing.

The Purchase Agreement also includes a standstill provision for a period of twenty-four (24) months following the last closing date, whereby each purchaser has agreed that, without our prior written consent, the purchaser will not: (i) acquire, offer to acquire, or agree to acquire any of our securities if such acquisition would result in the purchaser and its affiliates beneficially owning more than 40% of our outstanding common stock on an as-converted basis; (ii) make, or in any way participate in, any solicitation of proxies or consents with respect to any of our securities; or (iii) propose or participate in any merger, tender offer, business combination, recapitalization, or similar transaction involving us.

The independent members of our Board reviewed the terms of the Private Placement, including the participation of certain of our officers, directors and other affiliates, and determined that the Private Placement is in our best interest and the best interests of our stockholders.

Debt Conversion

In August 2022, CTx, a wholly-owned subsidiary of Cingulate Inc. issued a promissory note to WFIA with a principal amount of $5.0 million, and in May 2023, CTx issued an amended and restated promissory note (the "WFIA Note") increasing the principal amount under the promissory note by $3.0 million to $8.0 million.

On September 8, 2023, Cingulate Inc. and CTx entered into a note conversion agreement with WFIA, pursuant to which WFIA agreed to convert $5.0 million of principal under the WFIA Note plus all accrued interest thereon, or $5,812,500, into pre-funded warrants (the "September WFIA Pre-Funded Warrants") to purchase 28,493 shares of our common stock at a conversion price per September WFIA Pre-Funded Warrant of $204.00. The closing price of our common stock on Nasdaq on September 8, 2023 was $138.60 per share. The September WFIA Pre-Funded Warrants had no expiration date and were exercisable immediately at an exercise price of $0.024 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Exchange Act, no more than 19.99% of the outstanding shares of our common stock.

On January 25, 2024, Cingulate Inc. and CTx entered into a note conversion agreement with WFIA, pursuant to which WFIA agreed to convert the remaining $3.0 million of principal under the WFIA Note plus all accrued interest thereon, or $3,287,500, into pre-funded warrants (the "January WFIA Pre-Funded Warrants") to purchase 57,254 shares of our common stock, at a conversion price per January WFIA Pre-Funded Warrant of $57.42. The closing price of the Common Stock on Nasdaq on January 24, 2024 was $52.20 per share. The January WFIA Pre-Funded Warrants had no expiration date and were exercisable immediately at an exercise price of $0.0012 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Exchange Act, no more than 19.99% of the outstanding shares of our common stock. In March of 2024, we issued to WFIA an additional pre-funded warrant to purchase 588 shares of common stock as a result of an error in the interest calculation, on the same form and at the same conversion price as the January WFIA Pre-Funded Warrants.

The WFIA Note was unsecured with interest accruing at 15% per annum. After the conversion of the remaining principal amount plus all accrued interest thereon and the issuance of the January WFIA Pre-Funded Warrants, the WFIA Note was paid in full and we have no further obligations under the WFIA Note. WFIA exercised all of its pre-funded warrants in April 2024.

Public Offerings

On February 2, 2024, we entered into agreements, including a Securities Purchase Agreement, with investors, pursuant to which we issued 114,583 shares of our common stock, pre-funded warrants to purchase up to an aggregate of 197,917 shares of our common stock, Series A warrants to purchase up to 312,500 shares of our common stock and Series B warrants to purchase up to 312,500 shares of our common stock (the "February 2024 Offering"). The February 2024 Offering closed on February 6, 2024. The combined purchase price per share of common stock and accompanying Series A and Series B warrants was $24.00. The combined purchase price per pre-funded warrant and accompanying Series A and Series B warrants was $23.9988, which represents the public offering price per share of common stock and accompanying warrants less the $0.0012 per share exercise price for each pre-funded warrant. The pre-funded warrants are exercisable at any time after the date of issuance and have no expiration date. The holder of pre-funded warrants may not exercise the warrants if the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. The Series A warrants have an exercise price of $24.00 per share, were exercisable immediately, and will expire five years after the issuance date, and the Series B warrants have an exercise price of $24.00 per share, were exercisable immediately, and will expire two years after the issuance date. We received gross proceeds of approximately $7.5 million, before deducting $750,950 of placement agent's fees and other offering expenses, pursuant to the February 2024 Offering. All pre-funded warrants were exercised during 2024.

Warrant Inducement

On June 28, 2024, we entered into an inducement offer letter agreement (the "June 2024 Warrant Inducement"), pursuant to which certain holders ("Holders") of certain of our existing warrants to purchase 265,625 shares of common stock issued to the Holders on February 6, 2024 (the "February 2024 Warrants") agreed to exercise for cash their February 2024 Warrants at a reduced exercise price of $7.02 per share. In consideration for the exercise of the February 2024 Warrants, the

Holders received new Series C common stock purchase warrants to purchase an aggregate of 354,167 shares of common stock and new Series D common stock purchase warrants to purchase an aggregate of 177,083 shares of common stock. Such new warrants have an exercise price of $7.02 per share. We received net proceeds of $1.6 million from the closing of the June 2024 Warrant Inducement, which occurred on July 1, 2024. The Series C and Series D warrants have an exercise price of $7.02 per share and were exercisable beginning on August 24, 2024, the effective date of stockholder approval of the shares issuable pursuant to the warrants. The Series C warrants have a five-year term and the Series D warrants have a two-year term from the initial exercise date.

Debt Issuance

On December 20, 2024, we entered into a Note Purchase Agreement (the "2024 Note Purchase Agreement") with Streeterville Capital, LLC, a Utah limited liability company ("Lender"), pursuant to which we issued and sold to Lender an unsecured promissory note in the amount of $5,480,000 (the "2024 Note"). The principal amount included an original issue discount of $450,000 and expenses payable by us of $30,000. In exchange for the 2024 Note, Lender paid a purchase price of $5,000,000 in cash. The 2024 Note bore interest at a rate of 9% per annum and had a maturity 18 months after its issuance date. Our wholly-owned subsidiaries Cingulate Therapeutics LLC and Cingulate Works, Inc., provided a guarantee of our obligations to Lender under the 2024 Note and the other transaction documents. We used the net proceeds from the sale of the 2024 Note for working capital and other general corporate purposes.

From time to time, beginning on July 2, 2025, Lender could redeem a portion of the 2024 Note. Pursuant to the terms of the 2024 Note, we were charged a monitoring fee equal to the outstanding balance on the 90-day anniversary of the effective date of the 2024 Note divided by 0.85 less the outstanding balance on such date.

During 2025, we entered into exchange agreements with Lender to exchange an aggregate of $4,675,000 in principal for 1,167,300 shares of common stock, thereby extinguishing that portion of the 2024 Note. Subsequent to December 31, 2025, we entered into exchange agreements with Lender to exchange an aggregate of $2,308,947 in principal for 460,122 shares of common stock, thereby extinguishing the remaining balance of the 2024 Note. See Note 8 to our consolidated financial statements for additional information regarding the 2024 Note and the 2024 Note Purchase Agreement.

On November 7, 2025, we entered into a note purchase agreement (the "2025 Note Purchase Agreement") with Avondale Capital, LLC, a Utah limited liability company ("Avondale"), pursuant to which we issued and sold to Avondale an unsecured promissory note in the amount of $6,570,000 (the "2025 Note"). The principal amount includes an original issue discount of $540,000 and expenses payable by us of $30,000. In exchange for the 2025 Note, Avondale paid a purchase price of $6,000,000 in cash. The 2025 Note bears interest at a rate of 9% per annum and matures 18 months after its issuance date. Our wholly-owned subsidiaries Cingulate Therapeutics LLC and Cingulate Works, Inc., provided a guarantee of our obligations to Avondale under the 2025 Note and the other transaction documents. We intend to use the net proceeds from the sale of the 2025 Note for working capital and other general corporate purposes.

From time to time, beginning on May 7, 2026, Avondale may redeem a portion of the 2025 Note, not to exceed an amount of $660,000 per month; and provided that we have not previously received a "complete response letter" from the FDA with respect to CTx-1301, we may defer up to two redemptions for up to thirty (30) days each. If we exercise our deferral right, the outstanding balance of the 2025 Note will be increased by 1% of the outstanding balance on the date of the deferral. We were charged a monitoring fee equal to the outstanding balance on the 90-day anniversary of the effective date of the 2025 Note divided by 0.85 less the outstanding balance on such date. Subject to the terms and conditions set forth in the 2025 Note, we may prepay all or any portion of the outstanding balance of the 2025 Note at any time.

Pursuant to the 2025 Note Purchase Agreement, while the 2025 Note is still outstanding, we will not enter into any arrangement that prohibits us from entering into a variable rate transaction, as defined in the 2025 Note Purchase Agreement, with Avondale or its affiliates, or from issuing our securities to Avondale or its affiliates. We are also prohibited from entering into a variable rate transaction while the 2025 Note is outstanding, subject to certain exceptions. At any time while the 2025 Note is still outstanding, Avondale will have the right, but not the obligation, with our consent, to reinvest up to an additional $5.0 million in one or more tranches on the same terms and conditions as the 2025 Note. Additionally, so long as the 2025 Note is outstanding, upon any issuance by us of any debt security with any economic term or condition more favorable to the holder of such security that was not provided to Avondale pursuant to the 2025 Note, then, at Avondale's option, such additional term shall become part of the 2025 Note and related documents for the benefit of Avondale. See Note 8 to our consolidated financial statements for additional information regarding the 2025 Note and 2025 Note Purchase Agreement.

Components of Operating Results

Revenue

Since inception, we have not generated any revenue and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration of license agreements.

Operating Expenses

Research and Development Expenses

Research and development expenses consist of costs incurred in the discovery and development of our product candidates, and primarily include:

- expenses incurred under third party agreements with contract research organizations (CROs), and investigative sites, that conducted or will conduct our clinical trials and a portion of our pre-clinical activities;
- costs of raw materials, as well as manufacturing cost of our materials used in clinical trials and other development testing;
- expenses, including salaries and benefits of employees engaged in research and development activities;
- costs of manufacturing equipment, depreciation and other allocated expenses; and
- fees paid for contracted regulatory services as well as fees paid to regulatory authorities including the FDA for review and approval of our product candidates.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued costs.

Research and development activities are central to our business model. Subject to successful regulatory approval and commercialization of CTx-1301, we expect that our research and development expenses will continue to increase for the foreseeable future as we continue clinical development for our product candidates, as well as adding additional PTR product candidates to our pipeline. As products enter later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Historically, our research and development costs have primarily related to the development of CTx-1301. We expect to fund our research and development expenses from our current cash and cash equivalents and any future equity or debt financings, or other capital sources.

General and Administrative Expenses

General and administrative expenses consist primarily of (i) professional fees for legal, accounting, audit, tax and consulting services, (ii) salaries and related costs for our employees in administrative, executive and finance functions and (iii) pre-commercialization expenses for CTx-1301. General and administrative expenses also include insurance, office, and travel expenses.

We expect that our general and administrative expenses will increase in the future as we increase our general and administrative headcount to support our growing operations, including the potential commercialization of CTx-1301, and incur costs related to pre-commercialization activities. We have experienced, and will continue to experience, increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services; director and officer insurance; and investor and public relations costs.

Issuance cost and change in fair value of derivative and interest and other income (expense), net

Issuance cost and change in fair value of derivative relates to the consideration for Lincoln Park's commitment to purchase shares under the 2025 LP Purchase Agreement and the change in fair value of the derivative asset or liability. Interest and other income (expense), net consists of interest expense on our notes payable and interest earned on our cash and cash equivalents, including money market funds. The primary objective of our investment policy is liquidity and capital preservation.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of expenses during a reporting period. Actual results could differ from estimates.

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

Research and Development Costs

Research and development costs are expensed as incurred and include all direct and indirect costs associated with the development of our product candidates. These expenses include payments to third parties for research, development and manufacturing services, personnel costs and depreciation on manufacturing equipment. At the end of the reporting period, we compare payments made to third party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to service providers and the progress that we estimate have been made as a result of the service provided, we may record net prepaid or accrued expense relating to these costs.

Stock-Based Compensation

Under our 2021 Omnibus Equity Incentive Plan (the "2021 Plan"), we granted non-qualified stock options to certain employees, directors and consultants in 2025 and 2024. The options were granted with strike prices ranging from $3.44 to $4.22 in 2025 and $3.46 to $13.34 per share in 2024. The term of these options is ten years with vesting periods ranging from immediate to four years.

On each of July 8, 2025 and November 3, 2025, we granted non-qualified stock options to an officer of the Company to purchase 30,000 shares of common stock at an exercise price of $4.51 and $3.80, respectively. These grants were inducement awards in accordance with Nasdaq Listing Rule 5635(c)(4) and were not granted from the 2021 Plan. The term of these options is ten years with vesting over four years.

We recorded stock-based compensation expense of $1,427,159 and $995,484 during the years ended December 31, 2025 and 2024, respectively, based on the grant-date fair value of the options granted. The fair value of each option grant was estimated as of the date of grant using the Black-Scholes option-pricing model. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period.

See Note 12 to our consolidated financial statements for the assumptions that were used to estimate the fair value of stock options granted using the Black-Scholes option pricing model.

Results of Operations

Comparison of the years ended December 31, 2025 and December 31, 2024

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

(in thousands)	Year ended December 31, 2025	2024	Increase (Decrease)	% Increase (Decrease)
Operating Expenses:				
Research and development	$ 9,774	$ 9,445	$ 329	3.5%
General and administrative	10,164	6,200	3,964	63.9%
Loss from operations	(19,938)	(15,645)	4,293	27.4%
Issuance cost and change in fair value of derivative	(1,151)	(1,014)	137	13.5%
Interest and other income (expense), net	(1,361)	99	(1,460)	NM
Net Loss	$ (22,450)	$ (16,560)	$ 5,890	35.6%

Research and development expenses

The following table summarizes our research and development expenses ("R&D") for the years ended December 31, 2025 and 2024:

(in thousands)	Year ended December 31, 2025	2024	Increase (Decrease)	% Increase (Decrease)
Clinical operations	$ 2,696	$ 4,712	$ (2,016)	(42.8)%
Drug manufacturing and formulation	3,251	2,696	555	20.6%
Personnel expenses	2,781	1,761	1,020	57.9%
Regulatory costs	1,046	276	770	279.0%
Total research and development expenses	$ 9,774	$ 9,445	$ 329	3.5%

R&D expenses were $9.8 million for the year ended December 31, 2025, an increase of $0.3 million or 3.5% from the year ended December 31, 2024. This change was primarily the result of an increase in personnel expenses, regulatory costs and manufacturing costs, partially offset by a decrease in clinical operations. Personnel expenses increased due to separation costs for an executive in August 2025, costs related to a contingent bonus plan, which were earned upon NDA submission of CTx-130l, and the reinstatement of base salaries in September 2024 following salary reduction measures which had been implemented in late 2023. Regulatory costs increased due to preparation for the pre-NDA meeting with the FDA and the NDA submission. The increase in manufacturing costs was due to the manufacturing of pre-process validation batches of CTx-1301. Clinical operations costs decreased due to more prior year costs related to the close-out and analytical activities related to the fixed dose pediatric and adolescent safety and efficacy study and the pediatric dose optimization and duration study compared to the current year.

General and administrative expenses

The following table summarizes our general and administrative ("G&A") expenses for the years ended December 31, 2025 and 2024:

(in thousands)	Year ended December 31, 2025	2024	Increase (Decrease)	% Increase (Decrease)
Pre-commercialization costs	$ 2,381	$ 116	$ 2,265	NM
Personnel expenses	2,992	1,862	1,130	60.7%
Legal and professional fees	3,121	2,396	725	30.3%
Occupancy	327	346	(19)	(5.5)%
Insurance	741	984	(243)	(24.7)%
Other	602	496	106	21.4%
Total general and administrative expenses	$ 10,164	$ 6,200	$ 3,964	63.9%

G&A expenses were $10.2 million for the year ended December 31, 2025, an increase of $4.0 million or 63.9% from the year ended December 31, 2024. This is primarily the result of an increase in pre-commercialization costs, personnel expenses and legal and professional fees. Pre-commercialization costs increased as we prepare for the potential product launch of CTx-1301, pending FDA approval. The increase in personnel expenses was due to costs related to a contingent bonus plan, which were earned upon NDA submission of CTx-1301 and the reinstatement of base salaries in September 2024 following salary reduction measures which had been implemented in late 2023. The increase in legal and professional fees was due to an increase in certain professional, financial and accounting fees.

Issuance cost and change in fair value of derivative and interest and other income (expense), net

The following table summarizes issuance cost and change in fair value of derivative and interest and other income (expense), net for the years ended December 31, 2025 and 2024:

(in thousands)	Year ended December 31, 2025	2024	Increase (Decrease)	% Increase (Decrease)
Issuance cost and change in fair value of derivative	$ (1,151)	$ (1,014)	$ 137	13.5%
Interest and other income (expense), net	(1,361)	99	(1,460)	NM

Issuance cost and change in fair value of derivative in 2025 and 2024 relates to the consideration for Lincoln Park's commitment to purchase shares under the 2025 LP Purchase Agreement and the change in fair value of the derivative asset or liability. Interest and other income (expense), net in 2025 and 2024 relates to interest incurred on outstanding notes payable, offset by interest earned on invested balances. The increase in interest expense in 2025 is related to interest expense incurred on the 2024 Note which was executed in December 2024, including loss on debt extinguishments.

Cash Flows

	Year ended December 31,	
	2025	**2024**
Net cash (used in) operating activities	$ (17,245)	$ (18,451)
Net cash (used in) investing activities	(162)	(212)
Net cash provided by financing activities	16,149	30,822
Net decrease in cash and cash equivalents	$ (1,258)	$ 12,159

Cash Flows from Operating Activities

Net cash used in operating activities was $17.2 million for the year ended December 31, 2025. Cash used in operating activities was primarily due to the use of funds in our operations to develop CTx-1301 resulting in a net loss of $22.4 million, prior to the effects of significant noncash items, including stock-based compensation expense of $1.5 million, issuance cost and change in fair value of derivative of $1.2 million, loss on debt extinguishment of $0.8 million, depreciation expense of $0.5 million and accretion of discount on note payable of $0.3 million. Changes in operating assets and liabilities included an increase in trade accounts payable and accrued expenses of $1.5 million primarily due to increases in accrued commercial costs and accrued interest on the outstanding note payable. These are partially offset by an increase in prepaid expenses and other current assets due to payments for manufacturing materials.

Net cash used in operating activities was $18.5 million for the year ended December 31, 2024. Cash used in operating activities was primarily due to the use of funds in our operations to develop CTx-1301 resulting in a net loss of $16.6 million, prior to the effects of significant noncash items including stock-based compensation expense of $1.0 million, issuance cost and change in fair value of derivative of $1.0 million and depreciation expense of $0.7 million. Changes in operating assets and liabilities included a decrease in trade accounts payable and accrued expenses of $4.5 million primarily due to the payment of vendor balances in the first quarter of 2024 with the cash proceeds from the issuance of common stock pursuant to our ATM Agreement in January 2024 and the issuance of equity in the February 2024 Offering.

Cash Flows from Investing Activities

Net cash used in investing activities for both the years ended December 31, 2025 and December 31, 2024 was primarily related to the purchase of equipment to support our research and development.

Cash Flows from Financing Activities

Net cash provided by financing activities in the year ended December 31, 2025 was related to the cash proceeds from the issuance of common stock pursuant to the ATM Agreement, the Original LP Purchase Agreement, the 2025 LP Purchase Agreement, as well as the issuance of the 2025 Note in November 2025.

Net cash provided by financing activities in the year ended December 31, 2024 was related to the cash proceeds from the issuance of common stock pursuant to the ATM Agreement, Original LP Purchase Agreement, the February 2024 Offering and the June 2024 Warrant Inducement, as well as the issuance of the 2024 Note in December 2024.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2012 through December 31, 2025, we have not generated any revenue and have incurred significant operating losses and negative cash flow from our operations.

In November 2025, we received net proceeds of $6,000,000 from the issuance of the 2025 Note with Avondale pursuant to the 2025 Note Purchase Agreement.

