As filed with the Securities and Exchange Commission on November 10, 2021

Registration No. 333-259408

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

AMENDMENT NO. 4
TO

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

CINGULATE INC.
(Exact name of registrant as specified in its charter)

Delaware	**2834**	**86-3825535**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

1901 W. 47th Place
Kansas City, KS 66205
(913) 942-2300
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Shane J. Schaffer
Chief Executive Officer
Cingulate Inc.
1901 W. 47th Place
Kansas City, KS 66205
(913) 942-2300
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to public:
As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to Be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)(3)
Common Stock, $0.0001 par value per share	$ 28,750,000	$ 2,665.13
Underwriter Warrants(4)	—	—
Shares of Common Stock underlying Underwriter Warrants(5)	$ 1,562,500	$ 144.84
Total	$ 30,312,500	$ 2,809.97

(1) Includes offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any. Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) of the Securities Act of 1933, as amended (the “Securities Act”).
(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.
(3) Previously paid.
(4) No separate registration fee required pursuant to Rule 457(g) under the Securities Act.
(5) Estimated solely for the purposes of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. The Underwriter Warrants will represent the right to purchase 5.0% of the aggregate number of shares of common stock sold in this offering, excluding the over-allotment option, at an exercise price equal to 125% of the offering price per share.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information contained in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **SUBJECT TO COMPLETION** **DATED NOVEMBER 10, 2021**

3,571,428 Shares

Common Stock

Cingulate Inc.

This is a firm commitment initial public offering of shares of common stock of Cingulate Inc. We are selling 3,571,428 shares of common stock. We anticipate that the initial public offering price will be between $6.00 and $8.00 per share of common stock.

Prior to this offering, there has been no public market for the common stock. We have applied for listing of our common stock on the Nasdaq Capital Market, or Nasdaq, under the symbol “CING.” There can be no assurance that we will be successful in listing our common stock on Nasdaq.

We are an “emerging growth company” under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements.

Investing in our common stock is highly speculative and involves a high degree of risk. See “Risk Factors” beginning on page 11 of this prospectus for a discussion of information that should be considered in connection with an investment in our common stock.

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

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions [(1)]	$	$
Proceeds to us, before expenses	$	$

(1) The underwriters will receive compensation in addition to the underwriting discount. See “Underwriting” beginning on page 142.

We have granted the underwriters an option to purchase up to 535,714 additional shares of common stock at the public offering price per share, less the underwriting discount, for 45 days after the date of this prospectus to cover over-allotments, if any. If the underwriters exercise this option in full, the total underwriting discounts and commissions will be $ and the additional proceeds to us, before expenses, from the over-allotment option exercise will be $.

The underwriters expect to deliver the shares of our common stock in the offering on or about , 2021.

Aegis Capital Corp. **Laidlaw & Company (UK) Ltd.**

The date of this prospectus is , 2021

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We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

We and the underwriters are offering to sell, and seeking offers to buy, our common stock only in jurisdictions where offers and sales are permitted. Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our common stock and the distribution of this prospectus outside of the United States.

BASIS OF PRESENTATION

In connection with the consummation of this offering, on September 29, 2021, we effected certain organizational transactions. Cingulate Inc. acquired Cingulate Therapeutics LLC, or CTx, through the merger of a wholly owned acquisition subsidiary of Cingulate with and into CTx (the "Reorganization Merger"). As a result of the Reorganization Merger, CTx became a wholly owned subsidiary of Cingulate. Unless otherwise stated or the context otherwise requires, all information in this prospectus reflects the consummation of the Reorganization Merger and this offering.

Our board of directors approved a stock dividend of 0.029 shares of common stock for each share of common stock outstanding as of the date of the dividend payable prior to the effective date of the registration statement of which the prospectus forms a part (the "Stock Dividend"), or an aggregate of 448,045 shares of common stock. The Stock Dividend became effective on September 30, 2021. No fractional shares of common stock were issued in connection with the Stock Dividend, and all such fractional interests were rounded down to the nearest whole number. Our board of directors approved the Stock Dividend for the purpose of establishing the correct number of our shares outstanding based upon our valuation prior to the offering as determined by us and the underwriters. Unless noted otherwise, all information presented in this prospectus, including the aggregate number of shares of common stock outstanding prior to the offering, reflects the Stock Dividend.

Our board of directors, with the approval of the holders of outstanding shares of our capital stock entitled to vote thereon, approved a reverse stock split (the "Reverse Stock Split") of our issued and outstanding shares of common stock at a ratio of 0.699-for-1, which reverse stock split became effective on October 12, 2021. No fractional shares of common stock were issued in connection with the reverse stock split, and all such fractional interests were rounded down to the nearest whole number. Our board of directors approved the Reverse Stock Split for the purpose of establishing the correct number of our shares outstanding based upon our valuation prior to the offering as determined by us and the underwriters. Unless noted otherwise, all information presented in this prospectus reflects the 0.699-for-1 reverse stock split of our outstanding shares of common stock.

Unless we state otherwise or the context otherwise requires, the terms (i) "we," "us," "our," "our business," "the Company" and "Cingulate" refer to and similar references refer: (1) on or following the consummation of the Reorganization Merger, including this offering, to Cingulate Inc. and its consolidated subsidiaries, including CTx, and (2) prior to the consummation of the Reorganization Merger, including this offering, to CTx and its consolidated subsidiaries.

CTx is the predecessor of the issuer, Cingulate Inc., for financial reporting purposes. Cingulate Inc. will be the reporting entity following this offering. Accordingly, this prospectus contains the historical financial statements of CTx and its consolidated subsidiaries.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider before making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto and the information set forth in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the risks materialize, our business, financial condition, operating results, and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment. Unless we state otherwise or the context otherwise requires, the terms (i) "we," "us," "our," "our business," "the Company" and "Cingulate" refer to and similar references refer: (1) on or following the consummation of the Reorganization Merger, including this offering, to Cingulate Inc. and its consolidated subsidiaries, including Cingulate Therapeutics LLC, or CTx, and (2) prior to the consummation of the Reorganization Merger, including this offering, to CTx and its consolidated subsidiaries.