During 2025, we sold 785,784 shares of common stock under the ATM Agreement, for net proceeds of $3,574,574, after deducting $122,576 of compensation to HCW and other administration fees. Subsequent to December 31, 2025, we sold 210,158 shares of common stock under the ATM Agreement, for net proceeds of $1,304,011, after deducting $43,300 of compensation to HCW and other administration fees. On March 16, 2026, we terminated the ATM Agreement, effective March 23, 2026. We anticipate that we will enter into another at-the-market offering agreement with a different counterparty in the near future.

During 2025, we sold 897,415 shares of common stock under the Original LP Purchase Agreement for net proceeds of $3,513,236.

During 2025, we sold 852,948 shares of common stock under the 2025 LP Purchase Agreement, for net proceeds of $3,238,007. Subsequent to December 31, 2025, we sold 1,526,628 shares of common stock under the 2025 LP Purchase Agreement, for net proceeds of $8,506,791. As of March 18, 2026, we had approximately $13.3 million of availability under the 2025 LP Purchase Agreement.

As of December 31, 2025, we had cash and cash equivalents of $11.0 million. Taking into account the $12.0 million we received in the Private Placement, we believe our cash will satisfy our capital needs late into the fourth quarter of 2026 under our current business plan. Changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control. Our policy is to invest any cash in excess of our immediate requirements in investments designed to preserve the principal balance and provide liquidity while producing a modest return on investment. Accordingly, our cash equivalents are invested primarily in money market funds which are currently providing only a minimal return given the current interest rate environment.

We expect to continue to incur substantial additional operating losses for the near term as we seek marketing approval for CTx-1301 and conduct pre-commercialization activities. If we obtain marketing approval for CTx-1301, we will incur significant sales, marketing and outsourced manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- Whether we receive FDA approval for CTx-1301 and the timing of such approval;
- the cost and timing of the FDA review process for CTx-1301;
- the cost and timing of manufacturing the clinical supply of our product candidates;
- the initiation, progress, timing, costs and results of clinical trials for our product candidates;
- the clinical development plans we establish for each product candidate;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration or license agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA or other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the cost and timing of the implementation of commercial scale manufacturing activities; and
- the cost and timing of outsourcing our commercialization efforts, including, sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products.

To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, including clinical trials of our product candidates, and other operations and potential product acquisitions and in-licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in-license and develop additional products and product candidates to augment our internal development pipeline. Strategic transaction opportunities that we may pursue could materially affect our liquidity and capital resources and may

require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue development, acquisition or in-licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for general corporate purposes.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

For example, pursuant to the 2025 Note Purchase Agreement with Avondale, we are subject to certain restrictions on our ability to issue securities during the term of the 2025 Note. Specifically, we have agreed, among other things, to refrain from entering into any agreement or covenant that locks up, restricts or otherwise prohibits us from entering into a variable rate transaction with the lenders or any of their affiliates, or from issuing common stock or other equity or debt securities to the lenders or any of their affiliates. If we breach the 2025 Note Purchase Agreement, we may be obligated to indemnify Avondale for loss or damage arising as a result of any breach or alleged breach by us of the 2025 Note Purchase Agreement, which may affect our business operations and financial condition. Additionally, the 2025 Note provides that following an event of default under the 2025 Note, Avondale has the right to seek and receive injunctive relief from a court or an arbitrator prohibiting us from issuing any of our common stock or preferred stock to any party unless fifty percent of the gross proceeds received by us in connection with such issuance are simultaneously used to make a payment under the 2025 Note. Avondale also has the right to seek and receive injunctive relief from a court or arbitrator to prevent the consummation of any fundamental transaction, as defined in the 2025 Note, unless it contains a closing condition that the 2025 Note are paid in full upon consummation of the transaction or Avondale has provided its written consent to such transaction.

Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our existing stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

Contractual Obligations

The following summarizes our contractual obligations as of December 31, 2025 that will affect our future liquidity.

We entered into a patent and know-how licensing agreement with BDD Pharma Limited in August 2018. See "Item 1. Business – Material Agreements" for a description of this agreement. We are required to pay BDD certain amounts in connection with clinical trial and regulatory milestones. The final milestone payment of $250,000 will be due to BDD upon FDA approval of CTx-1301. Additional royalty payments will become due upon potential sales of CTx-1301 pursuant to the terms of the agreement.

We entered into an agreement with Bend Bioscience, our CDMO, for the manufacture of process validation batches of CTx-1301 with a total estimated cost of approximately $7.0 million.

In May 2025, the Company executed a lease to renew the office space for its headquarters in Kansas City, Kansas. The lease has a five-year term that commenced on June 1, 2025 with total rent of $33,145 per month over the lease term. The operating lease right-of-use asset was $1,339,086, the current portion of the operating lease liability was $238,864 and the long-term portion of the lease liability was $1,100,222 as of December 31, 2025.

Going Concern

Since inception we have been engaged in organizational activities, including raising capital and research and development activities. We have not generated revenues and have not yet achieved profitable operations, nor have we ever generated positive cash flow from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. We are subject to those risks associated with any pre-clinical stage pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, we operate in an environment of rapid technological change that is largely dependent on the

services of our employees and consultants. Further, our future operations are dependent on the success of our efforts to raise additional capital. These uncertainties raise substantial doubt about our ability to continue as a going concern for one year after the issuance date of our financial statements. The accompanying consolidated financial statements have been prepared on a going concern basis. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the company to continue as a going concern, which contemplates the continuation of operations, realization of assets and liquidation of liabilities in the ordinary course of business. We have incurred a net loss for the years ended December 31, 2025 and 2024 and had accumulated losses of $132.4 million since inception to December 31, 2025. We anticipate incurring additional losses until such time, if ever, that we can generate significant revenue from our product candidates currently in development. Our sources of capital have included private capital raises in various classes of units of CTx prior to the Reorganization Merger, the issuance of equity securities in connection with our initial public offering (IPO), follow-on public offerings in September 2023 and February 2024, sales of common stock under the ATM Agreement, Original LP Purchase Agreement and 2025 LP Purchase Agreement, a private placement with WFIA, the WFIA Note, which was subsequently converted to equity, the June 2024 warrant inducement, the issuance of the promissory notes in December 2024 and November 2025 and the Private Placement in February 2026. Additional financings will be needed by us to fund our operations, to complete development of and to commercially develop CTx-1301 and our other product candidates. There is no assurance that such financing will be available when needed or on acceptable terms.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company". As an "emerging growth company," we are electing to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for emerging growth companies.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation. These exemptions will apply until the fifth anniversary of the completion of our IPO or until we no longer meet the requirements for being an "emerging growth company," whichever occurs first.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements, together with the report of our independent registered public accounting firm, appear at pages F-1 through F-24 of this annual report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures that is designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") 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 the our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Our Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act) as of December 31, 2025, have concluded that our disclosure controls and procedures were effective as of December 31, 2025.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of this evaluation, management has concluded that the Company's internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2025.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This annual report does not include an attestation report of our registered public accounting firm on our internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies." In addition, we are currently a non-accelerated filer and are therefore not required to provide an attestation report on our internal control over financial reporting until such time as we are an accelerated filer or large accelerated filer.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal year 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

ATM Agreement

On March 16, 2026, we delivered written notice to HCW terminating the ATM Agreement, effective March 23, 2026. The ATM Agreement permitted us to offer and sell shares of our common stock from time to time through HCW as our sales agent.

We exercised our termination right pursuant to the terms of the ATM Agreement. We did not incur any early termination penalties, and we have no further obligations under the ATM Agreement following termination other than customary indemnification and expense reimbursement provisions that survive termination.

10b5-1 Trading Arrangements

In the fourth quarter of 2025, no director or officer (as defined in Exchange Act Rule 16a-1(f)) of the Company adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement for the purchase or sale of securities of the Company, within the meaning of Item 408 of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers and Directors

The following table provides information regarding our executive officers and directors with their respective ages as of March 17, 2026:

Name	Age	Position
Executive Officers:		
Shane J. Schaffer, PharmD	51	Chief Executive Officer
Jennifer L. Callahan	55	Executive Vice President, Chief Financial Officer & Secretary
Raul R. Silva, MD	68	Executive Vice President and Chief Science Officer
Matthew N. Brams, MD	62	Executive Vice President and Chief Medical Officer
Nilay D. Patel	48	Executive Vice President, Chief Legal Officer & Chief Compliance Officer
Bryan Downey	54	Executive Vice President and Chief Commercial Officer
Directors:		
Jeffrey S. Ervin	48	Director
Bryan Lawrence	60	Director
John A. Roberts	67	Director, Chairman
Peter J. Werth	87	Director
Jeff Hargroves	59	Director

Shane J. Schaffer, PharmD co-founded Cingulate in 2012 and has served as our Chief Executive Officer from 2012 to August 2025 and from December 2025 to present. He served as Chairman of our Board from 2012 through December 2025. Prior to his work at Cingulate, Dr. Schaffer served as the Managing Director of Sabre Scientific Solutions, from July 2009 through December 2012. Previously, Dr. Schaffer worked as a Director of National Accounts at Pri-Med Access from September 2008 through May 2009, Senior Marketing at Sanofi from February 2004 through December 2007, and as a Marketing Manager at Novartis from June 2001 through October 2003. From July 1999 through June 2001, he served as Chief Fellow of the Rutgers Pharmaceutical Industry Fellowship Program and was Senior Fellow at Warner Lambert/Parke Davis and Pfizer. From June 1997 to July 1999, he worked as a clinical research associate at Hoechst Marion Roussel. Dr. Schaffer has over 25 years' experience in drug development, commercialization and biotech commercial operation. Dr. Schaffer received his Doctor of Pharmacy from The University of Kansas School of Pharmacy. We believe that Dr. Schaffer's extensive knowledge of the pharmaceutical industry, his clinical and commercial background in a wide range of therapeutic areas, and his experience serving as our Chief Executive Officer, qualifies him to serve on our Board.

Jennifer L. Callahan was appointed as our Senior Vice President and Chief Financial Officer in January 2024 and Secretary in June 2024 and became our Executive Vice President, Chief Financial Officer and Secretary in January 2026. Ms. Callahan served as Interim Chief Executive Officer from August 2025 to December 2025. She has served the Company in an accounting role since January 2017 and was our Vice President, Corporate Controller from January 2019 to January 2024. Prior to her role at the Company, Ms. Callahan served as the Director of Accounting for Meridian Business Services, a local Kansas City accounting firm since 2014 where she provided outsourced controller services to various companies, including start-up companies and companies in need of process improvements. Over the tenure of her career, Ms. Callahan has provided consulting services to companies in a variety of industries and stages. She started her career with Deloitte where she served in various roles in the audit practice from June 1992 to December 1998. Ms. Callahan holds a CPA designation and received a BSBA in Accounting and Finance from Creighton University.

Raul R. Silva, MD co-founded Cingulate in 2012 and has served as our Executive Vice President and Chief Science Officer since January 2018. He has been in private practice specializing in child and adolescent psychiatry since 2009. Previously, Dr. Silva served as Executive Director of Rockland Children's Psychiatric Center from 2006-2009. He also served as Vice Chairman of The New York University Child Study Center 2005 through 2009. Dr. Silva served as Deputy Director of Child Psychiatry at Bellevue Hospital Center from 1999 through 2006. Prior to that, he was Director of Child and Adolescent Psychiatry at St. Luke's/Roosevelt Hospital in New York City from 1995 through 1990. He completed his fellowship in child and adolescent psychiatry at Columbia University's St. Luke's/Roosevelt Hospital Center in 1990. Dr. Silva completed a psychopharmacology research fellowship at New York University Medical Center. Dr. Silva is board certified in general, child and adolescent psychiatry. Dr. Silva received his Doctor of Medicine degree from Ross University and his Bachelor of Science in Biology from Fairleigh Dickinson University.

Matthew N. Brams, MD co-founded Cingulate in 2012 and has served as our Executive Vice President and Chief Medical Officer since January 2018 and served as a director of Cingulate from January 2018 through July 2021. Dr. Brams served as a Principal of Bayou City Research, a position he held from April 1999 to January 2021. Prior to that, he served as a consultant medical director and/or admitting Psychiatrist at numerous medical facilities including Taylor Recover Center (April 2019 to present); Lakeview Health Rehabilitation Center (2018-2019); The Parc, Houston Tx (2012-2015); GeroPsych Unit Gulf Coast Hospital (2009-Present). Dr. Brams has been integral to the research teams for all the major pharmaceutical companies participating in the ADHD clinical arena. Dr. Brams completed residency and fellowship at Baylor College of Medicine in adult and child psychiatry, respectively. He is board certified in Adult and Child Psychiatry (1994) and is an acting Senior Board Examiner for the American Board of Psychiatry and Neurology. He received his Doctor of Medicine from The University of Texas Science Center and his Bachelor of Arts in Biology from the University of Texas.

Nilay Patel was appointed as our Senior Vice President, Chief Legal Officer and Chief Compliance Officer in July 2025 and became our Executive Vice President, Chief Legal Officer and Chief Compliance Officer in October 2025. Patel Mr. Patel previously served as Chief Legal Officer, Chief Compliance Officer and Corporate Secretary at Ironshore Pharmaceuticals from September 2019 to September 2024 where he played a key role in launching the company's flagship ADHD therapy and led legal and compliance functions through its acquisition by Collegium Pharmaceuticals. Mr. Patel held senior legal roles at Grifols, where he served as Assistant General Counsel for the company's U.S. Bioscience division from October 2011 to September 2019. Mr. Patel began his legal career as a patent attorney at Cooper & Dunham LLP in New York, and later practiced at Life Sciences Law PLLC, where he advised emerging biotech companies on M&A, licensing, and venture financing transactions. He holds a Juris Doctor from Columbia Law School and dual Bachelor of Science degrees in Biochemistry and Chemistry from North Carolina State University.

Bryan Downey has been our Executive Vice President and Chief Commercial Officer since November 2025. Mr. Downey served as Managing Director with CRA | Admired Leadership from 2021 to November 2025, where he advised Fortune 100 and biopharma executives on leadership, strategy, and organizational excellence. Mr. Downey was President, Radiopharmacies division and Senior Vice President (2020-2021), President, HollisterStier Allergy (2014-2017) and Interim President, Cadista (2016) at Jubilant Pharma. Mr. Downey was President and Chief Executive Officer and a member of the Board of Directors at Alfasigma from 2017-2020. From 1997 to 2014, Mr. Downey held various positions, including Vice President and Head of the U.S. Allergy and Cardiovascular Business Unit, with Sanofi, Inc. Mr. Downey holds an M.B.A. from Cornell University and both B.S. and M.S. degrees from Texas A&M University–Kingsville.

Jeffrey S. Ervin has served on our Board since February 2024. Mr. Ervin has served as Chief Financial Officer of Allarity Therapeutics, Inc. (NASDAQ: ALLR), a clinical-stage, precision medicine company actively advancing a pipeline of in-licensed oncology therapeutics, since July 2025. From June 2024 to January 2025, he served in a fractional capacity as co-chief financial officer of DDC Enterprise, Ltd (NYSE: DDC). Prior to DDC, he served as chairman and chief executive officer of IMAC Holdings, Inc. between February 2015 and May 2024. Mr. Ervin was co-founder of IMAC Holdings, Inc. and led an initial public offering in February 2019 (Nasdaq: BACK). Mr. Ervin earned his Master of Business Administration from Vanderbilt University and his Bachelor of Science in Finance from Miami University. We believe that Mr. Ervin's extensive experience in the healthcare industry, as well as his experience as an executive of a public company qualifies him to serve on our Board.

Bryan Lawrence has served on our Board since February 2024. Mr. Lawrence has been an entrepreneur and philanthropist since October 2007. Mr. Lawrence has previously held positions at Xcenda, a division of AmerisourceBergen, Johnson & Johnson Health Care Systems, Janssen Pharmaceutica and Sandoz Pharmaceuticals Corporation. Mr. Lawrence also has experience in healthcare consulting and has held roles at Navigant Consulting and Applied Health Outcome. Mr. Lawrence is currently a member of the University of Kansas School of Pharmacy Advisory Council. He did a two-year Pharmacoeconomics Fellowship from Glaxo Inc. and the University of South Carolina. Mr. Lawrence earned a Doctor of Pharmacy from University of Kansas School of Pharmacy and a Master of Business Administration from the Wharton School at the University of Pennsylvania. We believe that Mr. Lawrence's extensive experience in the life sciences and healthcare industries qualifies him to serve on our Board.

John A. Roberts has served on our Board since February 2024 and has been Chairman of the Board since December 2025. He served as Executive Chairman of the Board from August 2025 through December 2025. Mr. Roberts is currently serving as an Executive Advisor for Life365, a Partner with the international life science venture catalyst firm Ventac Partners since July 2024 and also a Venture Partner for DigiLife Fund II, a position he has held since September 2023. From April 2018 to February 2023, he served as Chief Executive Officer and President of Vyant Bio, Inc., a biotechnology company formerly listed on Nasdaq. Prior to that, Mr. Roberts had been the interim Chief Executive Officer of Vyant Bio, Inc. since February 2018. Mr. Roberts had previously served as Vyant Bio, Inc.'s Chief Operating Officer since July 2016. From July 2015 to June

2016, Mr. Roberts served as the Chief Financial Officer for VirMedica, Inc., a company that provides an end-to-end platform that enables specialty drug manufacturers and pharmacies to optimize product commercialization and management. Prior to VirMedica, from August 2011 to July 2015, Mr. Roberts was the Chief Financial and Administrative Officer for AdvantEdge Healthcare Solutions, a global healthcare analytics and services organization. Prior to that, Mr. Roberts was the Chief Financial Officer and Treasurer for InfoLogix, Inc., a publicly-traded healthcare-centric mobile software and solutions provider. He has also held CFO roles at leading public medical device and healthcare services firms including Clarient, Inc., a publicly-traded provider of diagnostic laboratory services and Daou Systems, Inc., a publicly-traded healthcare IT software development and services firm. In addition, he has held senior executive roles with MEDecision, Inc., HealthOnline, Inc. and the Center for Health Information. Mr. Roberts currently serves on the board of directors of U.S. Pharmacopia, Vyant Bio, Inc., Caidya, Inc., a global, multi-therapeutic clinical research organization, Navipoint Health, Inc., a biotechnology company, and VeriSkin, Inc., a medical device company. He also is a member of the Fellows of the Drug Information Association, a global neutral forum enabling drug developers and regulators access to education and collaboration. Mr. Roberts earned a Bachelor of Science and a master's degree in business administration from the University of Maine. We believe that Mr. Robert's extensive experience in the healthcare industry, as well as his experience as an executive of public companies qualifies him to serve on our Board.

Peter J. Werth has served on our Board since June 2018. Mr. Werth founded ChemWerth Inc., a full-service generic drug development and supply company providing active pharmaceutical ingredients to regulated markets worldwide, in 1982 and served as its President and CEO until June 2024. Mr. Werth continues to serve as Chairman of the Board of ChemWerth Inc. Mr. Werth previously served as Vice President at Ganes Chemicals, a subsidiary of Siegfried Chemicals, from March 1975 through May 1982. From 1965 through 1975, Mr. Werth worked in Research and Development for Upjohn Pharmaceuticals, now Pfizer (NYSE: PFE). In addition to serving on the Board of Cingulate, Mr. Werth has served on the Board of Directors of VM Pharma LLC since December 2010, VM Therapeutics LLC since May 2012, VM Oncology LLC since August 2014, Perseus Science Group LLC since January 2015, Likarda LLC since August 2017, Techtona LLC since September 2017, MedRhythms LLC since June 2018 and Bastion Healthcare LLC since September 2020. He earned his Master of Science in Organic Chemistry from Stanford University and his Bachelor of Science in Chemistry and Math from Fort Hays State University. We believe that Mr. Werth's extensive experience in the life sciences industry and his knowledge in business and international markets qualifies him to serve on our Board.