Overview

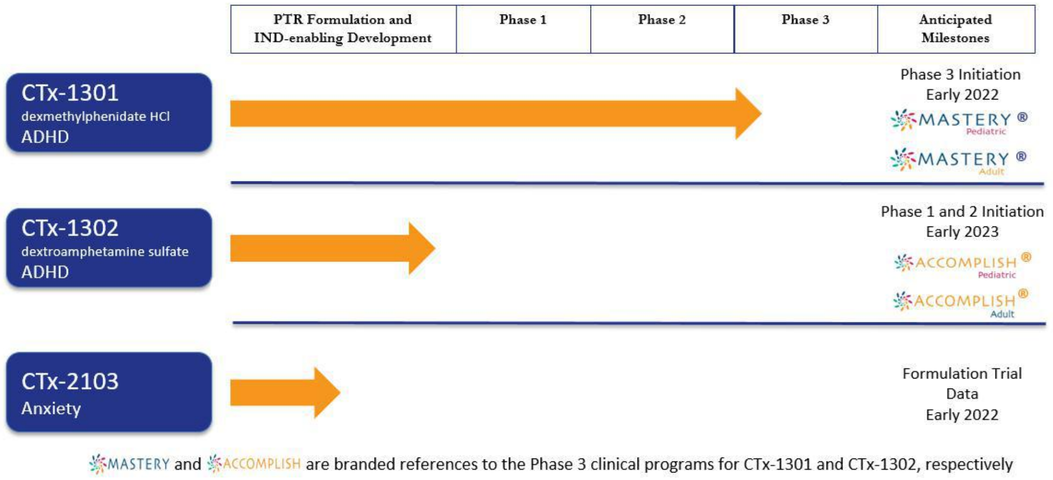
We are a clinical stage biopharmaceutical company using our proprietary Precision Timed Release, or PTR, drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. We are initially focusing our efforts on the treatment of Attention Deficit/Hyperactivity Disorder, or ADHD. Our PTR platform incorporates a proprietary Erosion Barrier Layer, or 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 initially targeting the ADHD stimulant-based treatment market, with an estimated US market size of $15.3 billion in 2020. Stimulants are the most commonly prescribed class of medications for ADHD and account for more than 90% of all ADHD medication prescriptions in the United States, where approximately 70 million stimulant prescriptions were written last year alone. By contrast, non-stimulant medications are typically employed only in the second-line or adjunctive therapy setting and account for 9-10% of all ADHD medication prescriptions. Extended-release, or long-acting, dosage forms of stimulant medications are most frequently deployed as the first-line treatment for ADHD and constitute approximately 60% of ADHD stimulant prescriptions by volume and nearly 85% of the dollars. 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 entire active-day coverage and suffer from a multitude of unwanted side effects as a result. We believe there remains a significant, unmet need within the current treatment paradigm for true once-daily ADHD stimulant medications with lasting duration and a superior side effect profile to better serve the needs of patients throughout their 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, in the three main patient segments: children (ages 6 -12), adolescents (ages 13-17), and adults (ages18+). Both CTx-1301 and CTx-1302 are designed to address the key shortcomings of currently approved stimulant therapies: to provide an immediate onset of action (within 30 minutes); offer 'entire active-day' duration; eliminate the need for a 'booster/recovery' dose of short-acting stimulant medications; minimize or eliminate the rebound/crash symptoms associated with early medication 'wear-off;' and provide favorable tolerability with a controlled descent of drug blood levels. Furthermore, by eliminating the 'booster' dose used by up to 60% of ADHD patients in conjunction with their primary medication, we believe our product candidates may 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 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. We plan to initiate Phase 3 trials in early 2022 for CTx-1301 with results expected in early 2023. Assuming we receive positive clinical results from our pivotal Phase 3 trials for CTx-1301, we plan to submit a new drug application, or NDA, for CTx-1301 using an accelerated approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act in late 2023. In addition, we plan to initiate a Phase 1/2 bioavailability study in ADHD patients for CTx-1302 in early 2023 and, if the results from this study are successful, we plan to initiate pivotal Phase 3 clinical trials in all patient segments for CTx-1302 in late 2023 with results expected in late 2024.

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 two or more active pharmaceutical ingredients (API) 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 to overcome unmet medical needs. We plan to initiate a formulation trial in human subjects for our third candidate, CTx-2103, to treat anxiety disorders in the fourth quarter of 2021. CTx-2103 contains one of the most widely prescribed anxiolytic agents which must be taken several times a day. In 2020, United States sales for this API accounted for over $2 billion of sales in the $5.2 billion anxiety market. CTx-2103 will be designed as a once-daily, multi-dose tablet with clear differentiation and compelling advantages over standard treatment options. Further indications we intend to evaluate include insomnia, non-opioid pain, eating disorders, post-traumatic stress disorder, epilepsy, Alzheimer's, hypothyroidism, psychosis, depression, cardiovascular disorders, Parkinson's disease, migraine, oral oncology, and bipolar disorder, among others.

Our Clinical Development Pipeline

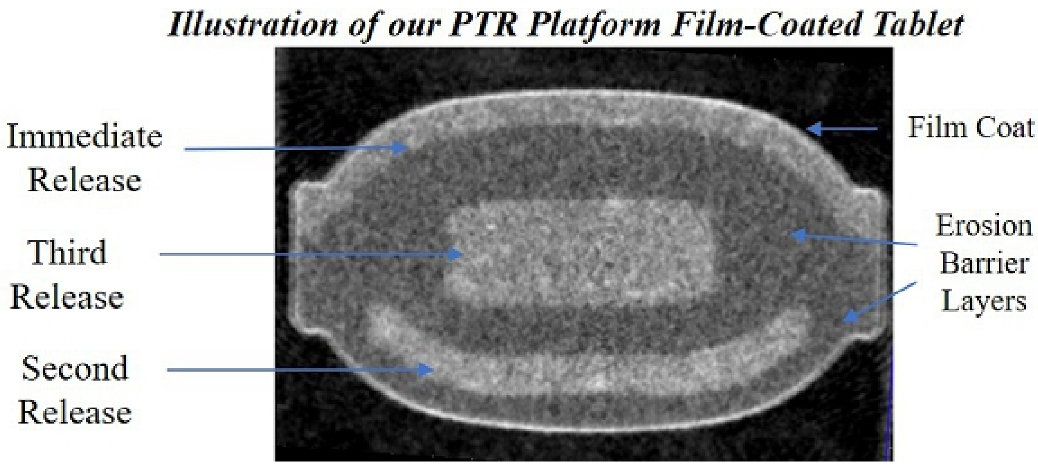


We are still in the early stages of development of our two lead product candidates, CTx-1301 and CTx-1302 for the treatment of ADHD, which are in product development (CTx-1302) and clinical development (CTx-1301) and are not yet approved. Development will require the commitment of substantial financial resources, extensive product candidate development, and clinical trials. This process can take years of effort and there can be no assurance that we will receive regulatory approval for such product candidates or any other product candidates (i.e. CTx-2103), which is necessary before they can be commercialized. Even if any of our product candidates CTx-1301, CTx-1302, and/or CTx-2103 obtain regulatory approval, they may not gain sufficient market acceptance among physicians, patients, third-party payors, and the healthcare community.

In addition, 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. Further, 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 at some time.

Our Proprietary Precision Timed Release Drug Delivery Platform Technology

We are developing ADHD medications capable of achieving true once-daily dosing using our internally developed, Precision Timed Release (PTR) drug delivery platform technology. Our CTx-1301 and CTx-1302 product candidates both contain 3 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 Erosion Barrier Layer (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 target efficacious period of up to 16 hours.