Jeff Hargroves has served as a member of our Board of Directors since February 2026. He previously served as a member of our Board of Directors from June 2018 to September 2022. In July 2001, Mr. Hargroves founded ProPharma Group, at which he served as a Board Member through its sale in September 2020. He served as President and Chief Executive Officer of ProPharma Group from its inception until May 2018. Previously, he served as the Director of Production at Ivy Animal Health (subsidiary of Elanco) from 1999 through 2001, and prior to that, as a Director of ALZA (subsidiary of Johnson and Johnson) from 1996 through 1999. Mr. Hargroves earned both his Bachelor of Science in Computer Engineering and Bachelor of Science in Electrical Engineering from the University of Missouri. We believe that Mr. Hargroves' experience in product launch and commercialization in the pharmaceutical industry and his extensive knowledge in financial management and corporate development qualifies him to serve on our Board of Directors.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Code of Business Conduct and Ethics

Our Board adopted a Code of Business Conduct and Ethics (the "Code of Conduct") that applies to our employees, officers and directors. A copy of the Code of Conduct is posted on the Corporate Governance section of the Investor Relations page of our website, which is located at www.cingulate.com/investors. We intend to disclose future amendments to certain provisions of the Code of Conduct, or waivers of such provisions applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and our directors, on our website identified above or in future filings with the SEC.

Board Composition

Our Board currently consists of six members. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

In accordance with the terms of our amended and restated certificate of incorporation and bylaws, our Board is divided into three classes, class I, class II and class III, with each class serving staggered three-year terms. Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires. Our directors are divided among the three classes as follows:

- The Class I directors are Peter J. Werth and Jeff Hargroves; their terms will expire at the annual meeting of stockholders to be held in 2028.
- The Class II directors are Jeffrey S. Ervin and John A. Roberts; their terms will expire at the annual meeting of stockholders to be held in 2026.
- The Class III directors are Shane J. Schaffer and Bryan Lawrence; their terms will expire at the annual meeting of stockholders to be held in 2027.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our Board into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the authorized number of directors may be changed only by resolution of our Board. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause, and that any vacancy on our Board, including a vacancy resulting from an enlargement of our Board, may be filled only by vote of a majority of our directors then in office.

We do not have a formal policy with regard to the consideration of diversity in identifying director nominees. The Board evaluates each individual in the context of the Board as a whole, with the objective of assembling a group that can best perpetuate the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

Audit Committee and Audit Committee Financial Expert

Our Audit Committee consists of Messrs. Ervin, Hargroves, Lawrence and Roberts, with Mr. Ervin serving as the Chairman of the Audit Committee. Our Board has determined that the four directors currently serving on our Audit Committee are independent within the meaning of the NASDAQ Marketplace Rules and Rule 10A-3 under the Exchange Act. In addition, our Board has determined that Messrs. Ervin and Roberts qualify as an audit committee financial expert within the meaning of SEC regulations and The NASDAQ Marketplace Rules.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors, executive officers and persons who beneficially own more than 10% of our outstanding common stock to file reports with the SEC regarding their stock ownership and changes in their ownership of our common stock. Based on our records and representations from our directors and executive officers, we believe that all Section 16(a) filing requirements applicable to our directors and executive officers were complied with during fiscal year 2025, except for the following: due to administrative error, Raul Silva filed a late Form 4 on July 1 and November 10, 2025 to report the grant of non-qualified stock options on March 31, and September 30, 2025, respectively, and due the timing of receiving his EDGAR submission codes, Bryan Downey filed a late Form 4 on November 10 to report the grant of non-qualified stock options on November 3, 2025.

Insider Trading Policy

We have adopted an insider trading policy that governs the purchase, sale, and other transactions of our securities by our directors, officers and employees that we believe is reasonably designed to promote compliance with insider trading laws, rules, and regulations, as well as Nasdaq listing standards. A copy of our insider trading policy is filed as Exhibit 19 to this Annual Report. In addition, with regard to the Company’s trading in its own securities, it is our policy to comply with the federal securities laws and the applicable exchange listing requirements.

ITEM 11. EXECUTIVE COMPENSATION

EXECUTIVE COMPENSATION

The following tables and accompanying disclosure set forth information about the compensation earned by our named executive officers during 2025. Our named executive officers include (i) all individuals that served as principal executive officer during 2025, (ii) the two most highly compensated executive officers (other than our principal executive officer) serving as executive officers as of December 31, 2025 and (iii) a former executive officer who would have been one of the two most highly-compensated executive officers (other than our principal executive officer) had they been serving as an executive officer as of December 31, 2025 as set forth below:

- Shane J. Schaffer, Chief Executive Officer;
- Jennifer L. Callahan, Executive Vice President, Chief Financial Officer and Secretary;
- Matthew N. Brams, Executive Vice President and Chief Medical Officer;
- Nilay D. Patel, Executive Vice President, Chief Legal Officer and Chief Compliance Officer;
- Laurie A. Myers, Former Executive Vice President and Chief Operating Officer

SUMMARY COMPENSATION TABLE

The following table sets forth information regarding compensation awarded to, earned by or paid to each of our named executive officers for the years shown.

Name and Principal Position	Year	Salary ($)	Bonus ($)[1]	Option Awards ($)[2]	All Other Compensation ($)	Total ($)
Shane J. Schaffer,	2025	479,527	314,847	1,102,151	0	1,896,525
Chairman and CEO	2024	319,281	251,500	199,546	0	770,327
Jennifer L. Callahan	2025	373,000	246,505	349,412	0	968,917
EVP and CFO	2024	253,981	105,000	87,084	0	446,065
Matthew N. Brams	2025	165,000	41,313	286,180	0	492,493
EVP and CMO						
Nilay D. Patel	2025	230,483[3]	50,000	124,143	0	404,626
EVP, CLO and CCO						
Laurie A. Myers[4]	2025	263,152	0	199,277	145,573[5]	608,002
Former EVP and COO	2024	282,667	84,800	90,715	0	458,182

(1) The bonus amounts represent the bonuses earned by our named executive officers in 2025 and 2024, respectively. For 2025: (i) in October 2025, Dr. Schaffer ($235,152) and Ms. Callahan ($106,505) received a contingent bonus as described below, (ii) in February 2026, Dr. Schaffer ($32,695), Ms. Callahan ($35,000), Mr. Brams ($10,313) and Mr. Patel ($12,500) received a portion of their 2025 bonus in cash and (iii) on March 9, 2026, Dr. Schaffer ($47,000), Ms. Callahan ($105,000), Mr. Brams ($31,000) and Mr. Patel ($37,500) received a portion of their 2025 bonus in shares of our common stock with the number of shares determined by dividing the dollar amount by the closing price of our common stock on the grant date. In January 2025, Dr. Schaffer, Ms. Callahan and Ms. Myers received one-half of their 2024 bonus in cash and one-half as a grant of non-qualified stock options with a grant date fair value equal to the cash bonus.

(2) For 2025, the amounts reflect the grant date fair value of the non-qualified stock option awards on February 18 and July 7, 2025 (Schaffer, Callahan, Brams and Myers) and on July 8, 2025 (Patel), in accordance with FASB ASC Topic 718. The value of the non-qualified stock option awards on January 17, 2025 (Schaffer, Callahan and Myers) is included in the 2024 Bonus column as the grants were made in lieu of a portion of 2024 cash bonus.

For 2024, the amounts reflect the grant date fair value of the non-qualified stock option awards on March 4, 2024 (Schaffer, Callahan and Myers). Dr. Schaffer, Ms. Callahan and Ms. Myers received two stock option grants on March 4, 2024, one of which was contingent on stockholder approval at the June 2024 annual meeting to increase in the shares of common stock available in the Company's equity incentive plan. For accounting purposes, the March 2024 contingent stock option grants used different assumptions to determine the grant date value than the grants that were not contingent on stockholder approval.

The fair market value of the option awards was determined using the Black-Scholes Model. The assumptions used to estimate the grant date fair value for the Company's 2024 and 2025 non-qualified stock options awards, shown on a weighted average basis, were as follows:

	2025	2024
Risk-free interest rate	4.15%	4.24%
Expected term (in years)	5.82	5.43
Expected volatility	1.4	1.5
Expected dividend yield	0%	0%
Grant date fair value	$ 4.04 – 4.22	$ 7.49 - 13.33

(3) Amount represents (i) $184,233 of base salary beginning on July 8, 2025, the date of Mr. Patel's employment, and (ii) $46,250 paid to Mr. Patel as consulting fees prior to his employment with the Company.

(4) Ms. Myers' employment with the Company terminated on August 7, 2025.

(5) Amount represents separation pay pursuant to Ms. Myers' Separation Agreement described below.

Employee Benefit Plans

We currently provide broad-based health and welfare benefits that are available to all of our employees, including our named executive officers, including medical, dental, and vision insurance.

401(k) Plan

We sponsor a 401(k) savings plan (the "401(k) Plan") for all eligible employees. Under the 401(k) Plan, we do not make matching contributions into the 401(k) Plan other than the annual required safe harbor match.

Contingent Bonus Plan

In connection with the reduction in annual base salary for employees, effective December 16, 2023, and to incentivize employees to remain with the Company, the independent members of the Board approved a contingent bonus plan. Pursuant to this plan, on the date that is three months after the filing date of the NDA for CTx-1301 with the FDA (the "payment date") each impacted employee would receive an amount equal to the aggregate dollar amount of base salary that was not paid to the employee due to the salary reductions ("unpaid salary") plus 20% of the unpaid salary amount. The Board reinstated base salaries for employees in September 2024 and we filed the NDA for CTx-1301 on July 31, 2025. The unpaid salary amount for Dr. Schaffer ($195,960) and Ms. Callahan ($88,754) plus 20% was paid in cash on October 31, 2025.

Employment Arrangements with our Named Executive Officers

Shane J. Schaffer

On September 23, 2021, we entered into an employment agreement with Dr. Schaffer. Under the terms of Dr. Schaffer's employment agreement, he holds the position of Chief Executive Officer. The employment agreement originally provided for a base salary of $475,000 annually, which was increased to $503,500, effective January 1, 2023. In connection with cost containment measures, Dr. Schaffer's base salary was reduced to $226,350, effective December 16, 2023. In September 2024, Dr. Schaffer's base salary was reinstated to $503,500 and effective January 1, 2025, Dr. Schaffer's base salary was increased to $523,120. In connection with his administrative leave, Dr. Schaffer's base salary was reduced to $392,340, effective August 14 to December 15, 2025. Effective December 15, 2025, Dr. Schaffer's employment agreement was amended and restated and his base salary was reinstated from the reduced salary he received while on administrative leave.

In addition, Dr. Schaffer is eligible to receive an annual bonus, with a target amount equal to twenty-five percent (25%) of Dr. Schaffer's base salary. The actual amount of each bonus will be determined by the sole discretion of our Compensation Committee and will be based upon both the Company's performance and Dr. Schaffer's individual performance. Pursuant to the terms of his employment agreement, Dr. Schaffer is also eligible to participate in all incentive and deferred compensation programs available to other executives or officers of the Company, and will be eligible to participate in any employee benefit plans and equity plans that we may adopt, which plans may be amended by the Company from time to time in its sole discretion.

We may terminate Dr. Schaffer's employment at any time upon providing written notice to Dr. Schaffer, and Dr. Schaffer may terminate his employment at any time for any reason, including for Good Reason (as that term is defined in Dr. Schaffer's employment agreement).

If Dr. Schaffer's employment is terminated by the Company without cause or by Dr. Schaffer for Good Reason, Dr. Schaffer will be entitled to receive, subject to his signing a general release of claims in favor of the Company and related persons and entities within twenty-one (21) days of the date of termination and following the expiration of seven (7) days thereafter, a severance payment of a lump sum amount in cash equal to one and one (1) times Dr. Schaffer's base salary and annual target bonus, within 60 days following the date of termination. In addition, all stock options and stock appreciation rights held by Dr. Schaffer, which would have vested if he had remained employed for an additional four (4) months following the date of termination, shall become vested and exercisable as of the date of termination for the remainder of their full term. If Dr. Schaffer's employment is terminated by the Company without cause or by Dr. Schaffer for Good Reason within twelve (12) months of a Change of Control, Dr. Schaffer will be entitled to receive, subject to his signing a general release of claims in favor of the Company and related persons and entities within twenty-one (21) days of the date of termination and following the expiration of seven (7) days thereafter, a severance payment of a lump sum amount in cash equal to one and one half (1 ½) times Dr. Schaffer's base salary and annual target bonus, within 60 days following the date of termination; provided however, if any payment or benefits would constitute an "parachute payment" as defined in Section 280(G) of the Internal Revenue Code, the payments will be the greater of (i) the largest amount to ensure that no portion of those payments be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code and (ii) the amount of the full payment, less all taxes, including the excise tax imposed by Section 4999 of the Internal Revenue Code. In addition, all stock options and stock appreciation rights held by Dr. Schaffer shall become vested and exercisable as of the date of termination for the remainder of their full term.

The definition of "cause" in the amended and restated employment agreement was modified (i) to include a determination by a court that Dr. Schaffer has violated the provisions of any court-imposed probation and (ii) to remove the requirement that certain actions by Dr. Schaffer be willful, and the number of directors required to determine whether termination is for cause was reduced from 80% to a majority (excluding Dr. Schaffer).

Jennifer L. Callahan

On January 25, 2024, we entered into an employment agreement with Ms. Callahan. Under the terms of Ms. Callahan's employment agreement, she holds the positions of Executive Vice President and Chief Financial Officer. The employment agreement originally provided for a base salary of $350,000 annually. In connection with cost containment measures, Ms. Callahan's base salary as Chief Financial Officer was reduced to $210,000, effective December 16, 2023. In September 2024, Ms. Callahan's base salary was reinstated to $350,000 and effective January 1, 2025, Ms. Callahan's base salary was increased to $364,000. Effective October 1, 2025, Ms. Callahan's base salary was increased to $400,000. In addition, Ms. Callahan is eligible to receive an annual bonus, with a target amount equal to twenty-five percent (25%) of Ms. Callahan's base salary. The actual amount of each bonus will be determined by the sole discretion of our Compensation Committee and will be based upon both the Company's performance and Ms. Callahan's individual performance, as recommended by the Chief Executive Officer. Pursuant to the terms of her employment agreement, Ms. Callahan is also eligible to participate in all incentive and deferred compensation programs available to other executives or officers of the Company, and will be eligible to participate in any employee benefit plans and equity plans that we may adopt, which plans may be amended by the Company from time to time in its sole discretion.

We may terminate Ms. Callahan's employment at any time upon providing written notice to Ms. Callahan, and Ms. Callahan may terminate her employment at any time for any reason, including for Good Reason (as that term is defined in Ms. Callahan's employment agreement).

If Ms. Callahan's employment is terminated by the Company without cause or by Ms. Callahan for Good Reason, Ms. Callahan will be entitled to receive, subject to her signing a general release of claims in favor of the Company and related persons and entities within twenty-one (21) days of the date of termination and following the expiration of seven (7) days thereafter, a severance payment of a lump sum amount in cash equal to one (1) times Ms. Callahan's base salary and annual target bonus, within 60 days following the date of termination. In addition, all stock options and stock appreciation rights held by Ms. Callahan, which would have vested if she had remained employed for an additional four (4) months following the date of termination, shall become vested and exercisable as of the date of termination for the remainder of their full term. If Ms. Callahan's employment is terminated by the Company without cause or by Ms. Callahan for Good Reason within twelve (12) months of a Change of Control, Ms. Callahan will be entitled to receive, subject to her signing a general release of claims in favor of the Company and related persons and entities within twenty-one (21) days of the date of termination and following the expiration of seven (7) days thereafter, a severance payment of a lump sum amount in cash equal to one (1) times Ms. Callahan's base salary and annual target bonus, within 60 days following the date of termination; provided however, if any payment or benefits would constitute an "parachute payment" as defined in Section 280(G) of the Internal Revenue Code, the payments will be the greater of (i) the largest amount to ensure that no portion of those payments be subject to the excise tax imposed by

Section 4999 of the Internal Revenue Code and (ii) the amount of the full payment, less all taxes, including the excise tax imposed by Section 4999 of the Internal Revenue Code. In addition, all stock options and stock appreciation rights held by Ms. Callahan shall become vested and exercisable as of the date of termination for the remainder of their full term.

Matthew N. Brams

On September 23, 2021, we entered into an employment agreement with Mr. Brams. Under the terms of Mr. Brams's employment agreement, he holds the positions of Executive Vice President and Chief Medical Officer. The employment agreement originally provided for a base salary of $200,000 annually, which was increased to $250,000, effective January 1, 2023. In connection with cost containment measures, Mr. Brams' annual base salary was reduced to $125,000, effective December 16, 2023. Effective January 1, 2024, Mr. Brams' employment agreement was amended (i) to modify Mr. Bram's annual base salary to an amount to allow (a) Mr. Brams to contribute to the 401(k) Plan the maximum amount permitted by the Internal Revenue Service and (b) the Company to withhold the minimum statutory amount to satisfy federal, state and local taxes and (ii) to provide that the Company will grant Mr. Brams 1,000 non-qualified stock options on the last business day of each calendar quarter pursuant to the 2021 Plan. Effective January 1, 2025, Mr. Brams' employment was amended to prove him with an annual base salary of $165,000 and to eliminate the quarterly equity grants. Effective January 1, 2026, we entered into a new employment agreement with Mr. Brams' pursuant to which Mr. Brams' will receive an annual base salary of $400,000 through June 30, 2026. After June 30, 2026, the Company's Chief Executive Officer will determine whether to maintain Mr. Brams as a full-time employee or return Mr. Brams' to a part-time role with a lower salary.

Mr. Brams is eligible to receive an annual bonus, with a target amount equal to twenty-five percent (25%) of Mr. Brams's annual base salary. The actual amount of each bonus will be determined by the sole discretion of our Compensation Committee and will be based upon both the Company's performance and Brams's individual performance, as recommended by the Chief Executive Officer. Pursuant to the terms of his employment agreement, Mr. Brams is also eligible to participate in all incentive and deferred compensation programs available to other executives or officers of the Company, and will be eligible to participate in any employee benefit plans and equity plans that we may adopt, which plans may be amended by the Company from time to time in its sole discretion.

We may terminate Mr. Brams's employment at any time upon providing written notice to Mr. Brams, and Mr. Brams may terminate his employment at any time for any reason, including for Good Reason (as that term is defined in Mr. Brams's employment agreement).

If Mr. Brams's employment is terminated by the Company without cause or by Mr. Brams for Good Reason, Mr. Brams will be entitled to receive, subject to his signing a general release of claims in favor of the Company and related persons and entities within twenty-one (21) days of the date of termination and following the expiration of seven (7) days thereafter, a severance payment in twelve (12) equal monthly payments equal to $165,000, beginning 30 days following the date of termination. In addition, all stock options and stock appreciation rights held by Mr. Brams, which would have vested if he had remained employed for an additional four (4) months following the date of termination, shall become vested and exercisable as of the date of termination for the remainder of their full term. If Mr. Brams's employment is terminated by the Company without cause or by Mr. Brams for Good Reason within twelve (12) months of a Change of Control, Mr. Brams will be entitled to receive, subject to his signing a general release of claims in favor of the Company and related persons and entities within twenty-one (21) days of the date of termination and following the expiration of seven (7) days thereafter, a severance payment of a lump sum amount in cash equal to one (1) times Mr. Brams's base salary, within 60 days following the date of termination; provided however, if any payment or benefits would constitute an "parachute payment" as defined in Section 280(G) of the Internal Revenue Code, the payments will be the greater of (i) the largest amount to ensure that no portion of those payments be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code and (ii) the amount of the full payment, less all taxes, including the excise tax imposed by Section 4999 of the Internal Revenue Code. In addition, all stock options and stock appreciation rights held by Mr. Brams shall become vested and exercisable as of the date of termination for the remainder of their full term.

Nilay D. Patel

On July 8, 2025, we entered into an employment agreement with Mr. Patel. Under the terms of Mr. Patel's employment agreement, he holds the positions of Executive Vice President, Chief Legal Officer and Chief Compliance Officer. Mr. Patel's principal place of employment may be his residence in North Carolina; provided, that he performs his duties from the Company's headquarters in Kansas City on average eight (8) days per month. Provided the Company reimburses Mr. Patel for his relocation expenses, Mr. Patel must relocate to the Kansas City metropolitan area by January 8, 2027 unless otherwise agreed by the Company's Chief Executive Officer. The employment agreement originally provided for a base salary of

$364,000 annually, which was increased to $400,000 upon the FDA's acceptance of the NDA for CTx-1301 on October 1, 2025. In addition, Mr. Patel is eligible to receive an annual bonus, with a target amount equal to twenty-five percent (25%) of Mr. Patel's base salary. The actual amount of each bonus will be determined by the sole discretion of our Compensation Committee and will be based upon both the Company's performance and Mr. Patel's individual performance, as recommended by the Chief Executive Officer. Pursuant to the terms of his employment agreement, Mr. Patel is also eligible to participate in all incentive and deferred compensation programs available to other executives or officers of the Company, and will be eligible to participate in any employee benefit plans and equity plans that we may adopt, which plans may be amended by the Company from time to time in its sole discretion.

We may terminate Mr. Patel's employment at any time upon providing written notice to Mr. Patel, and Mr. Patel may terminate his employment at any time for any reason, including for Good Reason (as that term is defined in Mr. Patel's employment agreement).

If Mr. Patel's employment is terminated by the Company without cause or by Mr. Patel for Good Reason, Mr. Patel will be entitled to receive, subject to his signing a general release of claims in favor of the Company and related persons and entities that becomes irrevocable within twenty-eight (28) days of the date of termination, a severance payment of a lump sum amount in cash equal to one-half (1/2) times (increasing to one (1) times upon Mr. Patel's relocation to the Kansas City metropolitan area or otherwise agreed by the Company's Chief Executive Officer) Mr. Patel's base salary and annual target bonus. In addition, all stock options and stock appreciation rights held by Mr. Patel, which would have vested if he had remained employed for an additional four (4) months following the date of termination, shall become vested and exercisable as of the date of termination for the remainder of their full term. If Mr. Patel's employment is terminated by the Company without cause or by Mr. Patel for Good Reason within twelve (12) months of a Change of Control, Mr. Patel will be entitled to receive, subject to him signing a general release of claims in favor of the Company and related persons and entities within twenty-one (21) days of the date of termination and following the expiration of seven (7) days thereafter, a severance payment of a lump sum amount in cash equal to one (1) times Mr. Patel's base salary and annual target bonus, within 60 days following the date of termination; provided however, if any payment or benefits would constitute an "parachute payment" as defined in Section 280(G) of the Internal Revenue Code, the payments will be the greater of (i) the largest amount to ensure that no portion of those payments be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code and (ii) the amount of the full payment, less all taxes, including the excise tax imposed by Section 4999 of the Internal Revenue Code. In addition, all stock options and stock appreciation rights held by Mr. Patel shall become vested and exercisable as of the date of termination for the remainder of their full term.

Laurie A. Myers

On September 23, 2021, we entered into an employment agreement with Ms. Myers. Under the terms of Ms. Myers' employment agreement, she held the positions of Executive Vice President and Chief Operating Officer. The employment agreement originally provided for a base salary of $400,000 annually, which was increased to $436,720, effective January 1, 2025.

In connection with Ms. Myers' termination of employment on August 7, 2025, we entered into a Separation Agreement and Release of All Claims on August 28, 2025 (the "Separation Agreement"). Pursuant to the Separation Agreement: (i) Ms. Myers is subject to confidentiality, noncompetition and nonsolicitation covenants pursuant to her employment agreement; and (ii) Ms. Myers (a) released claims against the Company and its affiliates, (b) will receive a separation pay of $436,720 payable in semi-monthly installments for twelve (12) months, (c) unvested stock options vested and will be exercisable for their full term, and (d) is subject to certain post-employment restrictive covenants, including non-disparagement obligations.

Outstanding Equity Awards at 2025 Fiscal Year-End

Name	Grant date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date
Shane J. Schaffer	3-4-2024(1)(2)	17,186	5,731	14.16	3-4-2034
	1-17-2025 (3)	27,638	0	4.76	1-17-2035
	2-18-2025 (4)	0	70,489	4.32	2-18-2035
	7-7-2025 (4)	0	199,500	4.42	7-7-2035
Jennifer L. Callahan	3-4-2024(1)(2)	7,499	2,502	14.16	3-4-2034
	1-17-2025 (3)	11,539	0	4.76	1-17-2035
	2-18-2025 (4)	0	21,140	4.32	2-18-2035
	7-7-2025 (4)	0	64,500	4.42	7-7-2035
Matthew N. Brams	3-4-2024(1)(2)	4,999	1,668	14.16	3-4-2034
	3-31-2024 (3)	84	0	13.20	3-31-2034
	6-28-2024 (3)	84	0	3.84	6-28-2034
	9-30-2024 (3)	1,000	0	5.04	9-30-2034
	12-31-2024 (3)	1,000	0	4.93	12-31-2034
	1-17-2025 (3)	2,748	0	4.76	1-17-2035
	2-18-2025 (4)	0	17,630	4.32	2-18-2035
	7-7-2025 (4)	0	52,500	4.42	7-7-2035
Nilay D. Patel	7-8-2025 (4)	0	30,000	4.51	7-8-2035
Laurie A. Myers	3-4-2024(1)(5)	10,418	0	14.16	3-4-2034
	1-17-2025 (5)	9,319	0	4.76	1-17-2035
	2-18-2025 (5)	17,630	0	4.32	2-18-2035
	7-7-2025 (5)	31,000	0	4.42	7-7-2035

(1) Number of shares of our common stock underlying stock options and option exercise price reflects the 1-for-12 reverse stock split of our issued and outstanding common stock, which became effective on August 9, 2024.

(2) The option vests as follows: 50% on the six-month anniversary of the date of grant and the remaining shares in substantially equal monthly installments over the 30-month period following the initial vesting date.

(3) The option vested immediately on the grant date.

(4) The option vests as follows: 25% on the one-year anniversary of the date of grant and the remaining shares in substantially equal monthly installments over the 36-month period following the initial vesting date.

(5) The option vested upon Ms. Myers termination of employment pursuant to her separation agreement.

Stock Option Grant Practices

The Compensation Committee approves and grants annual equity awards at approximately the same time every year. Annual stock option grants for employees are generally made in mid to late February or early March and annual stock option grants for non-employee directors are generally made on the date of the annual meeting of stockholders. Outside of the annual grant cycle, the employment agreement of certain executive officers has provided for stock option grants on the last business day of each calendar quarter in lieu of base salary and the Compensation Committee has provided Dr. Schaffer with authority to make stock option grants within certain limits to non-Section 16 officers on the last business day of a calendar quarter.

All stock options are granted at an exercise price at or above the closing market price of our common stock on the date of grant. Stock options are not granted in anticipation of the release of material non-public information, and the release of material non-public information is not timed on the basis of stock option grant dates.

During fiscal year 2025, we did not grant stock options to any named executive officer during any period beginning four business days before and ending one business day after the filing of any periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of any Form 8-K that disclosed any material non-public information.

Director Compensation

The following table sets forth information regarding compensation awarded to, earned by or paid to each of the non-employee members of our Board for their service as a director during 2025 other than for reimbursement of reasonable expenses incurred in attending meetings of our Board and committees of our Board.

2025 Director Compensation Table

Name	Fees earned or paid in cash ($)(1)	Option awards ($)(2)	Total ($)
Jeff Ervin	62,083	55,905	117,988
Bryan Lawrence	60,250	55,905	116,155
John Roberts	82,761	55,905	138,666
Peter Werth	38,750	55,905	94,655

(1) Amounts reflect Board fees earned by each director during 2025. For Mr. Roberts, the amount includes $40,484 in fees received during his service as Executive Chairman of the Board form August 2025 to December 2025.

(2) The amounts reflect the aggregate grant date fair value of the non-qualified stock options awarded on June 20, 2025 to the non-employee directors in accordance with FASB ASC Topic 718. The fair market value of the option awards was determined using the Black-Scholes Model. The assumptions used to estimate the grant date fair value for the Company's 2025 non-qualified stock options awards, shown on a weighted average basis, were as follows:

	June 2025
Risk-free interest rate:	4.15%
Expected term (in years):	5.82
Expected volatility:	1.4
Expected dividend yield	0%
Grant date fair value:	$ 3.73

As of December 31, 2025: Mr. Ervin held 17,825 stock options, of which 2,825 had vested; Mr. Lawrence held 17,846 stock options, of which 2,846 had vested; Mr. Roberts held 17,898 stock options, of which 2,898 had vested; and Mr. Werth held 16,703 stock options, of which 1,703 had vested.

Director Compensation Program

Our Compensation Committee and Board approved a director compensation program for our non-employee directors in June 2025, which was modified in December with Mr. Robert's appointment as Chairman of the Board. This program provides for the following annual cash compensation:

- Director Retainer - $40,000
- Chairman of the Board Retainer - $75,000
- Committee Chair Retainer:
    - Audit - $15,000
    - Compensation - $10,000
    - Nominating and Corporate Governance - $8,000
- Committee Member Retainer:
    - Audit - $7,500
    - Compensation - $5,000
    - Nominating and Corporate Governance - $4,000
- Equity Awards:
    - 15,000 stock options for each continuing non-employee director
    - 15,000 stock options for each new non-employee director appointed during the year

Annual equity awards shall be granted on the date the awards are approved by the Board and shall vest on the earlier of the first anniversary of the grant date and the date of the 2026 annual meeting of stockholders.

Cash retainers shall be paid quarterly in arrears and shall be pro-rated based on the number of whole or partial months served during a calendar year; provided, that the Board may decide to grant equity awards to non-employee directors in lieu of paying cash retainers depending on the cash needs of the Company.

The Lead Independent Director and/or the Chairman of the Compensation Committee may determine to pay meeting fees for one or more meetings to the extent the number of Board or committee meetings exceeds the typical number of meetings during the year.

Dr. Schaffer, our Chief Executive Officer, served as Chairman of our Board until December 2025 but does not receive additional compensation for his service as a director. See the Summary Compensation Table for a description of Dr. Schaffer's 2025 compensation.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Equity Compensation Plans

In September 2021, our board of directors and stockholders adopted the 2021 Omnibus Equity Incentive Plan (the "Equity Plan"), which provides for the grant of non-qualified stock options to purchase shares of our common stock and other types of awards. At our 2024 and 2025 annual meetings, stockholders approved an amendment to the Equity Plan to increase the number of shares of common stock authorized for issuance. The general purpose of the Equity Plan is to provide a means whereby eligible employees, officers, non-employee directors and consultants develop a sense of proprietorship and personal involvement in our development and financial success, and to encourage them to devote their best efforts to our business, thereby advancing our interests and the interests of our stockholders.

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

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column a) (c)[2]
Equity compensation plans approved by security holders [1]	956,017	$ 5.36	185,831
Equity compensation plans not approved by security holders[3]	60,000	$ 3.78	—
Total	1,016,017	$ 5.27	185,831

(1) The amounts shown in this row include securities under the Equity Plan.

(2) In accordance with the "evergreen" provision in our Equity Plan, an additional 216,250 shares of our common stock were automatically made available for issuance on the first day of 2025, which represents 5% of the number of fully-diluted shares outstanding on December 31, 2025 (rounded to the nearest 1,000 share increment). These shares are excluded from the shares disclosed in the table.

(3) Amounts shown in this row represent inducement awards made in accordance with Nasdaq Listing Rule 5635(c)(4).

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information about the beneficial ownership of our common stock as of March 13, 2026 (unless otherwise noted) by:

- each person or group known to us who beneficially owns more than 5% of our common stock;
- each of our directors;

- each of our Named Executive Officers; and
- all of our directors and current executive officers as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. Under these rules, beneficial ownership includes any shares of common stock as to which the individual or entity has sole or shared voting power or investment power. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options or warrants held by such person that are currently exercisable or will become exercisable within 60 days of March 13, 2026 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Name of Beneficial Owner (1)	Number of Shares Beneficially Owned	Percent of Class (2)
5% Beneficial Owners		
Falcon Creek Capital Advisors LLC	1,951,946(3)	16.79%
Named Executive Officers and Directors		
Shane J. Schaffer, Pharm.D.	140,026(4)	1.19%
Jennifer L. Callahan	58,898(5)	*
Matthew N. Brams	39,082(6)	*
Nilay D. Patel	3.389(7)	*
Laurie A. Myers	68,637(8)	*
Jeff S. Ervin	2,825(9)	*
Bryan Lawrence	2,846(10)	*
John. A. Roberts	2,898(11)	*
Peter J. Werth	119,279(12)	1.03%
Jeff Hargroves	97,503(13)	*
All Directors and Executive Officers as a group (11 persons)	517,983(14)	4.36%

* Denotes less than 1%.

(1) Unless noted otherwise, the address of all listed stockholder is 1901 W. 47th Place, Kansas City, KS 66205. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

(2) We have determined beneficial ownership in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended, which is generally determined by voting power and/or dispositive power with respect to securities. Percentage ownership is based on 11,628,613 shares of common stock issued and outstanding as of March 13, 2026, plus any shares issuable upon exercise of options or warrants that are exercisable within 60 days of March 13, 2026 held by such person.

(3) Represents shares of our common stock beneficially owned by Falcon Creek Capital Advisor LLC ("Falcon Creek"), as advisor for Falcon Creek Technology Fund I, LP and Ginkgo Capital Global Fund SPC – Xtalpi AI Fund SP, who purchased our equity securities in the Private Placement. Falcon Creek filed a Schedule 13D on February 9, 2026 that indicated that it does not have sole voting power or sole dispositive power over the shares but does have shared voting power and shared dispositve power over the shares. The Schedule 13D lists Falcon Creek's address as 21 Strathmore Road, Natick, MA 01760. This table does not include 954 shares of preferred stock or 1,712,062 Warrant Shares purchased in the Private Placement, as the preferred stock will not convert and the Warrant is not exercisable until stockholders approve the Issuance Proposal.

(4) Includes (i) 295 shares of our common stock issuable upon exercise of warrants that are currently exercisable, (ii) 125,480 shares of our common stock issuable upon the exercise of stock options that are exercisable within 60 days of March 13, 2026, and (iii) 10,175 shares of our common stock held by Fountainhead Shrugged, LLC. Dr. Schaffer is the manager of Fountainhead Shrugged, LLC and has voting and investment power over the securities held by Fountainhead Shrugged, LLC. Does not include (i) 195,064 shares of our common stock issuable upon the exercise of stock options that are not exercisable within 60 days of March 13, 2026 or (ii) 5,447 Warrant Shares purchased by Fountainhead Shrugged, LLC in the Private Placement.

(5) Includes (i) 88 shares of our common stock issuable upon exercise of warrants that are currently exercisable and (ii) 44,849 shares of our common stock issuable upon the exercise of stock options that are exercisable within 60 days of March 13, 2026. Does not include (i) 62,331 shares of our common stock issuable upon the exercise of stock options that are not exercisable within 60 days of March 13, 2026 or (ii) 3,891 Warrant Shares purchased by Ms. Callahan in the Private Placement.

(6) Includes 30,925 shares of our common stock issuable upon the exercise of stock options that are exercisable within 60 days of March 13, 2026. Does not include (i) 50,788 shares of our common stock issuable upon the exercise of stock options that are not exercisable within 60 days of March 13, 2026 or (ii) 1,556 Warrant Shares purchased by Mr. Brams in the Private Placement.

(7) Does not include 30,000 shares of our common stock issuable upon the exercise of stock options that are not exercisable within 60 days of March 13, 2026.

(8) The employment of Ms. Myers was terminated on August 7, 2025. Amount represents shares of our common stock issuable upon exercise of stock options that are currently vested.

(9) Includes 2,825 shares of our common stock issuable upon exercise of stock options that are currently exercisable. Does not include 15,000 shares of our common stock issuable upon the exercise of stock options that are not exercisable within 60 days of March 13, 2026.

(10) Includes 2,846 shares of our common stock issuable upon exercise of stock options that are currently exercisable. Does not include 15,000 shares of our common stock issuable upon the exercise of stock options that are not exercisable within 60 days of March 13, 2026.

(11) Includes 2,898 shares of our common stock issuable upon exercise of stock options that are currently exercisable. Does not include 15,000 shares of our common stock issuable upon the exercise of stock options that are not exercisable within 60 days of March 13, 2026.

(12) Includes (i) 35 shares of our common stock issuable upon exercise of warrants that are currently exercisable, (ii) 1,703 shares of our common stock issuable upon the exercise of stock options that are exercisable within 60 days of March 13, 2026, and (iii) 117,449 shares of our common stock held by Werth Family Investment Associates LLC ("WFIA"). Mr. Werth is the manager of WFIA and has voting and investment power over the securities held by WFIA. Does not include (i) 15,000 shares of our common stock issuable upon the exercise of stock options that are not exercisable within 60 days of March 13, 2026 or (ii) 15,564 Warrant Shares purchased by WFIA in the Private Placement.

(13) Includes (i) 35 shares of our common stock issuable upon exercise of warrants that are currently exercisable and (ii) 97,468 shares of our common stock held by Hargroves Family Investments, LLC ("HFI"). Mr. Hargroves is the manager of HFI and has voting and investment power over the securities held by HFI. Does not include (i) 15,000 shares of our common stock issuable upon the exercise of stock options that are not exercisable within 60 days of March 13, 2026 or (ii) 77,821 Warrant Shares purchased by HFI in the Private Placement.

(14) Includes (i) 453 shares of our common stock issuable upon exercise of warrants that are currently exercisable and (ii) 258,118 shares of our common stock issuable upon exercise of stock options that are currently exercisable. Does not include (i) 493,263 shares of our common stock issuable upon the exercise of stock options that are not exercisable within 60 days of March 13, 2026 or (ii) 104,279 Warrant Shares purchased in the Private Placement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The following is a description of transactions since January 1, 2024 to which we have been a participant in which the amount involved exceeded or will exceed the lesser of (i) $120,000 and (ii) one percent of the average of our total assets at year-end for the last two completed fiscal years in which any of our directors, executive officers or holders of more than 5% of our voting securities, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements.

WFIA Note

On August 9, 2022, CTx issued a $5.0 million promissory note to WFIA. Peter Werth, a member of our Board is manager of WFIA. The note was unsecured with interest accruing at 15% per annum. Outstanding principal and all accrued and unpaid interest were due and payable on August 8, 2025. CTx was permitted to prepay the note, in whole or in part, without premium or penalty; provided, that no amount repaid was permitted to be reborrowed.

On May 9, 2023, CTx amended and restated the promissory note in favor of WFIA that increased the principal amount of the original note from $5.0 million to $8.0 million.

On September 8, 2023, we entered into a note conversion agreement with WFIA, pursuant to which WFIA agreed to convert the original principal amount of $5.0 million plus all accrued interest on the original principal under the note payable to WFIA into pre-funded warrants to purchase 341,912 shares of our common stock at a conversion price per pre-funded warrant of $17.00. The pre-funded warrants had no expiration date and were exercisable immediately at an exercise price of $0.002 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Exchange Act, no more than 19.99% of the outstanding shares of our common stock.

On January 25, 2024, we entered into a note conversion agreement and converted the remaining $3.0 million of principal plus all accrued interest under the note payable to WFIA into pre-funded warrants to purchase 687,043 shares of common stock at a conversion price per pre-funded warrant of $4.785. The closing price of our common stock on January 24, 2024 was $4.35. The pre-funded warrants had no expiration date and were exercisable immediately at an exercise price of $0.0001 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Exchange Act, no more than 19.99% of the outstanding shares of our common stock. In March of 2024, we issued to WFIA an additional pre-funded warrant to purchase 7,053 shares of common stock as a result of an error in the interest calculation, on the same form and at the same conversion price as the January pre-funded warrants. WFIA exercised all of its pre-funded warrants in April 2024.