We believe our PTR technology affords our product 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 product 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.

- ***Elimination of Short-Acting Stimulant Boosters.*** With entire active-day coverage up to a 16-hour period, we believe our technology will eliminate the need for patients to take afternoon booster doses when their currently prescribed therapies wear off. By eliminating 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 be decreased.

- ***Elimination of 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, eliminating this uncomfortable experience for patients.

- ***Lower Cost.*** By providing entire active-day efficacy, our product 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 ADHD stimulant category are not significantly less expensive as they are in other categories of non-controlled medications. Generic stimulant medications cost anywhere from 55% - 90% the cost of their brand counterparts. We believe if approved, our drug candidates will offer a much more cost-effective solution to patients.

- ***Significantly Improved Tolerability.*** Because of the pharmacokinetic (PK) and pharmacodynamic (PD) profile of our product candidates, we believe patients will experience fewer treatment-related adverse events associated with existing stimulant therapies including insomnia, appetite suppression, and feelings of extreme restlessness, dysphoria, irritability, fatigue, and flattening of affect.

- ***Availability in 8 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 8 matching dosage strengths. We believe providing practitioners with the ability to properly titrate and optimize their patients’ daily dosing needs is critical. By offering 8 dosage strengths at launch, we believe we will provide a better alternative to practitioners who are currently needing to constantly switch their patients to other medications or supplement patients with more short-acting booster medications. Products that have launched with 3 dosage strengths are often ignored or avoided until at least 6 or 7 strengths are available. Both CTx-1301 and CTx-1302 contain active pharmaceutical ingredients (APIs) that are Schedule II controlled substances. The APIs of both product candidates utilize 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 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:

- Complete development and obtain regulatory approval for CTx-1301 for the treatment of ADHD.

- Advance development of CTx-1302 for the treatment of ADHD.

- Advance clinical trials for CTx-2103 for the treatment of anxiety.

- 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.

- Acquire or in-license additional assets or programs that complement our portfolio or leverage our technology.

- Further strengthen our intellectual property portfolio.

- Capitalize on our existing cGMP Manufacturing Expertise which incorporates Process Analytic Technology (PAT), continuous manufacturing, and the eventual real-time release of commercial product.

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, DuPont de Nemours, Inc. 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, Chairman 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. Laurie A. Myers, our Chief Operating Officer, has held leadership positions for leading global pharmaceutical companies, including Pfizer Inc., Novartis International AG, DuPont de Nemours, Inc. and Sanofi S.A. and has over 25 years of experience in drug development, marketing and commercialization.

Summary of Risks Associated with Our Business

Our ability to implement our business strategy is subject to numerous risks and uncertainties. You should carefully consider all of the information set forth in this prospectus and, in particular, the information in the section entitled “Risk Factors” beginning on page 11 before making an investment decision. Risks include, among others, the following:

- We are a clinical stage biopharmaceutical company with a limited operating history.

- 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.

- A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19 could cause a disruption to the development of our product candidates.

- We are dependent primarily on the successful development and commercialization of our lead products candidates, CTx-1301 and CTx-1302 for the treatment of Attention Deficit Hyperactivity Disorder, which are in product development (CTx-1302) and clinical development (CTx-1301) 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 (i.e. CTx-2103), which is necessary before they can be commercialized.

- Even if we obtain regulatory approval for CTx-1301, CTx-1302 and CTx-2103, 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, CTx-1302, and CTx-2103 as these are scheduled products, and any disruption in the chain of supply may impact production and sales of CTx-1301, CTx-1302, and CTx-2103 and cause delays in developing and commercializing our product candidates and currently manufactured and commercialized product.

- 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 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 CTx-1301, CTx-1302, and/or CTx-2103 will be significantly impacted and we may be subject to regulatory sanctions.

- 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 but these may not make it to the market.

- 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.

- No active trading market for our common stock currently exists, and an active trading market may not develop or be sustained following this offering.

For additional information about the risks we face, see the section entitled "Risk Factors."

Our Organizational Structure

Cingulate Inc. is a Delaware corporation that was formed to serve as a holding company. In connection with the consummation of this offering, on September 29, 2021, we effected certain organizational transactions. Cingulate acquired Cingulate Therapeutics LLC, or CTx, through the merger of a wholly owned acquisition subsidiary of Cingulate with and into CTx (the "Reorganization Merger"). As a result of the Reorganization Merger, CTx became a wholly owned subsidiary of Cingulate. Unless otherwise stated or the context otherwise requires, all information in this prospectus reflects the consummation of the Reorganization Merger and this offering.

Corporate Information

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 on, or that can be accessed through, our website is not part of this prospectus and should not be considered as part of this prospectus or in deciding whether to purchase our common stock.

Cingulate, PTR, Cingulate Therapeutics, Enfoqis, Enfoqus, Trodesca, Ivoqus, Taylerza, Tymprezi, Accomplish, Mastery and our logo are some of our trademarks used in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this prospectus may appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks and tradenames.

Stock Dividend

Our board of directors approved a stock dividend of 0.029 shares of common stock for each share of common stock outstanding as of the date of the dividend payable prior to the effective date of the registration statement of which the prospectus forms a part (the "Stock Dividend"), or an aggregate of 448,045 shares of common stock. The Stock Dividend became effective on September 30, 2021. No fractional shares of common stock were issued in connection with the Stock Dividend, and all such fractional interests were rounded down to the nearest whole number. Our board of directors approved the Stock Dividend for the purpose of establishing the correct number of our shares outstanding based upon our valuation prior to the offering as determined by us and the underwriters. Unless noted otherwise, all information presented in this prospectus, including the aggregate number of shares of common stock outstanding prior to the offering, reflects the Stock Dividend.

Reverse Stock Split

Our board of directors, with the approval of the holders of outstanding shares of our capital stock entitled to vote thereon, approved a reverse stock split (the "Reverse Stock Split") of our issued and outstanding shares of common stock at a ratio of 0.699-for-1, which reverse stock split became effective on October 12, 2021. No fractional shares of common stock were issued in connection with the reverse stock split, and all such fractional interests were rounded down to the nearest whole number. Our board of directors approved the Reverse Stock Split for the purpose of establishing the correct number of our shares outstanding based upon our valuation prior to the offering as determined by us and the underwriters. Unless noted otherwise, all information presented in this prospectus reflects the 0.699-for-1 reverse stock split of our outstanding shares of common stock.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our most recently completed fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of relief from certain reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- reduced obligations with respect to financial data, including presenting only two years of audited financial statements and only two years of selected financial data in this prospectus;
- an exception from compliance with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of exemptions for up to five years or such earlier time that we are no longer an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. We would cease to be an emerging growth company upon the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.07 billion in annual gross revenue or (2) following the fifth anniversary of the closing of this offering, (3) we are deemed to be a "large accelerated filer" under the rules of the U.S. Securities and Exchange Commission, or SEC, which means the market value of our securities that is held by non-affiliate exceeds $700 million, and (4) the issuance of, in any three year period, by us of more than $1.0 billion in non-convertible debt securities.

The JOBS Act also permits us, as an emerging growth company, to take advantage of an extended transition period to comply with the new or revised accounting standards applicable to public companies and thereby allow us to delay the adoption of those standards until those standards would apply to private companies. We have irrevocably elected to avail ourselves of this exemption 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.

THE OFFERING

Common stock being offered by us	3,571,428 shares.
Underwriters' over-allotment option	We have granted the underwriters an option to purchase up to 535,714 additional shares of common stock, at the public offering price, less the underwriting discounts and commissions, for 45 days from the date of this prospectus, to cover over-allotments, if any.
Common stock to be issued and outstanding after this offering(1)	14,687,208 shares (or 15,222,922 shares if the underwriters exercise in full their option to purchase additional shares of common stock)
Use of proceeds	We expect to receive net proceeds, after deducting underwriting discounts and commissions and estimated expenses payable by us, of approximately \$19.8 million (or approximately \$23.2 million if the underwriters exercise their option to purchase additional shares in full), based on an assumed initial public offering price of \$7.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus. We intend to use all of the net proceeds we receive from this offering for continued research and development and pre-commercialization planning of CTx-1301, continued research and development of CTx-1302, proof of concept study for CTx-2103, to satisfy obligations under certain related party notes, to satisfy outstanding accrued payroll expenses to employees, including our executive officers, and for working capital, capital expenditures and general corporate purposes, including investing further in research and development efforts. See "Use of Proceeds."

Lock-up	In connection with our initial public offering, our directors, executive officers, employees and 5% stockholders have agreed not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any of our common stock or securities convertible into or exchangeable for, or that represent the right to receive, shares of common stock, for a period of 180 days following the closing of the offering of the shares. This means that, subject to certain exceptions, for a period of 180 days following the closing of the offering of the shares, such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of Aegis Capital Corp. We have agreed, for a period of 365 days following the closing of the offering of the shares, that we will not, without the prior written consent of Aegis Capital Corp., issue, enter into any agreement to issue or announce the issuance or proposed issuance of any common stock, shares or share equivalents except for the issuance of shares of common stock or options to employees, consultants, officers or directors of our Company pursuant to any stock or option plan duly adopted for such purpose, approved by the Company's stockholders and issued for bona fide services permissible under Form S-8.
Underwriter Warrants	Upon the closing of this offering, we have agreed to issue to the underwriters warrants exercisable for a period of five years from the commencement of sales in this offering entitling the underwriters to purchase 5% of the number of shares of common stock sold in this offering (excluding the over-allotment option), at an exercise price equal to 125% of the public offering price. The warrants will not be exercisable for a period of 180 days from the date of commencement of sales in the offering. For additional information regarding our arrangement with the underwriters, please see "Underwriting."
Proposed Stock exchange symbol	We have applied for listing of our common stock on the Nasdaq Capital Market under the symbol "CING". No assurance can be given that our application will be approved.
Risk factors	Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 11, and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.

The number of shares of our common stock to be outstanding immediately after this offering is based on 11,115,780 shares of our common stock outstanding as of November 5, 2021 and excludes, as of such date, the following:

- 817,830 shares of our common stock issuable upon exercise of stock options to be issued to certain of our officers, directors and employees, effective as of the date of this prospectus, which options shall have an exercise price equal to the offering price of our common stock in this offering;
- 872,456 shares of our common stock that are available for future issuance under our 2021 Equity Incentive Plan (or the 2021 Plan) or shares that will become available under our 2021 Plan; and
- 178,571 shares of common stock issuable upon the exercise of the warrants to purchase shares of our common stock to be issued to the underwriters in connection with this offering based on an assumed initial public offering price of $7.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus.

Unless otherwise indicated, this prospectus reflects no exercise by the underwriters of their over-allotment option and reflects the Stock Dividend and Reverse Stock Split.

SUMMARY SELECTED FINANCIAL DATA

You should read the following summary selected financial data together with our financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the statements of operations for the nine months ended September 30, 2021 and September 30, 2020, and the balance sheet data as of September 30, 2021 from our unaudited interim financial statements appearing at the end of this prospectus. These unaudited financial statements have been prepared on a basis consistent with our audited financial statements and, in our opinion, contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such financial data. We have derived the statement of operations data for the years ended December 31, 2020 and December 31, 2019 from our audited financial statements appearing at the end of this prospectus. Our historical results are not necessarily indicative of results that should be expected in any future period.

(in thousands)	Years ended December 31		Nine Months ended September 30 (unaudited)	
	2020	**2019**	**2021**	**2020**
Statement of Operations Data:				
Operating expenses:				
Research and development	$ 5,093	$ 9,095	$ 7,147	$ 4,463
General and administrative	1,991	2,552	10,885	1,467
Loss from operations	(7,084)	(11,647)	(18,032)	(5,930)
Interest and other income (expense)	(100)	101	(24)	(60)
Loss before income taxes	$ (7,184)	$ (11,546)	$ (18,056)	$ (5,990)
Income tax benefit (expense)	-	-	-	-
Net loss	$ (7,184)	$ (11,546)	$ (18,056)	$ (5,990)

(in thousands)	As of December 31		As of September 30 (unaudited)
	2020	**2019**	**2021**
Balance Sheet Data:			
Cash, cash equivalents, and short-term investments	$ 1,199	$ 437	$ 1,916
Property and equipment, net	3,038	3,024	2,615
Total assets	5,788	5,281	9,082
Total liabilities	4,495	4,665	6,003
Accumulated deficit	(31,022)	(23,839)	(49,078)

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before you invest in our common stock, you should carefully consider the following risks, as well as general economic and business risks, and all of the other information contained in this prospectus. Any of the following risks could have a material adverse effect on our business, operating results and financial condition and cause the trading price of our common stock to decline, which would cause you to lose all or part of your investment. When determining whether to invest, you should also refer to the other information contained in this prospectus, including our financial statements and the related notes thereto.

Risks Related to Our Financial Position and Need for Capital

We are a clinical stage biopharmaceutical company with a limited operating history.

We are a clinical stage specialty pharmaceutical 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 clinical 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 current business plan, and we cannot assure you that our business plan is sound;
- successfully complete product development/formulation, and clinical trials for CTx-1301, CTx-1302, and 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;
- secure adequate intellectual property protection for our products;
- attract and retain an experienced management and advisory team;
- raise sufficient funds in the capital markets to effectuate our business plan, including the preparation and completion of our Phase 3 clinical program for CTx-1301;
- 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 collaboration with others;
- comply with post-marketing regulatory requirements;
- raise sufficient funds in the capital markets or otherwise to effectuate our business plan; and
- utilize the funds that we do have and/or raise in this offering or in the future to efficiently execute our business strategy.