Private Placement

On January 27, 2026, we entered into a securities purchase agreement with several purchasers, including a lead investor and certain of our officers, directors and other affiliates, for the private placement of: (i) 2,147,472 shares of our common stock, (ii) 954 shares of Series A convertible preferred stock with a stated value of $1,000 and a conversion price equal to a $5.04 per share of common stock and (iii) a warrant to purchase 1,869,415 shares of common stock (the "Warrant Shares") for aggregate gross proceeds of approximately $12.0 million, at a price per share of $5.14 per share of common stock (including $0.10 per Warrant Share). The Warrant Shares have an exercise price of $5.04 per share of common stock, subject to adjustment as provided in the warrant.

The closing of the private placement occurred on February 6 and 13, 2026. At a special meeting of stockholders scheduled for March 24, 2026, stockholders are being asked to approve the issuance of common stock upon conversion of the preferred Stock and the exercise of the warrant. Upon stockholder approval (i) each outstanding share of the preferred stock, without any further action by us or the holder, will automatically convert into shares of common stock determined by dividing the $1,000 stated value plus all unpaid accrued and accumulated preferential dividends on such share by the $5.04 conversion price and (ii) the warrant will be exercisable.

The following officers, directors and other affiliates participated, directly or indirectly, in the private placement that closed on February 6, 2026 and purchased the number of shares of our common stock and Warrant Shares set forth after their name: Shane J. Schaffer (6,809 common shares and 5,447 Warrant Shares); Jennifer L. Callahan (4,864 common shares and 3,891 Warrant Shares); Matthew N. Brams (1,946 common shares and 1,556 Warrant Shares; Peter J. Werth (19,455 common shares and 15,564 Warrant Shares); Larry Schaffer, the father of Shane Schaffer (58,366 common shares and 46,693 Warrant Shares).

Indemnification of Officers and Directors

We have entered into indemnification agreements with each of our directors and executive officers. These agreements require us to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

Policies and Procedures for Related Party Transactions

We adopted policies and procedures for related party transactions that prohibit our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock, any members of the immediate family of any of the foregoing persons and any firms, corporations or other entities in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest, or related parties, from entering into a transaction with us without the prior consent of our Board acting through the Audit Committee or, in certain circumstances, the chairman of the Audit Committee. Any request for us to enter into a transaction with a related party, in which the amount involved will, or may be expected to, exceed $100,000 and such related party would have a direct or indirect interest must first be presented to our Audit Committee, or in certain circumstances the chairman of our Audit Committee, for review, consideration and approval. In approving or rejecting any such proposal, our Audit Committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, the extent of the benefits to us, the availability of other sources of comparable products or services and the extent of the related person’s interest in the transaction.

Director Independence

Pursuant to the rules of Nasdaq, a director will only qualify as an “independent director” if, in the opinion of that company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our Board has determined that Jeff Ervin, Jeff Hargroves, Bryan Lawrence and John Roberts are “independent directors” as such term is defined by Nasdaq Marketplace Rule 5605(a)(2). Due to the promissory note issued by CTx in favor of WFIA, of which Mr. Werth is manager, which was last converted into shares of our common stock in January 2024, our Board determined that Mr. Werth is not an independent director. In addition, Shane Schaffer is not an independent director due to his position as Chief Executive Officer of the Company. We have established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee, each of which are comprised of independent directors.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Principal Accountant Fees and Services

Our independent registered public accounting firm is KPMG LLP, Kansas City, MO, Auditor Firm ID: 185. The following table summarizes the fees billed by KPMG for audit and other services provided to the Company for the fiscal years ended December 31, 2025 and 2024:

	2025	2024
Audit Fees (1)	$ 502,614	$ 440,000
Audit-Related Fees	—	—
Tax Fees (2)	44,000	35,000
All Other Fees	—	—
Total	$ 546,614	$ 475,000

(1) Audit fees consist of fees for our quarterly reviews and audits of our financial statements, and fees relating to registration statement reviews, consents and comfort letters.

(2) Tax fees consist of fees for tax compliance services, including preparation and review of tax returns and general tax consulting services.

Pre-Approval Policy

The Audit Committee or its Chairman pre-approves audit and non-audit services to be rendered to the Company and establishes a dollar limit on the amount of fees the Company will pay for each category of services. Generally, management will submit to the Audit Committee a list of services that it recommends the Audit Committee engage the independent registered public accounting firm to provide for the fiscal year. The Audit Committee is informed from time to time of the non-audit services provided pursuant to the pre-approval process. During the year, the Audit Committee periodically reviews the types of services and dollar amounts approved and adjusts such amounts, as it deems appropriate. Unless a service to be provided by the independent registered public accounting firm has received general pre-approval, it will require specific pre-approval by the Audit Committee or its Chairman. Any service pre-approved by the Chairman will be presented to the Audit Committee at its next regularly scheduled meeting. The Audit Committee also periodically reviews all non-audit services to ensure such services do not impair the independence of the Company's independent registered public accounting firm. All services rendered by KPMG LLP in our fiscal years ended December 31, 2025 and 2024 were pre-approved by our Audit Committee.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

See the Index to Financial Statements on page F-2 for a list of all financial statements filed as part of this annual report.

(a)(2) Financial Statement Schedules

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

(b) Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Exhibit	Filing Date
2.1†	Agreement and Plan of Merger, dated August 30, 2021, among Cingulate, Inc., Cingulate Therapeutics LLC, and Cingulate Pharma LLC	S-1	2.1	9/9/2021
3.1	Amended and Restated Certificate of Incorporation of Cingulate Inc., as amended to date	10-Q	3.1	8/13/2024
3.2	Amended and Restated Bylaws of Cingulate Inc.	10-K	3.2	3/28/2022
3.3	Form of Certificate of Designation of the Company's Series A Convertible Stock, dated January 27, 2026	8-K	3.1	1/28/2026
4.1	Specimen Certificate representing shares of common stock of Cingulate Inc.	S-1	4.1	9/9/2021
4.2	Form of Underwriter Common Stock Purchase Warrant	S-1	4.2	11/10/2021
4.3	Form of Common Stock Purchase Warrant	S-1	4.3	12/9/2021
4.4	Form of Warrant Agent Agreement	S-1	4.4	12/9/2021
4.5*	Description of Cingulate Inc. Securities			
4.6	Form of September 2023 Series A Warrant	S-1/A	4.6	8/29/2023
4.7	Form of September 2023 Series B Warrant	S-1/A	4.7	8/29/2023
4.8	Form of September 2023 Placement Agent Warrant	S-1/A	4.8	8/29/2023
4.9	Form of September 2023 WFIA Pre-Funded Warrant	8-K	4.1	9/11/2023
4.10	Form of January 2024 WFIA Pre-Funded Warrant	8-K	4.1	1/29/2024
4.11	Form of February 2024 Series A Warrant	8-K	4.2	2/7/2024
4.12	Form of February 2024 Series B Warrant	8-K	4.3	2/7/2024
4.13	Form of February 2024 Placement Agent Warrant	8-K	4.4	2/7/2024
4.14	Form of March 2024 WFIA Pre-Funded Warrant	10-K	4.16	4/1/2024
4.15	Form of July 2024 Series C/D Warrant	8-K	4.1	7/1/2024
4.16	Form of July 2024 Placement Agent Warrant	8-K	4.1	7/1/2024
4.17†	Form of January 2026 Warrant	8-K	4.1	1/28/2026
4.18	Promissory Note issued to Streeterville Capital, LLC, dated December 20, 2024	8-K	4.1	12/23/2024
4.19	Promissory Note issued to Avondale Capital, LLC, dated November 7, 2025	8-K	4.1	11/10/2025
10.1#	Patent and Know-How License Agreement, dated August 8, 2018, between BDD Pharma Limited, Cingulate Therapeutics LLC and Drug Delivery International Limited	S-1	10.2	9/9/2021
10.2#	Master Services Agreement between Cingulate Therapeutics LLC and Societal CDMO, Inc., dated October 24, 2022	8-K	10.1	10/25/2022
10.3	Amendment No. 1 to Master Services Agreement, effective February 12, 2025, between Cingulate Therapeutics LLC and Societal CDMO, Inc. (DBA Bend Bioscience)	10-K	10.2	3/27/2025
10.4+	Amended and Restated Employment Agreement, dated December 15, 2025, between Cingulate Therapeutics LLC and Shane J. Schaffer	8-K	10.1	12/15/2025

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Exhibit	Filing Date
10.5+	Employment Agreement, dated September 23, 2021, between Cingulate Therapeutics LLC and Matthew N. Brams	S-1	10.5	9/27/2021
10.6+	Amendment to Employment Agreement, effective January 1, 2025, between Cingulate Therapeutics LLC and Matthew N. Brams	8-K	10.1	1/24/2025
10.7*+	Employment Agreement, effective January 1, 2026, between Cingulate Therapeutics LLC and Matthew N. Brams			
10.8+	Employment Agreement, dated September 23, 2021, between Cingulate Therapeutics LLC and Laurie A. Myers	S-1	10.6	9/27/2021
10.9*+	Separation Agreement and Release of All Claims, effective August 7, 2025, between Cingulate Therapeutics LLC and Laurie A. Myers			
10.10+	Employment Agreement, dated September 23, 2021, between Cingulate Therapeutics LLC and Raul R. Silva	S-1	10.9	9/27/2021
10.11+	Amendment to Employment Agreement, effective January 1, 2023, between Cingulate Therapeutics LLC and Raul R. Silva	10-K	10.10	3/10/2023
10.12+	Amendment to Employment Agreement, effective July 7, 2025, between Cingulate Therapeutics, LLC and Raul A. Silva	S-1	10.11	7/22/2025
10.13*+	Employment Agreement, effective January 1, 2026, between Cingulate Therapeutics LLC and Raul R. Silva			
10.14+	Employment Agreement, dated January 25, 2024, between Cingulate Therapeutics LLC, and Jennifer L. Callahan	8-K	10.2	1/29/2024
10.15+	Employment Agreement, effective July 8, 2025, between Cingulate Therapeutics LLC and Nilay D. Patel	10-Q	10.3	8/19/2025
10.16*+	Employment Agreement, effective October 13, 2025, between Cingulate Therapeutics LLC and Bryan Downey			
10.17+	Form of Indemnification Agreement	S-1	10.10	9/9/2021
10.18+	Cingulate Inc. 2021 Omnibus Equity Incentive Plan	S-1	10.1	9/27/2021
10.19+	Amendment No. 1 to the Cingulate Inc. 2021 Omnibus Equity Incentive Plan	10-Q	10.1	8/13/2024
10.20+	Amendment No. 2 to the Cingulate Inc. 2021 Omnibus Equity Incentive Plan	8-K	10.1	6/11/2025
10.21+	Form of Nonqualified Stock Option Award under 2021 Plan	10-Q	10.1	5/12/2022
10.22+	Form of Incentive Stock Option Award under 2021 Plan	10-Q	10.2	5/12/2022
10.23+	Form of Restricted Stock Unit Award under 2021 Plan	S-1	10.20	9/27/2021
10.24+	Form of Restricted Stock Award under 2021 Plan	S-1	10.21	9/27/2021
10.25	At The Market Offering Agreement, dated January 3, 2023, by and between Cingulate Inc. and H.C. Wainwright & Co., LLC	S-3	1.2	1/3/2023
10.26	Amendment to ATM Agreement, dated May 2, 2023, by and between Cingulate Inc. and H.C. Wainwright & Co., LLC	10-Q	10.5	5/10/2023
10.27	Master Services Agreement, effective May 7, 2025, by and between Cingulate Therapeutics, LLC and Indegene, Inc.	10-Q	10.4	5/8/2025
10.28	Purchase Agreement, dated April 24, 2023, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	10.1	4/25/2023
10.29	Purchase Agreement, dated July 21, 2025, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	10.1	7/22/2025
10.30	Registration Rights Agreement, dated July 21, 2025, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	10.2	7/22/2025
10.31	Amended and Restated Promissory Note, dated May 9, 2023, between Cingulate Therapeutics, LLC and Werth Family Investment Associates LLC	8-K	10.1	5/10/2023
10.32	Securities Purchase Agreement, dated August 11, 2023, by and between the Company and Werth Family Investment Associates LLC	8-K	10.1	8/14/2023
10.33	Form of September 2023 Securities Purchase Agreement	S-1/A	10.1	8/29/2023
10.34	Note Conversion Agreement, dated September 8, 2023, by and between the Company, Cingulate Therapeutics, LLC and Werth Family Investment Associates LLC	8-K	10.1	9/11/2023

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Exhibit	Filing Date
10.35	Note Conversion Agreement, dated January 25, 2024, by and between the Company, Cingulate Therapeutics, LLC and Werth Family Investment Associates LLC	8-K	10.1	1/29/2024
10.36	Form of February 2024 Securities Purchase Agreement	8-K	10.1	2/7/2024
10.37	Form of Inducement Letter, dated June 28, 2024	8-K	10.1	7/1/2024
10.38	Securities Purchase Agreement between Cingulate Inc. and Streeterville Capital, LLC, dated December 20, 2024	8-K	10.1	12/23/2024
10.39	Note Purchase Agreement between Cingulate Inc. and Avondale Capital, LLC, dated November 7, 2025	8-K	10.1	11/10/2025
10.40	Guaranty by Cingulate Therapeutics LLC and Cingulate Works, Inc., dated November 7, 2025	8-K	10.2	11/10/2025
10.41†	Form of Securities Purchase Agreement, dated as of January 27, 2026, by and among the Company and the Purchasers	8-K	10.1	1/28/2026
19	Cingulate Inc. Statement of Company Policy on Insider Trading and Policy Regarding Special Trading Procedures	10-K	19	3/27/2025
21.1	List of Subsidiaries of Cingulate Inc.	10-K	21.1	4/1/2024
23.1*	Consent of Independent Registered Public Accounting Firm			
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
32.2**	Certification of 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	Cingulate Inc. Compensation Recovery Policy	10-K	97.1	4/1/2024
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH*	Inline XBRL Taxonomy Extension Schema			
101.CAL*	Inline XBRL Extension Calculation Linkbase			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase			
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase			
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase			
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)			

† Annexes, schedules and/or exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally a copy of any of the omitted schedules and exhibits to the SEC on a confidential basis upon request.

* Filed Herewith

** Furnished Herewith

+ Indicates a management contract or compensatory plan

Certain portions of this exhibit have been omitted because (i) the registrant customarily and actually treats that information as private or confidential and (ii) the omitted information is not material.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

CINGULATE INC.

Date: March 18, 2026

By: */s/ Shane J. Schaffer*
Shane J. Schaffer
Chief Executive Officer
(Principal Executive Officer)

Date: March 18, 2026

By: */s/ Jennifer L. Callahan*
Jennifer L. Callahan
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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

Signature	Title	Date
/s/ Shane J. Schaffer Shane J. Schaffer	Chief Executive Officer (Principal Executive Officer)	March 18, 2026
/s/ Jennifer L. Callahan Jennifer L. Callahan	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 18, 2026
/s/ Jeffrey S. Ervin Jeffrey S. Ervin	Director	March 18, 2026
/s/ Jeff Hargroves Jeff Hargroves	Director	March 18, 2026
/s/ Bryan Lawrence Bryan Lawrence	Director	March 18, 2026
/s/ John A. Roberts John A. Roberts	Director	March 18, 2026
/s/ Peter J. Werth Peter J. Werth	Director	March 18, 2026

KPMG LLP
Suite 1100
1000 Walnut Street
Kansas City, MO 64106-2162

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Cingulate Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cingulate Inc. and subsidiaries (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated 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 the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

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

Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

KPMG LLP

We have served as the Company's auditor since 2020.

Kansas City, Missouri
March 18, 2026

Cingulate Inc.
Consolidated Balance Sheets
December 31, 2025 and 2024

	2025	2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,953,383	$ 12,211,321
Miscellaneous receivables	8,013	26,325
Prepaid expenses and other current assets	1,046,862	423,157
Total current assets	12,008,258	12,660,803
Property and equipment, net	1,725,919	2,104,675
Operating lease right-of-use assets	1,339,086	99,011
Total assets	**15,073,263**	**14,864,489**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	2,035,685	1,270,280
Accrued expenses	1,742,116	1,039,625
Notes payable, current	6,295,960	2,527,108
Finance lease liability, current	-	4,430
Operating lease liability, current	238,864	130,662
Total current liabilities	10,312,625	4,972,105
Long-term liabilities:		
Note payable	1,151,509	2,436,879
Operating lease liability, net of current	1,100,222	-
Total long-term liabilities	2,251,731	2,436,879
Total liabilities	**12,564,356**	**7,408,984**
Stockholders' Equity		
Common Stock, $0.0001 par value; 240,000,000 shares authorized and 7,250,299 and 3,402,306 shares issued and outstanding as of December 31, 2025 and 2024	725	340
Preferred Stock, $0.0001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of December 31, 2025 and 2024	-	-
Additional Paid-in-Capital	134,883,213	117,380,285
Accumulated deficit	(132,375,031)	(109,925,120)
Total stockholders' equity	**2,508,907**	**7,455,505**
Total liabilities and stockholders' equity	**$ 15,073,263**	**$ 14,864,489**

See notes to consolidated financial statements.

Cingulate Inc.
Consolidated Statements of Operations and Comprehensive Loss
Years Ended December 31, 2025 and 2024

	2025	2024
Operating expenses:		
Research and development	$ 9,774,057	$ 9,445,265
General and administrative	10,164,051	6,199,708
Operating loss	**(19,938,108)**	**(15,644,973)**
Issuance cost and change in fair value of derivative	(1,150,673)	(1,013,868)
Interest and other income (expense), net	(1,361,130)	99,236
Loss before income taxes	(22,449,911)	(16,559,605)
Income tax benefit (expense)	-	-
Net loss and comprehensive loss	**$ (22,449,911)**	**$ (16,559,605)**
Net loss per share of common stock, basic and diluted	$ (4.44)	$ (10.86)
Weighted average number of shares used in computing net loss per share of common stock, basic and diluted	5,055,329	1,524,797

See notes to consolidated financial statements.

Cingulate Inc.
Consolidated Statements of Stockholders' Equity
Years Ended December 31, 2025 and 2024

	Common Stock		Additional Paid-in-	Accumulated	Accumulated Other Comprehensive	Stockholders'
	Shares	Amount	Capital	Deficit	Income	Equity
Balance January 1, 2024	**97,293**	**10**	**$ 86,496,076**	**$ (93,365,515)**	**$ -**	**$ (6,869,429)**
Share adjustment due to fractional rounding of August 2024 reverse split	130,602	13	(13)	-	-	-
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	2,455,456	245	17,240,466	-	-	17,240,711
Change in fair value of derivative	-	-	1,013,868	-	-	1,013,868
Warrant inducement	265,625	27	1,561,400	-	-	1,561,427
Issuance of common stock in public offering, net of fees	296,000	30	6,432,862	-	-	6,432,892
Issuance of pre-funded warrants in connection with the conversion of related party note payable	-	-	2,734,739	-	-	2,734,739
Capital contribution in connection with conversion of related party note payable	-	-	586,511	-	-	586,511
Issuance of common stock upon exercise of pre-funded warrants	102,832	10	(10)	-	-	-
Issuance of restricted common stock	54,498	5	318,916	-	-	318,921
Stock-based compensation expense	-	-	995,470	-	-	995,470
Net loss	-	-	-	(16,559,605)	-	(16,559,605)
Balance December 31, 2024	3,402,306	340	$117,380,285	$(109,925,120)	$ -	$ 7,455,505
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	2,536,147	254	10,153,558	-	-	10,153,812
Issuance cost and change in fair value of derivative	120,424	12	1,150,661	-	-	1,150,673
Issuance of common stock in public offering, net of fees		-		-	-	-
Issuance of restricted common stock	24,122	2	96,667	-	-	96,669
Issuance of common stock in connection with Promissory Note exchange agreements	1,167,300	117	4,674,883	-	-	4,675,000
Stock-based compensation expense	-	-	1,427,159	-	-	1,427,159
Net loss	-	-	-	(22,449,911)	-	(22,449,911)
Balance December 31, 2025	**7,250,299**	**$ 725**	**$134,883,213**	**$(132,375,031)**	**$ -**	**$ 2,508,907**

See notes to consolidated financial statements.