If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be 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, are unlikely to generate revenues for several years, 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. We expect to incur expenses without corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize our lead product candidates, CTx-1301 and CTx-1302, and our third asset CTx-2103. 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 and/or CTx-1302, development expenses will continue to increase for CTx-2103 and any future assets. As CTx-1301 advances to clinical trials and pursuit of FDA approval we will incur additional clinical development expenses.

We have incurred recurring losses since inception and had an accumulated deficit of approximately $31.0 million as of December 31, 2020 and $49.1 million as of September 30, 2021.

As of September 30, 2021, we had capital resources consisting of cash and cash equivalents of $1.9 million. 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. 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. In particular, our Phase 3 human trials in the United States will require substantial funds to complete. 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.

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 common stock and our ability to raise capital.

Even if this offering is successful, we will need to raise additional capital to complete the development and commercialization efforts for CTx-1301 and CTx-1302 and the product formulation and development for CTx-2103. If we are unable to raise capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.

We believe that the net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations through at least the next 12 months. 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. If our currently anticipated expenditures for the development of our product candidates, CTx-1301, CTx-1302 and CTx-2103, exceed the net proceeds from this offering and our existing cash and cash equivalents, we will need to raise additional capital following this offering to fund our operations and continue to support our planned development and commercialization activities. 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 collaborations, 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;
- 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; and
- personnel, facilities and equipment requirements.

We cannot be certain that additional funding will be available on acceptable terms, or at all. In addition, future debt financing into which we 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, we may be required to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, 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 stockholders 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 CTx-1301, CTx-1302, and/or CTx-2103 with third parties in ways that we currently do not intend or on terms that may not be favorable to us or our stockholders.

Raising additional capital may cause dilution to our stockholders, including investors in this offering, 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 U.S. 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 expire unused and be unavailable to offset future income tax liabilities because of their limited duration or 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. Under the CARES Act, NOL carryforwards arising in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss. We do not anticipate that such provision of the CARES Act will be relevant to us. The deductibility of federal NOLs, particularly for tax years beginning after December 31, 2020, may be limited. It is uncertain if and to what extent various states will conform to TCJA or the CARES Act.

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, 2020 and 2019 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, 2020 and December 31, 2019 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, such as this offering, 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 will be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, or 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

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19 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. In December 2019, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes COVID-19 (coronavirus disease 2019), surfaced in Wuhan, China and has since spread worldwide. The coronavirus pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus impacts our operations or those of our third-party partners, including our development studies or clinical trial operations, will also depend on future occurrences, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. Although the majority of our operations are conducted in the United States, the continued spread of COVID-19 globally could adversely impact our product candidate development or clinical trial operations in the United States and abroad, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19. For example, similar to other biopharmaceutical companies, we may experience delays in enrolling our clinical trials currently planned for 2021-2022 (CTx-1301 and CTx-1302). COVID-19 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. In addition, the patient populations that our lead and other core product candidates target may be particularly susceptible to COVID-19, which may make it more difficult for us to identify patients able to enroll in our future clinical trials and may impact the ability of enrolled patients to complete any such trials. Any negative impact COVID-19 has to 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.

Additionally, timely enrollment in planned clinical trials is dependent upon clinical trial sites which will be adversely affected by global health matters, such as pandemics. We plan to conduct clinical trials for our product candidates in geographies that are currently being affected by the coronavirus. Some factors from the coronavirus outbreak that may delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;

- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;

- the potential negative effect on the operations of our third-party manufacturers.

- interruption in United States or global shipping, affecting the transport of raw materials for our products, clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our prospective clinical trials; and

- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including allowing our employees to work remotely, suspending all non-essential travel worldwide for our employees and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business.

We are dependent primarily on the successful development and commercialization of our lead product candidates, CTx-1301 and CTx-1302 for the treatment of Attention Deficit / Hyperactivity Disorder ("ADHD"), which are in product development (CTx-1302) and clinical development (CTx-1301) 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 (i.e. CTx-2103), which is necessary before they can be commercialized.

We are still in the early stages of development of our two lead product candidates and have not completed development of and/or obtained regulatory approval for any of our product candidates. Development will require 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, which we do not expect will occur for several years, if ever, will depend heavily on their successful development, regulatory approval, and eventual commercialization. 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 United States Drug Enforcement Administration (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.

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.

Our product development efforts with respect to CTx-1301, CTx-1302 and/or CTx-2103 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 an 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 have not submitted a marketing application such as an NDA to the FDA or any similar application to any other regulatory authority in any jurisdiction.

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 CTx-1301, CTx-1302, CTx-2103 or any other 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 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 CTx-1301, CTx-1302, CTx-2103 or any other 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 active pharmaceutical ingredient, or API, used in our product candidates;
- may identify deficiencies in our own 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.

The time and expense of the approval process, as well as the unpredictability of future clinical trial results and other contributing factors, may result in our failure to obtain regulatory approval to market, in the United States or other jurisdictions, CTx-1301, CTx-1302, our discovery stage programs, or any other drug candidates we are developing or may seek to develop in the future, which would significantly harm our business, results of operations and prospects. In such case, we may also not have the resources to conduct new clinical trials and/or we may determine that further clinical development of any such drug candidate is not justified and may discontinue any such programs.

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 is 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 or obtaining marketing approvals. 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. 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.

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 monitoring. These additional studies may require investment of significant additional resources beyond those required for regulatory approval of the drugs in adults. Approval of CTx-1301 and CTx-1302 may be delayed due to these additional requirements and this may have an adverse effect on the commercial prospects of CTx-1301 and CTx-1302, as well as delay our ability to generate product revenue, possibly materially. In addition, as a result of COVID-19 (or other potential pandemics), there may be a smaller pool of children from which we can enroll for our clinical trials. We cannot guarantee that we will receive regulatory approval to commercialize our product candidates in the pediatric populations or the adult population.

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 lead 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 products, if approved, will be regulated as "controlled substances" as defined in the Controlled Substances Act of 1970, or 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;
- the drug has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and
- abuse of the drug may lead to severe psychological or physical dependence.

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 Risk Evaluation and Mitigation Strategy, or 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. 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 Risk Evaluation and Mitigation Strategy, or 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, 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 U.S. population and U.S. 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 are preparing to conduct our first Phase 3 clinical trials with CTx-1301 and may be unable to successfully complete it or any future clinical trials for any other 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 have not conducted a Phase 3 clinical trial before, and as a result may require more time and incur greater costs than we anticipate. 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 for CTx-1301, 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 (e.g., the outbreak of COVID-19).

Even if we obtain regulatory approval for CTx-1301, CTx-1302, and CTx-2103, such approval may be limited, and we will be subject to stringent, ongoing government regulation.

Even if regulatory authorities approve CTx-1301, CTx-1302, and CTx-2103 for commercialization, they 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 CTx-1301, CTx-1302, and CTx-2103 or limit the target population for our other product candidates. The advantages of CTx-1301, CTx-1302, and CTx-2103 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 CTx-1301, CTx-1302, and CTx-2103 may not have our expected competitive advantages when compared to other similar products. 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 contract manufacturing organizations, or CMOs, 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 contract manufacturing organizations, or CMOs, 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, 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, CMOs, 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 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 U.S. Patent and Trademark Office, or 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.

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

The ability of the FDA to review and approve new products 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, statutory, regulatory, and policy changes and other events that may otherwise affect FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved or cleared by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global pandemic of COVID-19 and public health emergency declaration in the United States, on March 10, 2020 the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities and products, and it subsequently postponed routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. As of May 2021, the FDA noted it was continuing to ensure timely reviews of applications for prescription drug products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission-critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. Utilizing a rating system to assist in determining when and where it is safest to conduct such inspections based on data about the virus's trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments, FDA is either continuing to, on a case-by-case basis, conduct only mission-critical inspections, or, where possible to do so safely, resuming prioritized domestic inspections, which generally include pre-approval inspections. Foreign pre-approval inspections that are not deemed mission-critical remain postponed, while those deemed mission-critical will be considered for inspection on a case-by-case basis. FDA will use similar data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so. The FDA may not be able to maintain this pace and delays or setbacks are possible in the future.

Should FDA determine that an inspection is necessary for NDA approval and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. Additionally, regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown or slowdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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.

Risks Related to Commercialization

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, the Patient Protection and Affordable Care Act, (or PPACA,) was enacted in 2010 to expand healthcare coverage. Since then, numerous efforts have been made to repeal, amend or administratively limit the PPACA in whole or in part. For example, the Tax Cuts and Jobs Act (TCJA), signed into law by President Trump in 2017, repealed the individual health insurance mandate, which is considered a key component of the PPACA. In December 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate was a critical and inseverable feature of the PPACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the PPACA were invalid and the law in its entirety was unconstitutional. In December 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether other reforms enacted as part of the PPACA but not specifically related to the individual mandate or health insurance could be severed from the rest of the PPACA so as not to be declared invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and allocated one hour for oral arguments, which occurred on November 10, 2020. A decision from the Supreme Court is expected to be issued in spring 2021. It is unclear how this litigation and other efforts to repeal and replace the PPACA will impact the implementation of the PPACA, the pharmaceutical industry more generally, and our business. Complying with any new legislation or reversing changes implemented under the PPACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Efforts to control prescription drug prices could also have a material adverse effect on our business. Among other pharmaceutical manufacturer industry-related proposals, Congress has proposed bills to change the Medicare Part D benefit to impose an inflation-based rebate in Medicare Part D and to alter the benefit structure to increase manufacturer contributions in the catastrophic phase. The volume of drug pricing-related bills proposed by Congress has dramatically increased, and the resulting impact on our business is uncertain and could be material.

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 U.S. 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, the Biden Administration, including his nominee for Secretary of DHHS, has 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 U.S., 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 U.S. 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.

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 CTx-1301, CTx-1302, and/or CTx-2103 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 CTx-1301, CTx-1302, and/or CTx-2103 will depend on many factors, including:

- the efficacy and potential advantages of CTx-1301, CTx-1302, and/or CTx-2103 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 CTx-1301 and/or CTx-1302;
- 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 relative to competing products;
- the ability to manufacture all our products CTx-1301, CTx-1302 as well as CTx-2103 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 CTx-1301 and/or CTx-1302 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.

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 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 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 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

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 and 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 on limited sources of supply for CTx-1301, CTx-1302, and CTx 2103 as these are scheduled products, and any disruption in the chain of supply may impact production and sales of CTx-1301, CTx-1302, and CTx-2103 and cause delays in developing and commercializing our product candidates and currently manufactured and commercialized product.

The NDAs we plan to submit for CTx-1301, CTx-1302, and CTx-2103 will include our proposed manufacturing process for each product candidate. Any change to our manufacturing process, facilities or suppliers could require that we amend our NDA. Any change to our manufacturing process, facilities or suppliers could require that we amend our NDA. 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 a time- consuming and costly endeavor. This would also require us to supplement our NDA filings to include the change of manufacturing site. 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.

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 lead 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.

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 CMO 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.

We have entered into agreements with CMOs for the clinical-stage manufacturing of our drug candidates, CTx-1301 and CTx-1302, and we plan to enter into agreements with one or more manufacturers to manufacture, supply, store, and distribute drug supplies for our current and future clinical trials and/or commercial sales. 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 CMOs. 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 CMOs 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 CMOs for compliance with cGMPs. Our agreements with our CMOs require them 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 CMOs to implement and maintain these standards. If our CMOs 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 CMO that can comply with such requirements, which we may not be able to do. Any such failure by any of our CMOs 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 third-party manufacturers, 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 third-party contract manufacturer to maintain DEA regulations as pertain 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 poses 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 contract manufacturer 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.

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 clinical research organizations (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 may seek collaborations with third parties for the development or 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.

We may seek third-party collaborators for the development and commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators include regional, national and international large and mid-size pharmaceutical companies. If we do enter into any collaboration arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our 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. Collaborations involving our product candidates would pose the following risks, including but not limited to:

- 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; 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.

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 establish 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 collaborate with pharmaceutical companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement 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.

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 CTx-1301, CTx-1302, and/or CTx-2103 will be significantly impacted and we may be subject to regulatory sanctions.

We may retain third-party service providers to perform a variety of functions related to the sale and distribution of any or all of our products 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. We would substantially rely on these third-party providers to perform services for us. 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 or 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 CTx-1301, CTx-1302, and CTx-2103 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 CTx-1301, CTx-1302 and/or CTx-2103 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 CTx-1301, CTx-1302 and/or CTx-2103 unless coverage is provided, and reimbursement is adequate to cover a significant portion of its cost.

In addition, in many foreign countries, particularly the countries of 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 some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products CTx-1301, CTx-1302, and/or CTx-2103 to other available therapies. We may face competition for CTx-1301 and/or CTx-1302 from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with CTx-1301, CTx-1302, and/or CTx-2103, which could negatively impact our profitability.

We believe CTx-1301, CTx-1302, and CTx-2103 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, CTx-1301, CTx-1302, and/or CTx-2103 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 CTx-1301, CTx-1302, and CTx-2103, and any future 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 CTx-1301, CTx-1302, and CTx-2103, 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 U.S. federal and state governments and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- 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;

- the federal Health Insurance Portability and Accountability Act of 1996, or 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 U.S. 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 the Health Information Technology and Clinical Health Act of 2009, or 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 Centers for Medicare and Medicaid Services, or 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 products.