Cingulate Inc.
Consolidated Statements of Cash Flows
Years Ended December 31, 2025 and 2024

	2025	2024
Operating activities:		
Net loss	$ (22,449,911)	$ (16,559,605)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	540,894	653,090
Stock-based compensation	1,523,828	995,484
Accretion of discount on note payable	326,006	-
Amortization of debt issue costs	26,525	-
Loss on debt extinguishment	805,951	-
Issuance cost and change in fair value of derivative	1,150,673	1,013,868
Changes in operating assets and liabilities:		
Miscellaneous receivables	18,312	(11,703)
Prepaid expenses and other current assets	(623,705)	88,399
Operating lease right-of-use assets	(1,240,075)	267,886
Trade accounts payable and accrued expenses	1,467,896	(4,540,719)
Current portion of operating lease liability	108,202	(227,424)
Long-term portion of operating lease liability	1,100,222	(130,663)
Net cash used in operating activities	**(17,245,182)**	**(18,451,387)**
Investing activities:		
Purchase of property and equipment	(162,138)	(211,800)
Net cash used in investing activities	**(162,138)**	**(211,800)**
Financing Activities:		
Proceeds from the issuance of common stock and pre-funded common stock purchase warrants, net of fees	10,153,812	25,875,168
Proceeds from notes payable	6,000,000	4,963,987
Principal payments on finance lease obligations	(4,430)	(17,063)
Net cash provided by financing activities	**16,149,382**	**30,822,092**
Cash and cash equivalents:		
Net increase (decrease) in cash and cash equivalents	(1,257,938)	12,158,905
Cash and cash equivalents at beginning of year	12,211,321	52,416
Cash and cash equivalents at end of year	**$ 10,953,383**	**$ 12,211,321**
Property and equipment accrued but not paid at end of year	$ -	$ 31,160
Cash payments:		
Interest paid	$ 19,895	$ 6,288

See notes to consolidated financial statements.

(1) Nature of the Business and Liquidity

Organization

Cingulate Inc. (Cingulate or the Company), a Delaware corporation, is a biopharmaceutical company focused on the development of products utilizing its drug delivery platform technology that enables the formulation and manufacture of once-daily tablets of multi-dose therapies, with an initial focus on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD) and anxiety. The Company is developing two proprietary, first-line stimulant medications, CTx-1301 (dexmethylphenidate) and CTx-1302 (dextroamphetamine), for the treatment of ADHD intended for all patient segments: children, adolescents, and adults. CTx-1301 and CTx-1302 utilize a flexible core tableting technology with target product profile designed to deliver a rapid onset and last the entire active day with a controlled descent of plasma drug level and have favorable tolerability. CTx1301 is in late-stage development and we plan to initiate the clinical plan for CTx-1302 pending additional capital resources. In addition, the Company has a third product to treat anxiety, CTx-2103, in a formulation stage. The Company submitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) on July 31, 2025 for lead asset CTx-1301 and received confirmation of acceptance of the NDA in early October 2025 with a Prescription Drug User Fee Act (PDUFA) target action date of May 31, 2026. A failure to receive FDA approval for CTx-1301, or a delay in receiving such approval, will likely have a material adverse impact on the Company's financial results and strategic position, as outlined in Item 1A. Risk Factors of this Annual Report on Form 10-K.

Liquidity

The Company has incurred losses and negative cash flows from operations since inception. As a pre-revenue entity, the Company is dependent on the ability to raise capital to support operations until such time as the product candidates under development are FDA approved, manufactured, commercially available to the marketplace and produce revenues. On December 31, 2025, the Company had cash and cash equivalents of approximately $11.0 million, and an accumulated deficit of approximately $132.4 million. However, the Company will need additional funding for operations and development. Management is evaluating various strategies to obtain additional funding, which may include additional offerings of equity, issuance of debt, or other capital sources, including potential collaborations with other companies or other strategic transactions. Successful implementation of these plans involves both the Company's efforts and factors that are outside its control, such as market factors and FDA approval of product candidates. The Company can give no assurance that its plans will be effectively implemented in such a way that they will sufficiently alleviate or mitigate the conditions and events noted above, which results in substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not reflect any adjustments that might result from the outcome of this uncertainty.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). The consolidated financial statements include the accounts of Cingulate and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

(b) Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during a reporting period. Actual results could differ from estimates.

Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the consolidated financial statements in the period they are determined to be necessary.

(c) Concentration of Credit Risk

The Company maintains cash equivalent deposits, which at various times throughout the fiscal year exceeded the amounts insured by the Federal Deposit Insurance Corporation limit of $250,000 (without regard to reconciling items). Management monitors the soundness of these financial institutions and does not believe the Company is subject to any material credit risk relative to the uninsured portion of the deposits.

(d) Recent Accounting Pronouncements

The Company continually assesses any new accounting pronouncements to determine their applicability. When it is determined that a new accounting pronouncement may affect the Company's financial reporting, the Company undertakes an analysis to determine any required changes to its consolidated financial statements and assures that there are proper controls in place to ascertain that the Company's consolidated financial statements properly reflect the change.

In November 2024, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures* (Subtopic 220-40): Disaggregation of Income Statement Expenses. ASU 2024-03 requires additional disclosures of certain expenses in the notes of the financial statements, to provide enhanced transparency into the expense captions presented on the consolidated statements of operations. Additionally, in January 2025, the FASB issued ASU 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40), to clarify the effective date of ASU 2024-03. The new standard is effective for the Company for its annual periods beginning January 1, 2028 and for interim periods beginning January 1, 2028, with early adoption permitted. The Company is currently evaluating the impact of adopting the standard.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes* (Topic 740): Improvements to Income Tax Disclosures. ASU 2023-09 requires entities to disclose specific rate reconciliations, amount of income taxes separated by federal and individual jurisdiction, and the amount of income (loss) from continuing operations before income tax expense (benefit) disaggregated between federal, state, and foreign. The Company adopted this standard effective January 1, 2026.

(e) Cash and Cash Equivalents

Bank demand deposit accounts and short-term liquid investments with an initial maturity of three months or less are considered cash and cash equivalents. Cash and cash equivalents as of December 31, 2025 and 2024 consisted of bank deposits and short-term money market funds. Cash and cash equivalents are carried at cost which is indicative of fair value.

(f) Property and Equipment, net

Property and equipment, net are stated at cost, less accumulated depreciation. Maintenance and repairs are charged to expense when incurred. Property and equipment are depreciated using the straight-line method over the estimated remaining useful lives or, for leasehold improvements or leased assets under a financing lease, the life of the lease if shorter.

(g) Leases

The Company is a lessee in a noncancellable operating lease, relating to office space at the Kansas City headquarters office and a finance lease, for certain furniture and equipment.

The Company determines if an arrangement is or contains a lease at contract inception. The Company recognizes a right-of-use (ROU) asset and a lease liability at the lease commencement date. For operating leases, the lease liability is initially and subsequently measured at the present value of the unpaid lease payments at the lease commencement date. For finance leases, the lease liability is initially measured in the same manner and date as for operating leases and is subsequently measured at amortized cost using the effective-interest method.

The Company determines the discount rate it uses to discount the unpaid lease payments to present value, which requires management judgement. Accounting Standards Codification (ASC) 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its

incremental borrowing rate. The implicit rate was stated in the agreement for one of the Company's leases; however, for the others, the implicit rate was not determinable as the Company did not have access to the lessor's estimated residual value or the amount of the lessor's deferred initial direct costs. Therefore, the Company uses its incremental borrowing rate as the discount rate for these leases. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. Because the Company has not been able to borrow on a collateralized basis, it has determined a synthetic credit rating based on factors that a credit rating agency would typically analyze when establishing an entity's credit rating. Due to the fact that the Company is a pre-revenue entity, the Company determined that its incremental borrowing rate should be based on the composite CCC and lower bond spreads at the lease measurement dates plus a risk-free rate based on specific lease maturities.

The ROU asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date, plus any initial direct costs incurred less any lease incentives received.

For operating leases, the ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, plus initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of cumulative lease incentives received. Lease expense is recognized on a straight-line basis over the lease term which includes the accretion of the lease liability and amortization of the ROU asset.

For finance leases, the ROU asset is subsequently amortized using the straight-line method from the lease commencement date to the earlier of the end of its useful life or the end of the lease term unless the lease transfers ownerships of the underlying asset to the Company or the Company is reasonably certain to exercise an option to purchase the underlying asset. In those cases, the ROU asset is amortized over the useful life of the underlying asset. Amortization of the ROU asset is recognized and presented separately from interest expense on the lease liability.

ROU assets for operating and finance leases are evaluated for impairment losses under the long-lived assets impairment guidance in ASC Subtopic 360-10, *Property and Equipment-Overall*. The ROU asset is assessed for impairment with the asset group within which it resides.

Operating lease ROU assets are presented as operating lease right-of-use assets on the consolidated balance sheet. The current and long-term portions of operating lease liabilities are presented separately on the consolidated balance sheet. Finance lease ROU assets are included in property, plant, and equipment. The current and long-term portions of finance lease liabilities are presented separately on the consolidated balance sheet.

(h) Impairment of Long-lived Assets

The Company assesses the carrying value of its long-lived assets, including property and equipment, as well as lease ROU assets, when events or circumstances indicate that the carrying value of such assets may not be recoverable. These events or changes in circumstances may include a significant deterioration of operating results, changes in business plans, or changes in anticipated future cash flows. If an impairment indicator is present, the Company evaluates recoverability by a comparison of the carrying amount of the assets to future undiscounted cash flows expected to be generated by the assets. If the sum of the expected future cash flows is less than the carrying amount, the Company would recognize an impairment loss. An impairment loss would be measured by comparing the amount by which the carrying value exceeds the fair value of the long-lived asset groups. No impairment was recognized during the years ended December 31, 2025 or 2024.

(i) Research and Development

Research and development costs are expensed as incurred and include all direct and indirect costs associated with the development of the Company's product candidates. These expenses include payments to third parties for research, development and manufacturing services, personnel costs and depreciation on manufacturing equipment. At the end of the reporting period, the Company compares payments made to third party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense relating to these costs.

(j) Stock-Based Compensation

The Company measures employee and director stock-based compensation expense for all stock-based awards based on their grant date fair value using the Black-Scholes option-pricing model. For stock-based awards with service conditions, stock-based compensation expense is recognized over the requisite service period using the straight-line method. Forfeitures are recognized as they occur. See additional information in Note 12.

(k) Derivative Instruments

The Company evaluates all financial instruments, including certain equity-linked contracts, to determine if such instruments or any embedded components qualify as derivatives under ASC 815, *Derivatives and Hedging*.

The Company evaluated the 2025 LP Purchase Agreement (as defined in Note 10) that includes the right to require Lincoln Park (as defined in Note 10) to purchase shares of common stock in the future ("purchased put right") considering the guidance in ASC 815-40, *Derivatives and Hedging*, and concluded that it is an equity-linked contract that does not qualify for equity classification, and therefore requires fair value accounting as a derivative asset (liability). The Company has analyzed the terms of the purchased put right and has concluded that it had insignificant value as of December 31, 2025.

(l) Reclassifications

In connection with the preparation of the annual consolidated financial statements as of and for the year ended December 31, 2025, the Company identified certain errors in its accounting for the Original LP Purchase Agreement (as defined in Note 10) in previously issued consolidated financial statements. Accordingly, the comparative financial statements included in this Report differ from our previously filed Annual Report on Form 10-K as of and for the year ended December 31, 2024, reflecting the error correction for the misclassification of the commitment shares issued on the Original LP Purchase Agreement and change in fair value of the derivative initially recorded as a deduction to additional paid-in-capital on the consolidated statements of stockholders' equity and now expensed through issuance cost and change in fair value of derivative on the consolidated statements of operations and comprehensive loss. The correction of this error resulted in an increase in issuance cost and change in fair value of derivative and net loss and net comprehensive loss; however, no change to total stockholders' equity or net cash used in operating activities on the consolidated statements of cash flows. In evaluating whether the Company's previously issued consolidated financial statements were materially misstated, the Company performed an analysis of quantitative and qualitative factors in accordance with Staff Accounting Bulletin ("SAB") No. 99, *Materiality*, and SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, and considered the guidance in ASC Topic 250, *Accounting Changes and Error Corrections*. The Company believes the adjustments recorded for correction of the error are immaterial to the previously issued consolidated financial statements either individually or in the aggregate for each of the respective comparative periods.

The corrections to the Company's consolidated balance sheet were as follows:

	December 31, 2024	
	As Reported	As Corrected
Common stock	340	340
Additional paid-in-capital	115,944,345	117,380,285
Accumulated deficit	(108,489,180)	(109,925,120)
Total stockholders' equity	**$ 7,455,505**	**$ 7,455,505**

The corrections to the Company's consolidated statements of operations and comprehensive loss were as follows:

	Year Ended December 31, 2024	
	As Reported	As Corrected
Issuance cost and change in fair value of derivative	-	(1,013,868)
Net loss and comprehensive loss	**$ (15,545,737)**	**$ (16,559,605)**
Net loss per share of common stock, basic and diluted	$ (10.20)	$ (10.86)

The corrections to the Company's statement of stockholders' equity were as follows:

	Additional Paid-in-Capital		Accumulated Deficit		Stockholders' Equity	
	As Reported	As Corrected	As Reported	As Corrected	As Reported	As Corrected
Balance January 1, 2024	**86,074,004**	**$ 86,496,076**	**(92,943,443)**	**(93,365,515)**	**(6,869,429)**	**(6,869,429)**
Change in fair value of derivative	-	1,013,868	-	-	-	1,013,868
Net loss	-	-	(15,545,737)	(16,559,605)	(15,545,737)	(16,559,605)
Balance December 31, 2024	**$115,944,345**	**$117,380,285**	**$(108,489,180)**	**$(109,925,120)**	**$ 7,455,505**	**$ 7,455,505**

The corrections of the Company's statement of cash flows were as follows:

	Year Ended December 31, 2024	
	As Reported	As Corrected
Operating activities:		
Net loss	$ (15,545,737)	$ (16,559,605)
Adjustments to reconcile net loss to net cash used in operating activities:		
Issuance cost and change in fair value of derivative	-	1,013,868
Net cash used in operating activities	(18,451,387)	(18,451,387)

(m) Segments

Operating segments are defined as components of an enterprise for which discrete financial information is available and regularly reviewed by the chief operating decision maker (CODM) in deciding how to allocate resources and in assessing performance. The Company manages its business activities on a consolidated basis and operates as a single operating segment dedicated to the research and development and manufacturing of its product candidates. The Company's CODM is its Chief Executive Officer. The CODM uses net loss, as reported in the Company's Consolidated Statements of Operations and Comprehensive Loss, in evaluating performance of its segment and determining how to allocate resources of the Company as a whole, including investing in its research and development activities.

The measure used by the CODM for segment assets is reported in the Consolidated Balance Sheets as total consolidated assets.

The following table presents the operating results of the Company's segment:

Operating expenses:	2025	2024
Research and development		
Clinical operations	$ 2,695,880	$ 4,711,745
Drug manufacturing and dormulation	3,251,481	2,695,896
Personnel	2,780,524	1,761,558
Regulatory	1,046,172	276,066
Total research and development	9,774,057	9,445,265
General and administrative		
Pre-commercialization costs	2,380,814	115,915
Personnel	2,992,049	1,862,356
Legal and professional fees	3,121,002	2,396,063
Occupancy	326,666	345,535
Insurance	741,556	983,758
Other	601,964	496,081
Total general and administrative	10,164,051	6,199,708
Operating loss	(19,938,108)	(15,644,973)
Issuance cost and change in fair value of derivative	(1,150,673)	(1,013,868)
Interest and other income (expense), net	(1,361,130)	99,236
Loss before income taxes	(22,449,911)	(16,559,605)
Income tax benefit (expense)	-	-
Net loss and comprehensive loss	$ (22,449,911)	$ (16,559,605)

(n) Income Taxes

Cingulate Inc. is taxed as a C corporation under the Internal Revenue Code. Cingulate Inc. records deferred income taxes to reflect the impact of temporary differences between the recorded amounts of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations. As of December 31, 2025, Cingulate Therapeutics LLC (CTx) is a wholly-owned disregarded entity of Cingulate Inc., and all of the activity for CTx, along with its wholly-owned subsidiary Cingulate Works Inc., is included in the calculation of the current and deferred tax assets and liabilities for Cingulate Inc. The Company determined that it was more likely than not that it would not realize its deferred tax assets, based on historical levels of income and future forecasts of taxable income, among other items, therefore a full valuation allowance is recorded.

The Company has not identified any uncertain tax positions. There have been no interest or penalties recognized in the consolidated financial statements related to uncertain tax positions. In addition, no tax positions exist for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next 12 months.

The Company files income tax returns in the federal and various state jurisdictions. These federal income taxes are immaterial.

(o) Common Stock Purchase Warrants

The Company issued warrants in connection with its initial public offering (IPO) in December 2021, common stock offerings in September 2023 and February 2024, and a warrant inducement in June 2024. These equity instruments were valued at fair value when they were issued. See additional information in Note 11.

(p) Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period, without consideration to potential dilutive securities. Diluted net loss per common share is computed by dividing the net loss by the sum of the weighted average number of common shares outstanding during the period plus the number of potential dilutive instruments outstanding during the period using the simplified method. Diluted net loss per share is the same as basic net loss per share since the effect of all outstanding potentially dilutive securities is anti-dilutive.

(3) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following at December 31, 2025 and 2024:

	2025	2024
Manufacturing materials	$ 813,381	$ 29,025
Marketing fees	125,000	34,167
Deferred capital raise costs	59,383	-
Insurance	16,655	-
Dues and subscriptions	11,743	4,575
Research and development	-	334,692
Other	20,700	20,698
	$ 1,046,862	$ 423,157

(4) Property and Equipment, net

Property and equipment, net consisted of the following at December 31, 2025 and 2024:

	Estimated Useful Life (in years)	2025	2024
Equipment	2-7	$ 4,662,280	$ 4,358,261
Furniture and fixtures	7	145,754	145,754
Computer equipment	5	46,994	46,994
Leasehold improvements	5	474,462	474,462
Construction-in-process	-	233,397	375,278
		5,562,887	5,400,749
Less: accumulated depreciation		(3,836,968)	(3,296,074)
		$ 1,725,919	$ 2,104,675

Depreciation expense was $540,894 and $653,090 for the years ended December 31, 2025 and 2024, respectively.

(5) Accrued Expenses

Accrued expenses consisted of the following at December 31, 2025 and 2024:

	2025	2024
Interest	$ 563,883	$ 15,089
Employee compensation	455,177	355,475
Commercial costs	393,076	-
Research and development	166,696	341,956
State franchise taxes	44,000	200,000
Professional fees	31,542	5,000
CIP- Equipment	-	31,160
Insurance	-	34,469
Other	87,742	56,476
	$ 1,742,116	$ 1,039,625

(6) Contingencies

The Company may, from time to time, be subject to legal proceedings and claims arising in the ordinary course of business and otherwise. A substantial legal liability against us could have an adverse effect on our business, financial condition and results of operations.

The Company records legal costs associated with loss contingencies as incurred and establishes reserves when those matters present material loss contingencies that management determines to be both probable and reasonably estimable in accordance with ASC Topic 450, *Contingencies.* If a range of loss is estimated, and some amount within that range appears to be a better estimate than any other amount within that range, then that amount is accrued. If no amount within the range can be identified as a better estimate than any other amount, we accrue the minimum amount in the range. These amounts are not reduced by amounts that may be recovered under insurance or claims against third parties, but undiscounted receivables from insurers or other third parties may be accrued separately if recovery is considered probable. Management's judgment is required related to loss contingencies because the outcomes are difficult to predict, and the ultimate resolution may differ from our current analysis. The Company revises accruals in light of new information. While it is not possible to predict the outcome of loss contingencies with certainty, management is of the opinion that adequate provision for potential losses associated with any such matters has been made in the financial statements.

(7) Related Party Notes Payable

In August 2022, the Company received $5.0 million of debt financing from Werth Family Investment Associates LLC (WFIA). Peter Werth, manager of WFIA, is a member of the Company's Board of Directors. The promissory note, dated August 9, 2022, was unsecured with interest accruing at 15% per annum. In May 2023, the Company received an additional $3.0 million of debt financing from WFIA by amending and restating the note to increase the principal amount to $8.0 million. All other terms of the note remained the same.