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 CTx-1301, CTx-1302, or any other product candidate. 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 will 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 are not adequate to support our business plan and near-term future growth. We will need to further expand our chemistry and 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 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 CTx-1301, CTx-1302, or CTx-2103. As a result, we must build this organization, or enter into a marketing collaboration with a third party, in order to commercialize CTx-1301, CTx-1302, and CTx-2103. The establishment and development of our own sales force in the United States to market CTx-1301, CTx-1302, and CTx-2103 will 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.

We also intend to enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States and may also enter into strategic partnerships with third parties for certain aspects of our commercialization efforts within the United States. We may 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. 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 may not make it to the market.

Our development research and clinical development efforts to date have resulted in two product candidates, CTx-1301 and CTx-1302. 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 you make 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;
- 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 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. 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.

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, U.S. 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 U.S. 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 U.S. 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 typically 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 candidates, we will be required to certify 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 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 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, CTx-1302, and/or CTx-2103 and 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.

Risks Related to this Offering, the Securities Markets and Ownership of Our Common Stock

No active trading market for our common stock currently exists, and an active trading market may not develop or be sustained following this offering.

Prior to this offering, there has not been an active trading market for our common stock. If an active trading market for our common stock does not develop following this offering, you may not be able to sell your shares quickly or at the market price. Our ability to raise capital to continue to fund operations by selling shares of our common stock and our ability to acquire other companies or technologies by using shares of our common stock as consideration may also be impaired. The initial public offering price of our common stock will be determined by negotiations between us and the underwriters and may not be indicative of the market prices of our common stock that will prevail in the trading market.

The prices of our securities may be volatile, which could subject us to securities class action litigation and prevent you from being able to sell your shares at or above the offering price.

The initial public offering price for our shares will be determined by negotiations between us and the underwriters based on several factors. This price may vary from the market price of our common stock after this offering. You may be unable to sell your shares of common stock at or above the initial offering price. The market price for our common stock 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 shares; 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 by us, our insiders or our other stockholders; and
- general economic, market or political conditions in the United States or elsewhere (including, without limitation, conditions arising out the COVID-19 pandemic).

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 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 to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and Nasdaq Capital Market 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 common stock 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 could be an "emerging growth company" for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 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 common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and the price of our common stock may be more volatile.

As a public company, we will be 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 common stock.

Pursuant to Section 404 of Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2022. 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. 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 may decline.

We cannot assure you that there will not be 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 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 a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and will be 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 of directors, 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 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 will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. If we obtain securities or industry analyst coverage and 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 or securities convertible into our common stock may depress our stock price.

Sales of a substantial number of shares of our common stock or securities convertible into our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have 14,687,208 outstanding shares of common stock, based on the number of shares issued and outstanding as of November 5, 2021, that may be sold after the expiration of lock-up agreements at least 180 days after the closing of the offering of the shares, unless held by an affiliate of ours, as more fully described in the section entitled “Shares Eligible for Future Sale.” Moreover, we also intend to register all shares of common stock that we may issue after this offering under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements. If a large number of shares of our common stock or securities convertible into our common stock are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our common stock and impede our ability to raise future capital. See “Shares Eligible for Future Sale.”

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock.

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

Anti-takeover provisions contained in our certificate of incorporation and bylaws to be adopted upon the closing of this offering, as well as provisions of Delaware law, could impair a takeover attempt.

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

- classifying our board of directors into three classes;
- authorizing "blank check" preferred stock, which could be issued by our board of directors 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 of directors;
- controlling the procedures for the conduct and scheduling of board of directors and stockholder meetings; and
- providing our board of directors 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 and could also affect the price that some investors are willing to pay for our common stock.

Because management has broad discretion as to the use of the net proceeds from this offering, you may not agree with how we use them, and such proceeds may not be applied successfully.

Our management will have considerable discretion over the use of proceeds from this offering. We currently intend to use the net proceeds from this offering for continued research and development and pre-commercialization planning of CTx-1301, continued research and development of CTx-1302, proof of concept study for CTx-2103, and for working capital, capital expenditures, and general corporate purposes, including investing further in research and development efforts. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock, or that you otherwise do not agree with. You will be relying on the judgment of our management concerning these uses and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The failure of our management to apply these funds effectively could, among other things, result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline.

If you purchase shares of common stock sold in this offering, you will incur immediate and substantial dilution.

If you purchase shares of our common stock in this offering, you will experience substantial and immediate dilution in the pro forma net tangible book value per share after giving effect to this offering of $5.44 per share as of September 30, 2021, based on an assumed initial public offering price of $7.00 per share, which is the midpoint of the estimated offering price range set forth on the cover of this prospectus, because the price that you pay will be substantially greater than the pro forma net tangible book value per share of the common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased shares of our capital stock. You will experience additional dilution upon exercise of the outstanding stock options and other equity awards that may be granted under our equity incentive plans, and when we otherwise issue additional shares of our common stock. For more information, see “Dilution.”

Except with respect to the Stock Dividend, we have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

Except with respect to the Stock Dividend, we have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future. Our board of directors approved the Stock Dividend for the purpose of establishing the correct number of our shares outstanding based upon our valuation prior to the offering as determined by us and the underwriters. 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 after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

Our directors, executive officers and principal stockholders will continue to have substantial control over us after this offering and could delay or prevent a change of corporate control.

Upon completion of this offering, our directors, executive officers and holders of more than 5% of our common stock, together with their affiliates, will beneficially own, in the aggregate, 34.80% of our outstanding common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of us.

See “Principal Stockholders” below for more information regarding the ownership of our outstanding stock by our executive officers, directors and holders of more than 5% of our common stock, together with their affiliates.

Our amended and restated certificate of incorporation will designate 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, which will become effective upon the closing of this offering, will require 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 Securities Exchange Act of 1934, as amended, or 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.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This prospectus contains forward-looking statements 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 this prospectus 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 lack of operating history;
- our plans to develop and commercialize our product candidates;
- the timing of our planned clinical trials for CTx-1301, CTx-1302, and CTx-2103;
- the timing of our NDA submissions for CTx-1301, CTx-1302, and CTx-2103;
- the timing of and our ability to obtain and maintain regulatory approvals for CTx-1301, CTx-1302, CTx-2103, or any other future product candidate;
- the clinical utility of our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expected use of proceeds from this offering; our competitive position and the development of; 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 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, expenses and needs for additional financing.