On September 8, 2023, the Company and CTx entered into a note conversion agreement with WFIA, pursuant to which WFIA agreed to convert the original principal amount of $5.0 million under the note plus all accrued interest on the original principal, or $5,812,500, by issuing pre-funded warrants to purchase 28,493 shares of the Company's common stock at a conversion price per pre-funded warrant of $204.00. The closing price of the Company's common stock on Nasdaq on September 8, 2023, was $13.56 per share. The pre-funded warrants had no expiration date and were exercisable immediately at an exercise price of $0.024 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended (Exchange Act), no more than 19.99% of the outstanding shares of common stock of the Company.

On January 25, 2024, the Company and CTx entered into another note conversion agreement with WFIA, pursuant to which WFIA agreed to convert the remaining principal amount of the note payable of $3.0 million plus all accrued interest, or $3,287,500, by issuing pre-funded warrants to purchase 57,254 shares of the Company's common stock at a conversion price per pre-funded warrant of $57.42. The closing price of the Company's common stock on Nasdaq on January 24, 2024, was $52.20 per share. The pre-funded warrants had no expiration date and were exercisable immediately at an exercise price of $0.0012 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Exchange Act, no more than 19.99% of the outstanding shares of common stock of the Company.

WFIA exercised all of its pre-funded warrants in April 2024, as described in Note 10.

The Company considered ASC 470-60, *Troubled Debt Restructurings by Debtors*, in accounting for the debt conversions. Due to the related party nature of the transactions, the difference between the fair value of the pre-funded warrants issued and the carrying value of the debt settled in the transactions were recognized as capital contributions in the Statement of Stockholders' Equity.

(8) Unsecured Promissory Notes

On December 20, 2024, the Company entered into a note purchase agreement (2024 Note Purchase Agreement) with Streeterville Capital, LLC, a Utah limited liability company (Lender), pursuant to which the Company issued and sold to Lender an unsecured promissory note in the amount of $5,480,000 (2024 Note). The 2024 Note included an original issue discount of $450,000 and Lender expenses payable by the Company of $30,000. In exchange for the 2024 Note, the Lender paid a purchase price of $5,000,000 in cash. The 2024 Note bore interest at a rate of 9% per annum and had a maturity 18 months after its issuance date.

From time to time, beginning on July 2, 2025, Lender could redeem a portion of the 2024 Note. Pursuant to the terms of the 2024 Note, we were charged a monitoring fee equal to the outstanding balance on the 90-day anniversary of the effective date of the 2024 Note divided by 0.85 less the outstanding balance on such date. Subject to the terms and conditions set forth in the 2024 Note, the Company could prepay all or any portion of the outstanding balance of the Promissory Note at any time. As of December 31, 2025, the Company had entered into exchange agreements with Lender to exchange a total of $4,675,000 principal for 1,167,300 shares of common stock, thereby extinguishing a portion of the Promissory Note. In connection with the exchange agreements, the Company recorded the pro rata portion of the monitoring fee as well as accrued interest on the pro rata portion of the monitoring fee. As of December 31, 2025, the pro rata portion of the monitoring fee recognized was $671,792 as a loss on debt extinguishment within interest and other income (expense), net and the accrued interest on the pro rata portion of the monitoring fee was $48,704.

In connection with the 2024 Note, the Company incurred $46,277 of debt issuance costs. The debt issuance costs, the debt discount of $450,000 and the expenses payable by the Company of $30,000 have been recorded as a reduction in the carrying amount of the 2024 Note and are being amortized over the term of the 2024 Note using the effective interest rate method.

As of December 31, 2025 and 2024, the outstanding balances relating to this note are as follows:

	12/31/2025	12/31/2024
2024 Note Purchase Agreement:		
Principal	$ 805,000	$ 5,480,000
Monitoring fee on pro rata portion of exchanges	671,792	-
Unamortized discounts/deferred financing	(83,922)	(516,013)
Total outstanding debt	$ 1,392,870	$ 4,963,987
Accrued Interest	$ 474,598	$ 15,089

On November 7, 2025, the Company entered into a note purchase agreement (2025 Note Purchase Agreement) with Avondale Capital, LLC, a Utah limited liability company (Avondale), pursuant to which the Company issued and sold to Avondale an unsecured promissory note in the amount of $6,570,000 (2025 Note). The principal amount includes an original issue discount of $540,000 and expenses payable by the Company of $30,000. In exchange for the 2025 Note, Avondale paid a purchase price of $6,000,000 in cash. The 2025 Note bears interest at a rate of 9% per annum and matures 18 months after its issuance date.

From time to time, beginning on May 7, 2026, Avondale may redeem a portion of the 2025 Note, not to exceed an amount of $660,000 per month; and provided that the Company has not previously received a "complete response letter" from the FDA, the Company may defer up to two redemptions for up to thirty (30) days each. If the Company exercises its deferral right, the outstanding balance of the 2025 Note will be increased by 1% of the outstanding balance on the date of the deferral. The Company was charged a monitoring fee equal to the outstanding balance on the 90-day anniversary of the effective date of the 2025 Note divided by 0.85 less the outstanding balance on such date. Subject to the terms and conditions set forth in the 2025 Note, the Company may prepay all or any portion of the outstanding balance of the 2025 Note at any time. As the redemptions are outside of the control of the Company, the Company has recorded the gross amount of the expected FY 26 Avondale redemptions within current note payable on the balance sheet.

The 2025 Note provides for customary events of default (each as defined in the 2025 Note, an Event of Default), including, among other things, the event of nonpayment of principal, interest, fees or other amounts, a representation or warranty proving to have been incorrect when made, failure to perform or observe covenants within a specified cure period, a cross-default to certain other indebtedness and material agreements of the Company, and the occurrence of a bankruptcy, insolvency or similar event affecting the Company. Upon the occurrence of an Event of Default that is deemed a "Major Trigger Event" as defined in the promissory note, Avondale may increase the outstanding balance of the 2025 Note by 15%, and upon the occurrence of an Event of Default that is deemed a "Minor Trigger Event" as defined in the 2025 Note, Avondale may increase the outstanding balance of the 2025 Note by 5%. Avondale can exercise its right to increase the outstanding balance upon a Major or Minor Trigger Event three times each. Upon the occurrence of an Event of Default, Avondale may declare all amounts owed under the 2025 Note immediately due and payable. In addition, upon the occurrence of an Event of Default, upon the election of Avondale, interest shall begin accruing on the outstanding balance of the 2025 Note from the date of the Event of Default equal to the lesser of 22% per annum and the maximum rate allowable under law.

The debt discount of $540,000 and the expenses payable by the Company of $30,000 have been recorded as a reduction in the carrying amount of the 2025 Note and are being amortized over the term of the 2025 Note using the effective interest rate method.

As of December 31, 2025 the outstanding balances relating to this note are as follows:

2025 Note Purchase Agreement:	
Principal	6,570,000
Monitoring fee on pro rata portion of exchanges	-
Unamortized discounts/deferred financing	(515,401)
Total	$ 6,054,599
Accrued Interest	$ 89,285

The following table provides a breakdown of interest expense (income) for the periods presented:

	2025	2024
Interest expense - WFIA	$ -	$ 31,250
Interest expense - promissory notes	901,325	25,354
Interest expense - loss on debt extinguishment	805,951	
Interest expense - other	23,121	6,259
Interest income	(369,267)	(162,099)
	$ 1,361,130	$ (99,236)

(9) Stockholders' Equity

The Company has authorized 240,000,000 shares of $0.0001 par value common stock and 10,000,000 shares of $0.0001 par value preferred stock at December 31, 2025 and 2024 of which 7,250,299 and 3,402,306 shares of common stock were issued and outstanding, respectively. As of December 31, 2025, the Company had not issued any shares of preferred stock.

The holders of common stock are entitled to one vote for each share of common stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, after the payment or provision for payment of all debts and liabilities of the Company, the holders of common stock shall be entitled to share in the remaining assets of the Company available for distribution, if any. Holders of the shares of common stock are entitled to dividends when, as and if declared by the Board of Directors.

Reverse Stock Splits

On August 9, 2024, the Company completed a one-for-twelve reverse stock split (2024 Reverse Stock Split), which reduced the number of shares of the Company's common stock that were issued and outstanding immediately prior to the effectiveness of the 2024 Reverse Stock Split. The number of shares of the Company's authorized common stock was not affected by the 2024 Reverse Stock Split and the par value of the Company's common stock remained unchanged at $0.0001 per share. No fractional shares were issued in connection with the 2024 Reverse Stock Split.

Except where disclosed, all amounts related to number of shares and per share amounts have been retrospectively restated in these financial statements to reflect the 2024 Reverse Stock Split.

(10) Securities Issuances

Public Offerings

On February 2, 2024, the Company completed a public offering (February 2024 Offering) pursuant to which the Company issued 114,583 shares of its common stock and accompanying Series A and Series B warrants at a combined price of $24.00 per share, and pre-funded warrants to purchase up to an aggregate of 197,917 shares of its common stock and accompanying Series A and Series B warrants at a combined purchase price of $23.988 per pre-funded warrant, which represents the public offering price for the common stock less the $0.0012 per share exercise price per share for each pre-funded warrant. The pre-funded warrants were exercisable at any time after the date of issuance and had no expiration date. The holders of pre-funded warrants could not exercise the warrants if the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. Each share of common stock and each pre-funded warrant were sold along with one Series A and 0.5 Series B warrants. The February 2024 Offering resulted in gross proceeds to the Company of $7.5 million before deducting $750,950 of placement agent fees and other offering expenses. All of the pre-funded warrants issued in the February 2024 Offering were exercised in 2024.

Conversion of Related Party Note

On September 8, 2023, the Company issued to WFIA pre-funded warrants to purchase 28,493 shares of the Company's common stock as part of a note conversion agreement, as described in Note 7.

On January 25, 2024, the Company issued to WFIA pre-funded warrants to purchase 57,254 shares of the Company's common stock as part of a note conversion agreement, as described in Note 7. In March 2024, the Company issued to WFIA additional pre-funded warrants to purchase 588 shares of the Company's common stock as a result of an error in the interest calculation, on the same form and at the same conversion price as the pre-funded warrants issued in January 2024.

In April 2024, WFIA exercised all of its pre-funded warrants, as described in Note 7.

Warrant Inducement

On June 28, 2024, the Company entered into an inducement offer letter agreement (June 2024 Warrant Inducement), in which certain holders (Holders) of certain of its existing warrants to purchase 265,625 shares of the Company's common stock issued to the Holders in connection with the February 2024 Offering (February 2024 Warrants) agreed to exercise for cash their February 2024 Warrants at a reduced exercise price of $7.02 per share. In consideration for the exercise of the February 2024 Warrants, the Holders received, in addition to the reduced exercise price, new Series C common stock purchase warrants to purchase an aggregate of 354,167 shares of the Company's common stock and new Series D common stock purchase warrants to purchase an aggregate of 177,083 shares of the Company's common stock. The June 2024 Warrant Inducement is considered a modification of the existing warrants under ASC Subtopic 815-40, *Derivatives and Hedging, Contracts in Entity's Own Equity*. This modification is consistent with the equity issuance classification under ASC Subtopic 815-40 as the reason for the modification was to induce the holders of the existing warrants to exercise their warrants, which raised equity capital and generated net proceeds to the Company of approximately $1.6 million, after deducting the placement agent fees and other offering expenses payable by the Company. The modified warrants were classified as equity instruments before and after the modification, and the modification is directly attributable to an equity offering. The Company recognized the effect of modification of approximately $2.0 million as an equity issuance cost and accounting effect of the inducement is recognized in the Statement of Stockholders' Equity. The Company received net proceeds of $1.6 million on the closing of the June 2024 Warrant Inducement, which occurred on July 1, 2024.

Purchase Agreements with Lincoln Park

In April 2023, the Company entered into a purchase agreement (the Original LP Purchase Agreement) and a registration rights agreement (the Registration Rights Agreement) with Lincoln Park Capital Fund, LLC (Lincoln Park). Pursuant to the terms of the Original LP Purchase Agreement, Lincoln Park agreed to purchase from the Company up to $12 million of the Company's common stock. Pursuant to the terms of the Registration Rights Agreement, the Company filed with the SEC registration statements to register for resale under the Securities Act the shares of common stock that were issued to Lincoln Park under the Original LP Purchase Agreement. As of June 30, 2025, the Company sold to Lincoln Park the maximum dollar value worth of common stock pursuant to the Original LP Purchase Agreement, and the Original LP Purchase Agreement thereupon expired in accordance with its terms.

On July 21, 2025, the Company entered into a second purchase agreement with Lincoln Park (2025 LP Purchase Agreement), pursuant to which Lincoln Park has agreed to purchase from the Company up to an aggregate of $25.0 million of the Company's common stock (subject to certain limitations and satisfaction of the conditions set forth in the 2025 LP Purchase Agreement) from time to time and at the Company's sole discretion over the 36-month term of the 2025 LP Purchase Agreement. Pursuant to the terms of the 2025 LP Purchase Agreement, on July 21, 2025, the Company issued 120,424 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of common stock under the 2025 LP Purchase Agreement. The commitment shares were valued at $681,600 and recorded as an addition to equity for the issuance of the common stock and recorded as an expense in issuance cost and change in fair value of derivative on the consolidated statements of operations and comprehensive loss under the 2025 LP Purchase Agreement. The Company evaluated the 2025 LP Purchase Agreement under ASC 815-40 *Derivatives and Hedging-Contracts on an Entity's Own Equity* as it represents the right to require Lincoln Park to purchase shares of common stock in the future, similar to a put option. The Company concluded that the 2025 LP Purchase Agreement represents a freestanding derivative instrument that does not qualify for equity classification and therefore requires fair value accounting. The Company analyzed the terms of the contract and concluded that the derivative instrument had insignificant value as of December 31, 2025.

During 2025, the Company sold 852,948 shares of common stock under the 2025 LP Purchase Agreement and 897,415 shares of common stock under the Original LP Purchase Agreement, for net proceeds of $3,238,007 and $3,513,236, respectively. During 2024, the Company sold 1,472,363 shares of common stock under the Original LP Purchase Agreement, for net proceeds of $8,037,501.

The Company evaluated the 2025 LP Purchase Agreement under ASC 815-40 *Derivatives and Hedging-Contracts on an Entity's Own Equity* as it represents the right to require Lincoln Park to purchase shares of common stock in the future, similar to a put option. The Company concluded that the 2025 LP Purchase Agreement represents a freestanding derivative instrument that does not qualify for equity classification and therefore requires fair value accounting. The Company analyzed the terms of the contract and concluded that the derivative asset or liability had insignificant value as of December 31, 2025. Changes in fair value associated with the derivative instrument are recorded in issuance cost and change in fair value of derivative in the consolidated statements of operations and comprehensive loss. The Company recorded $1,150,673 and $1,013,868 for 2025 and 2024, respectively, associated with the change in fair value of the derivative instrument.

At the Market Offering

In January 2023, the Company entered into the At-the-Market Offering Agreement (ATM Agreement) with H.C. Wainwright & Co., LLC (HCW) pursuant to which the Company could issue and sell, from time to time, shares of the Company's common stock having an aggregate offering price of up to $23.5 million in at-the-market offerings sales. HCW acted as sales agent and was paid a 3% commission on each sale under the ATM Agreement. The Company's common stock was sold at prevailing market prices at the time of the sale, and, as a result, prices varied.

On March 18, 2024, the Company increased the maximum aggregate offering price of the shares of the Company's common stock issuable under the ATM Agreement from $4.97 million to $8.47 million and filed a prospectus supplement for an aggregate of $3.5 million. In connection with the filing of the prospectus supplement, on March 17, 2024, the Company received a waiver from the purchaser in the February 2024 Offering under the securities purchase agreement, dated February 2, 2024, by and between the Company and such purchaser. In consideration of the waiver set forth therein, the Company agreed to lower the exercise price of the Series A warrants to purchase up to an aggregate of 28,855 shares of common stock and Series B warrants to purchase up to an aggregate of 14,428 shares of common stock to $13.56, which warrants were previously issued by the Company to such purchaser on September 13, 2023 and to extend the exercise term of the Series A warrants to March 17, 2029 and the term of the Series B warrants to March 17, 2026. The modifications to the warrants had no impact on the consolidated financial statements.

On August 19, 2024, the Company increased the maximum aggregate offering price of shares of the Company's common stock issuable under the ATM Agreement from $8.47 million to $11.33 million and filed a prospectus supplement for an aggregate of $2.86 million.

On September 3, 2024, the Company increased the maximum aggregate offering price of shares of the Company's common stock issuable under the ATM Agreement from $11.33 million to $15.2 million and filed a prospectus supplement for an aggregate of $3.87 million.

On October 15, 2024, the Company increased the maximum aggregate offering price of shares of the Company's common stock issuable under the ATM Agreement from $15.2 million to $23.5 million and filed a prospectus supplement for an aggregate of $8.3 million.

During 2025 and 2024, the Company sold 785,784 and 983,093 shares of common stock, respectively, under the ATM agreement, for net proceeds of $3,574,574 and $9,393,550, respectively.

(11) Common Stock Purchase Warrants

Initial Public Offering

For each of the 17,361 shares of common stock issued in connection with the Company's IPO, one common stock purchase warrant was also issued and included in the unit price of $1,440.00. These warrants were immediately separable and tradeable. The underwriters purchased 2,604 additional common stock purchase warrants for $.012 per warrant less underwriting discounts and commissions. These 19,965 common stock purchase warrants have an exercise price of $1,440.00 per share and are exercisable from December 10, 2021 through December 10, 2026. Upon the termination date, these warrants will be automatically exercised via a cashless exercise.

In addition to the common stock purchase warrants noted above, the Company issued 868 common stock purchase warrants to the underwriters for the Company's IPO pursuant to the underwriting agreement. These warrants have an exercise price of $1,800.00 per share and provide for a cashless exercise feature. These warrants are exercisable from June 7, 2023 through December 10, 2026.

September 2023 Offering

For each of the 28,855 shares of common stock and pre-funded warrants issued in the September 2023 equity offering, the Company issued Series A warrants to purchase up to 28,855 shares of common stock and Series B warrants to purchase up to 14,428 shares of common stock. The Series A and Series B warrants had an original exercise price of $138.62 per share and became exercisable on the effective date of stockholder approval of the shares issuable pursuant to the warrants. In connection with the waiver granted in March 2024 by the purchaser in the February 2024 Offering to allow the Company to file a prospectus supplement to increase the maximum aggregate offering price of shares of the Company's common stock issuable under the ATM Agreement, the exercise price of the Series A and Series B warrants was lowered to $13.56 per share and the term of the Series A warrants was extended to March 17, 2029 and the term of the Series B warrants was extended to March 17, 2026.

The Company valued the pre-funded warrants to purchase 21,688 shares of common stock based on their issuance date fair value of $3,006,008. As of December 31, 2023, all of the pre-funded warrants relating to the September 2023 equity offering had been exercised.

In connection with the September 2023 equity offering, the Company issued placement agent warrants to purchase up to 1,443 shares of common stock. The placement agent warrants have an exercise price of $173.28 per share. These warrants have a five-year term ending September 11, 2028.

The gross proceeds of the September 2023 equity offering were allocated to the common stock and common stock purchase warrants using the relative fair value method shown as follows. Fair value of the warrants was recorded to Additional Paid-in-Capital on the Company's balance sheet.

	Fair Value	Percent of Total Fair Value	Amount Allocated
Common Stock	$ 993,472	10.6%	$ 423,945
Pre-Funded Warrants	3,006,003	32.0%	1,279,833
Series A, B and Placement Agent Warrants	5,388,376	57.4%	2,295,701
Total	$ 9,387,851	100.0%	$ 3,999,479

February 2024 Offering

For the 312,500 shares of common stock and pre-funded warrants issued in the February 2024 Offering, the Company issued Series A warrants to purchase up to 312,500 shares of common stock and Series B warrants to purchase up to 156,250 shares of common stock. The Series A and Series B warrants have an exercise price of $24.00 per share and became exercisable immediately. The Series A warrants have a five-year term and the Series B warrants have a two-year term from the initial exercise date of February 5, 2024.

The Company evaluated the pre-funded warrants and the Series A and B warrants for liability or equity classification in accordance with the provisions of ASC Topic 480, *Distinguishing Liabilities from Equity*, and ASC Topic 815, *Derivatives and Hedging*, and determined that equity treatment was appropriate. The Company valued the pre-funded warrants to purchase 197,917 shares of common stock based on their issuance date fair value of $24.00. All of the pre-funded warrants were exercised in 2024.

In connection with the February 2024 Offering, the Company issued placement agent warrants to purchase up to 12,500 shares of common stock. The placement agent warrants have an exercise price of $30.00 per share. These warrants have a five-year term ending February 2, 2029.

The Series A, Series B and placement agent warrants issued in the September 2023 Offering and the February 2024 Offering were valued using a Black-Scholes model with a risk-free rate of 4.5%-5.3%, the respective terms of five and two years, and a volatility of 1.29-1.32. The estimated volatility of the Company's common stock at the date of measurement is based on an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as the Company does not have sufficient trading history for its common stock. The risk-free rate is based on the expected term of the warrants based on the constant maturity of U.S. Treasury securities with similar maturities as of the date of grant. The expected term has been estimated using the contractual term of the warrants.

The gross proceeds of the February 2024 public offering was allocated to the common stock and common stock purchase warrants using the relative fair value method shown as follows. Fair value of the warrants was recorded to Additional Paid-in-Capital on the Company's balance sheet.

	Fair Value	Percent of Total Fair Value	Amount Allocated
Common Stock	$ 2,750,000	26.5%	$ 1,987,500
Pre-Funded Warrants	4,750,000	45.8%	3,435,000
Series A, B and Placement Agent Warrants	2,878,123	27.7%	2,077,500
Total	$ 10,378,123	100.0%	$ 7,500,000

Certain of the Series A and Series B warrants issued in connection with the February 2024 Offering were exercised as part of the June 2024 Warrant Inducement as described in Note 10. Series C and Series D warrants were issued as part of the June 2024 Warrant Inducement, which closed on July 1, 2024. The Series C and Series D warrants have an exercise price of $7.02 per share and became exercisable on the effective date of stockholder approval of the shares issuable pursuant to the warrants. The Series C warrants have a five-year term and the Series D warrants have a two-year term from the initial exercise date of August 28, 2024.

The following table summarizes the Company's outstanding common stock purchase warrants as of December 31, 2025:

	Number of Warrants	Exercise Price	Issuance Date Fair Value per Warrant	Issuance Date Fair Value Total
December 2021 Initial Public Offering Warrants	19,965	$ 1,440.00	$ 1,144.80	$ 22,855,932
December 2021 Underwriter Warrants	868	$ 1,800.00	$ 1,113.48	966,501
September 2023 Public Offering Series A Warrants	28,855	$ 13.56	$ 129.84	3,746,533
September 2023 Placement Agent Warrants	1,443	$ 172.80	$ 127.56	184,069
February 2024 Public Offering Series A Warrants	135,417	$ 24.00	$ 14.04	1,901,255
February 2024 Public Offering Series B Warrants	67,708	$ 24.00	$ 11.88	804,371
February 2024 Placement Agent Warrants	12,500	$ 30.00	$ 13.80	172,500
July 2024 Series C Warrants	354,167	$ 7.02	$ 3.24	1,147,501
July 2024 Series D Warrants	177,083	$ 7.02	$ 2.40	424,999
July 2024 Placement Agent Warrants	21,250	$ 8.78	$ 2.23	47,388
Balance- December 31, 2025	819,256			$ 32,251,049

(12) Stock-Based Compensation

In September 2021, the Company's board of directors and stockholders adopted the 2021 Equity Incentive Plan (2021 Plan), which provides for the grant of incentive stock options and non-qualified stock options to purchase shares of the Company's common stock, stock appreciation rights, restricted stock units, restricted or unrestricted shares of common stock, performance shares, performance units, incentive bonus awards, other stock-based awards and other cash-based awards. No awards may be made under the 2021 Plan on or after September 24, 2031, but the 2021 Plan will continue thereafter while previously granted awards remain outstanding.

At the Company's 2024 annual meeting, shareholders approved an amendment to the 2021 Plan to increase the number of shares of common stock authorized for issuance thereunder by 104,167 shares to 125,577. At the Company's 2025 annual meeting, shareholders approved an amendment to the 2021 Plan to increase the number of shares of common stock authorized for issuance thereunder by 800,000 shares to 1,141,826. As of December 31, 2025, 185,831 shares of common stock were available for issuance under the 2021 Plan. The number of shares of common stock available for issuance under the 2021 Plan will automatically increase on January 1st of each year until the expiration of the 2021 Plan, in an amount equal to 5% percent of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year, on a fully diluted basis, unless the board of directors takes action prior thereto to provide that there will not be an increase in the share reserve for such year or that the increase in the share reserve for such year will be of a lesser number of shares of common stock than would otherwise occur. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, repurchased or are otherwise terminated by the Company under the 2021 Plan will be added back to the shares of common stock available for issuance under the 2021 Plan.

The Company recorded stock-based compensation expense of $1,408,134 and $995,484 during the years ended December 31, 2025 and 2024, relating to options granted under the 2021 Plan. As of December 31, 2025 and 2024, there was $2,449,227 and $343,612 of unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the 2021 Plan, which is expected to be recognized over the next one to four years.

A summary of option activity under the 2021 Plan during the years ended December 31, 2025 and 2024 was as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term
Outstanding at January 1, 2024	4,821		
Grants	89,032	$ 13.16	9.42 years
Exercised	-		
Forfeitures or expirations	(4,447)	$ 757.08	
Outstanding at December 31, 2024	89,406	$ 14.81	9.41 years
Grants	868,901	$ 4.40	9.39 years
Exercised	-		
Forfeitures or expirations	(2,290)	$ 11.62	
Outstanding at December 31, 2025	956,017	$ 5.36	9.31 years
Vested and expected to vest at December 31, 2025	203,997		
Exercisable at December 31, 2025	203,997		

The Company's stock options issued qualify for equity accounting treatment under ASC 718, *Compensation- Stock Compensation*, and are measured at fair value as of their grant date accordingly. The fair value of the options were estimated using a Black-Scholes model. The assumptions that the Company used to estimate the grant-date fair value of stock options granted to employees and directors were as follows, shown on a weighted average basis for the respective years ended:

	2025	2024
Risk-free interest rate	4.150%	4.240%
Expected term (in years)	5.82	5.43
Expected volatility	1.4	1.5
Expected dividend yield	0%	0%

Risk-Free Interest Rate: The Company based the risk-free interest rate over the expected term of the options based on the constant maturity of U.S. Treasury securities with similar maturities as of the date of grant.

Expected Term: The expected term represents the period that the options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting dates and the end of the contractual term.)

Expected Volatility: The Company uses an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as the Company does not have sufficient trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding volatility of its own stock price becomes available.

Expected Dividend Yield: The Company has not paid and does not anticipate paying any dividends in the near future. Therefore, the expected dividend yield was zero.

The grant-date fair value of options granted during the year ended December 31, 2025 ranged from $3.44 to $4.22 and $3.46 to $13.34 for options granted during the year ended December 31, 2024.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock. Because there were no stock options with exercise prices lower than the fair value of the Company's common stock, the aggregate intrinsic value is zero as of December 31, 2025 and 2024.

On each of July 8, 2025 and November 3, 2025, the Company granted non-qualified stock options to an officer of the Company to purchase 30,000 shares of common stock at an exercise price of $4.51 and $3.80, respectively. These grants were inducement awards in accordance with Nasdaq Listing Rule 5635(c)(4) and were not granted from the 2021 Plan. The term of these options is ten years with vesting over four years. The Company recorded stock-based compensation expense of $19,135 during the year ended December 31, 2025 relating to options issued. As of December 31, 2025, there was $209,975 of unrecognized compensation cost related to nonvested share-based compensation related to the inducement grants, which is expected to be recognized over the next one to four years.

(13) Income Taxes

Cingulate Inc. is taxed as a C corporation under the Internal Revenue Code. Cingulate Inc. records deferred income taxes to reflect the impact of temporary differences between the recorded amounts of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations. CTx is a wholly-owned disregarded entity of Cingulate Inc., and all of the activity for CTx, along with its wholly-owned subsidiary Cingulate Works Inc., is included in the calculation of the current and deferred tax assets and liabilities for Cingulate Inc. No deferred income tax benefit or expense was recorded as of December 31, 2025 or December 31, 2024, for federal or state income taxes.

Income tax expense differed from the expected expense computed by applying U.S. Federal income tax rate for the respective years ended as follows:

	December 31, 2025	December 31, 2024
Federal income tax benefit at statutory rate	$ (4,714,067)	$ (3,477,517)
State income tax benefit	(300,532)	(541,359)
Discount on FMV of Shares Issued	241,641	212,858
Permanent differences	15,366	13,582
Change in valuation allowance	4,785,198	4,802,119
Research and development tax crediit- prior period	(540,085)	(972,372)
Cancellation of Debt applied to prior year NOL	514,342	
Other	(1,863)	(37,311)
Total income tax expense	$ -	$ -

At December 31, 2025, the Company has net operating loss ("NOL") carryforwards for federal income tax purposes of approximately $63,699,000. The NOL carryforwards generated do not expire and are carried forward indefinitely. The Company has state NOLs of approximately $50,852,000 at December 31, 2025. The Company also has approximately $2,269,000 of research and development tax credit carryforwards for federal purposes which have a 20-year carryforward period and will begin to expire in 2041. Due to the change in ownership provisions of the Internal Revenue Code, the availability of the Company's NOL carryforwards and research and development credit carryforwards may be subject to annual limitations under Section 382 of the Internal Revenue Code against taxable income in the future period, which could substantially limit the eventual utilization of such carryforwards.

Evaluating the need for, and amount of, a valuation allowance for deferred tax assets often requires significant judgment and extensive analysis of all available evidence on a jurisdiction-by-jurisdiction basis. Such judgments require the Company to interpret existing tax law and other published guidance as applied to its circumstances. As part of this assessment, the Company considers both positive and negative evidence about its profitability and tax situation. A valuation allowance is provided if, based on available evidence, it is more likely than not that all or some portion of a deferred tax asset will not be realized. The Company determined that it was more likely than not that it would not realize its deferred tax assets, based on historical levels of income and future forecasts of taxable income, among other items. The Company recorded a valuation allowance of its net deferred tax assets totaling $22,218,350 and $17,433,152, respectively, at December 31, 2025 and 2024, which was recorded as a component of income tax expense on the accompanying consolidated statements of operations and other comprehensive loss.

The Company files income tax returns in the U.S. federal and various state jurisdictions. The Company is not subject to U.S. federal and state income tax examinations by tax authorities for years before 2021.

The Company follows the provisions of ASC Topic 740, *Income Taxes*, to evaluate uncertain tax positions. This topic prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company has not identified any material uncertain tax positions requiring recognition in the consolidated financial statements as of December 31, 2025 or December 31, 2024.

	December 31, 2025	December 31, 2024
Deferred income tax assets:		
Current:		
Research and development costs	$ 2,914,603	$ 1,662,662
Other	1,286	443
Non-current:		
Net operating losses	15,987,951	9,314,876
Research and development costs	183,388	4,269,254
Unvested stock options	1,065,120	693,193
Research and development tax credits	2,268,580	1,728,495
Patents	145,465	146,433
Right-of-use liabilities	364,333	35,306
Gross deferred income tax assets	22,930,726	17,850,662
Less: valuation allowance	(22,218,350)	(17,433,152)
Net deferred income tax asset	712,376	417,510
Deferred income tax liabilities:		
Non-current		
Property and equipment	(348,043)	(391,634)
Right-of-use liabilities	(364,333)	(25,876)
Gross deferred income tax liabilities	(712,376)	(417,510)
Net deferred tax asset (liability)	$ -	$ -

On July 4, 2025, H.R. 1, commonly known as the One Big Beautiful Bill Act (the "OBBB"), was signed into law. This includes significant changes to the federal corporate tax provisions and extends certain otherwise expiring provisions of the 2017 Tax Cuts and Jobs Act. Among other things, the legislation reinstates expensing for domestic research and experimental expenditures, imposes new limitations on interest expense deductibility, and expands disallowed deductions for certain employee remuneration. FASB ASC 740 Income Taxes requires the effects of changes in tax rates and laws on deferred tax balances to be recognized in the period in which the relevant legislation is enacted. The OBBB may affect the Company's gross tax assets and liabilities in future periods. The Company accounted for the tax effects of the legislation during the year ended December 31, 2025, and elected to deduct domestic research and development expenses in 2025 and 2026 rather than amortize over multiple years.

(14) Leases

In May 2025, the Company executed a lease agreement to renew the office space for its headquarters in Kansas City, Kansas. The lease has a 60-month term that commenced on June 1, 2025 with total rent of $33,145 per month over the lease term.

In April 2020, the Company entered into a 60-month lease agreement for office furniture under a lease classified as a financing lease as title of the furniture transfers to the Company at the end of the lease term. Monthly lease payments are $1,491. The leased furniture is amortized on a straight-line basis over 7 years. The imputed interest rate relating to the lease obligation is 6.12% and the maturity date was in March 2025.

The components of lease cost for the years ended December 31, 2025 and 2024 were as follows:

	2025	2024
Operating lease cost	$ 366,089	$ 302,786
Finance lease cost:		
Amortization of right-of-use assets	2,747	10,990
Interest on lease liabilities	45	842
Total finance lease cost	2,792	11,832
Total lease cost	$ 368,881	$ 314,618

Amounts reported in the consolidated balance sheets as of December 31, 2025 and 2024 were as follows:

	2025	2024
Operating Leases:		
Operating lease right-of-use assets	$ 1,339,086	$ 99,011
Operating lease liability, current	238,864	130,662
Operating lease liabilities, net of current	1,100,222	-
Total operating lease liabilities	1,339,086	130,662
Finance leases:		
Property and equipment	76,928	76,928
Accumulated amortization	(76,928)	(75,759)
Property and equipment, net	-	1,169
Current installments of obligations under		
Finance lease liability, current	-	4,430
Total finance lease liabilities	$ -	$ 4,430

Other information relating to leases as of December 31, 2025 and 2024 was as follows:

Supplemental cash flow information:	2025	2024
Reductions to ROU assets resulting from reductions to lease obligations:		
Operating leases	224,485	267,886
Finance leases	2,747	10,990
Weighted average remaining lease term:		
Operating leases	53 months	5 months
Finance leases	-	3 months
Weighted average discount rate:		
Operating leases	13.25%	11.76%
Finance leases	-	6.12%

Maturities of lease liabilities under noncancellable leases as of December 31, 2025 are as follows:

	Operating leases	Finance leases
2026	397,740	-
2027	397,740	-
2028	397,740	-
2029	397,740	-
Thereafter	165,725	-
Total undiscounted lease payments	1,756,685	-
Less imputed interest	(417,599)	-
Total lease liabilities	$ 1,339,086	$ -

(15) Net Loss Per Share

Basic net loss per share is calculated by dividing net loss attributable to common shareholders by the weighted-average number of common shares and pre-funded warrants outstanding during the period. The pre-funded warrants are included in the calculation of the weighted-average number of shares outstanding because their exercise requires only nominal consideration for the delivery of shares. The following table sets forth the computation of the basic and diluted net loss per share for years ended December 31, 2025 and 2024:

	2025	2024
Numerator:		
Net loss	$ (22,449,911)	$ (16,559,605)
Denominator:		
Weighted average common shares outstanding	5,055,329	1,524,797
Net loss per share, basic and diluted	$ (4.44)	$ (10.86)

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	2025	2024
Stock options issued under the 2021 Equity Incentive Plan	956,017	89,406
Common stock purchase warrants outstanding	819,256	833,684
Total	1,775,273	923,090

(16) License Agreement

The Company has a licensing agreement with a company related to the patents and licensed know-how for use in the development of CTx-1301and CTx-1302. The Company will pay the following upon the occurrence of the following milestone events:

- $250,000 Milestone payment upon dosing of first patient in a Phase 3 Clinical Trial for each product in the field, payable on a per product basis.
- $250,000 Milestone payment upon licensee filing of new drug application for each product in the field, payable on a per product basis.
- $250,000 Milestone payment for CTx-1301 and CTx-1302 upon receipt of first marketing approval from the FDA, payable on a per product basis.

In early 2023, the Company paid the first milestone payment as the first patient in a CTx-1301 Phase 3 Clinical Trial was dosed. The second milestone payment of $250,000 was paid in September 2025 upon submission of the NDA. The Company has not recorded any expense relating to the other milestones for any other product as it has not deemed them probable of occurring as of December 31, 2025.

(17) Related Party Transactions

A member of the Company's Board of Directors, Peter Werth, is the manager of WFIA, the entity which provided $8.0 million in debt financing to the Company, $5.0 million of which was converted to equity in September 2023 and the remaining $3.0 million was converted to equity in January 2024, as described in Note 7.

(18) Subsequent Events

Management evaluated events that occurred subsequent to December 31, 2025 through March [ ], 2026, which is the date the financial statements were issued.

From January 1, 2026 through March 18, 2026, the Company entered into exchange agreements with Lender to exchange a total of $2,308,947 in principal for 460,122 shares of common stock, thereby extinguishing the remaining balance of the 2024 Note. See Note 8 for additional information regarding the 2024 Note.

From January 1, 2026 through March 18, 2026, the Company sold 210,158 shares of common stock under the ATM Agreement, for net proceeds of $1,304,011.

From January 1, 2026 through March 18, 2026, the Company sold 1,526,628 shares of common stock under the 2025 LP Purchase Agreement, for net proceeds of $8,506,791.

On January 12, 2026, the Company increased the maximum aggregate offering price of the shares of the Company's Common stock, par value $0.0001 per share issuable under the ATM Agreement from $23.5 million to $32.34 million and filed a prospectus supplement for an aggregate of $8.84 million. On March 16, 2026, the Company terminated the ATM Agreement, effective March 23, 2026.

On January 27, 2026, the Company entered into a securities purchase agreement with several purchasers, including certain officers, directors and other affiliates of the Company, for the private placement (Private Placement) of: (i) 2,147,472 shares of the Company's common stock, par value $0.0001 per share, (ii) 954 shares of Series A convertible preferred stock with a stated value of $1,000 (Stated Value) and a conversion price equal to a $5.04 per share of common stock (Preferred Stock) and (iii) a warrant (Warrant) to purchase 1,869,415 shares of common stock (Warrant Shares) for aggregate gross proceeds of approximately $12.0 million, at a price per share of $5.14 per share of common stock (including $0.10 per Warrant Share). The Warrant Shares have an exercise price of $5.04 per share of common stock, subject to adjustment as provided in the Warrant.

The closing of the Private Placement occurred on February 6 and 13, 2026. At a special meeting of stockholders scheduled for March 24, 2026, stockholders are being asked to approve the issuance of common stock upon conversion of the Preferred Stock and the exercise of the Warrant. Upon stockholder approval (i) each outstanding share of the Preferred Stock, without any further action by us or the holder, will automatically convert into shares of common stock determined by dividing the Stated Value plus all unpaid accrued and accumulated preferential dividends on such share by the $5.04 conversion price and (ii) the Warrant will be exercisable.

The following officers, directors and other affiliates participated, directly or indirectly, in the Private Placement that closed on February 6, 2026 and purchased the number of shares of our common stock and Warrant Shares set forth after their name: Shane J. Schaffer (6,809 common shares and 5,447 Warrant Shares); Jennifer L. Callahan (4,864 common shares and 3,891 Warrant Shares); Matthew N. Brams (1,946 common shares and 1,556 Warrant Shares; Peter J. Werth (19,455 common shares and 15,564 Warrant Shares); Larry Schaffer, the father of Shane Schaffer (58,366 common shares and 46,693 Warrant Shares).