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" section of this prospectus 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. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and 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 prospectus 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, however, review the factors and risks and other information we describe in the reports we will file from time to time with the SEC after the date of this prospectus.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

INDUSTRY AND OTHER DATA

We obtained the industry, statistical and market data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. While we are responsible for all disclosure in this prospectus and believe that each of these studies and publications is reliable, the industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by us.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $19.8 million (or approximately $23.2 million if the underwriters exercise in full their option to purchase additional shares), assuming the sale of shares of our common stock at an assumed initial public offering price of $7.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our financial flexibility, create a public market for our common stock and to facilitate our access to the public equity markets. We intend to use all of the net proceeds we receive from this offering for continued research and development and pre-commercialization planning of CTx-1301, continued research and development of CTx-1302, the proof of concept study for CTx-2103, to satisfy obligations under certain related party notes, to satisfy outstanding accrued payroll expenses to employees, including our executive officers, and for working capital, capital expenditures and general corporate purposes, including investing further in research and development efforts. We currently expect to use the net proceeds from this offering as follows:

- approximately $13.0 million for continued research and development and pre-commercialization planning of CTx-1301;
- approximately $0.3 million for continued research and development of CTx-1302;
- approximately $0.7 million for proof of concept study for CTx-2103;
- approximately $0.4 million for the repayment of the Related Party Notes;
- approximately $1.7 million to satisfy outstanding accrued payroll expenses to employees, including our executive officers; and
- the remainder for working capital, capital expenditures and general corporate purposes, including investing further in research and development efforts.

We believe that the net proceeds of this offering, together with our existing cash, will enable us to fund our operations for at least 12 months, including the continuation of our planned clinical trials for CTx-1301 and continued research and development of CTx-1302. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. With respect to commercialization of CTx-1301 and CTx-1302, we expect that we will require additional funds.

Although we currently anticipate that we will use the net proceeds from this offering as described above, there may be circumstances where a reallocation of funds is necessary. The amounts and timing of our actual expenditures will depend upon numerous factors, including our sales and marketing and commercialization efforts, demand for our products, our operating costs and the other factors described under “Risk Factors” in this prospectus. Accordingly, our management will have flexibility in applying the net proceeds from this offering. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

Each $1.00 increase (decrease) in the assumed initial public offering price of $7.00 per share (the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $3.3 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 1,000,000 in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $6.4 million, assuming the initial public offering price stays the same. We do not expect that a change in the offering price or the number of shares by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

Except with respect to the Stock Dividend, 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 of directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

CAPITALIZATION

The following table sets forth our cash and marketable securities and capitalization as of September 30, 2021:

- of Cingulate Inc. on an actual historical basis; and

- of Cingulate Inc. on an as adjusted basis, after giving effect to our sale of 3,571,428 shares of common stock in this offering at an assumed initial public offering price of $7.00 per share (which is the midpoint of the public offering price range set forth on the cover page of this prospectus) after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us (assuming no exercise of the underwriters' option to purchase additional shares) and (iii) the use of a portion of the proceeds from the offering for the repayment the Related Party Notes and to satisfy outstanding accrued payroll expenses to employees, including our executive officers.

You should read this table in conjunction with the unaudited condensed consolidated financial statements and the related notes, "Use of Proceeds" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	September 30, 2021 (unaudited)	
	Actual	**Pro Forma As Adjusted**
Cash and cash equivalents	$ 1,915,415	$ 20,284,282
Related Party Notes Payable	$ 350,335	$ -
Stockholders' equity:		
Common stock; $0.0001 par value per share; 11,115,780 shares outstanding actual; 14,687,208 shares outstanding on a pro forma as adjusted basis	1,112	1,469
Additional paid-in capital	52,156,476	71,923,376
Accumulated deficit	(49,078,372)	(49,078,372)
Total stockholders' equity	$ 3,079,216	$ 22,846,472
Total capitalization	$ 3,429,551	$ 22,846,472

Each $1.00 increase (decrease) in the assumed initial public offering price of $7.00 per share (the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) our cash and cash equivalents, total stockholders' equity and total capitalization on a pro forma as adjusted basis by approximately $3.3 million, assuming the number of shares, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares offered by us would increase (decrease) our cash and cash equivalents, total stockholders' equity and total capitalization on a pro forma as adjusted basis by approximately $6.4 million, assuming the assumed initial public offering price of $7.00 per share (the midpoint of the price range set forth on the cover page of this prospectus) remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of September 30, 2021, we had a net tangible book value of $3.1 million, or $0.28 per share of common stock. Our net tangible book value per share represents total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding as of September 30, 2021.

After giving effect to the sale of shares of common stock in this offering at an assumed initial public offering price of $7.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2021 would have been approximately $22.8 million, or approximately $1.56 per share. This amount represents an immediate increase in net tangible book value of $1.28 per share to our existing stockholders and immediate dilution of approximately $5.44 per share to new investors in this offering. We determine dilution by subtracting the as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock in this offering. The following table illustrates this dilution:

Assumed initial public offering price per share			$	7.00
Pro Forma tangible book value per share of common stock as of September 30, 2021	$	0.28		
Increase in net tangible book value per share attributable to this offering	$	1.28		
Pro forma, as adjusted, net tangible book value per share after this offering			$	1.56
Dilution per share to new investors purchasing common stock in this offering			$	5.44

The dilution information discussed above is illustrative only and may change based on the actual initial public offering price and other terms of this offering.

A $1.00 decrease in the assumed initial public offering price of $7.00 per share (the midpoint of the price range set forth on the cover page of this prospectus) would decrease our pro forma as adjusted net tangible book value after this offering by approximately $3.3 million, or approximately $0.22 per share, and would increase dilution to investors in this offering by approximately $0.22 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discount and estimated offering expenses payable by us. A $1.00 increase in the assumed initial public offering price of $7.00 per share (the midpoint of the price range set forth on the cover page of this prospectus) would increase our pro forma as adjusted net tangible book value after this offering by approximately $3.3 million, or approximately $0.22 per share, and would decrease dilution to investors in this offering by approximately $0.22 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discount and estimated offering expenses payable by us.

We may also increase or decrease the number of shares we are offering. An increase of 1,000,000 in the number of shares we are offering would increase our pro forma as adjusted net tangible book value after this offering by approximately $6.4 million, or approximately $0.31 per share, and would decrease dilution to investors in this offering by approximately $0.31 per share, assuming the assumed initial public offering price per share remains the same, after deducting the estimated underwriting discount and estimated offering expenses payable by us. A decrease of 1,000,000 in the number of shares we are offering would decrease our pro forma as adjusted net tangible book value after this offering by approximately $6.4 million, or approximately $0.35 per share, and would decrease dilution to investors in this offering by approximately $0.35 per share, assuming the assumed initial public offering price per share remains the same, after deducting the estimated underwriting discount and estimated offering expenses payable by us.

Each 1,000,000 share increase in the number of shares offered by us together with a concomitant $1.00 increase in the assumed initial public offering price of $7.00 per share (the midpoint of the estimated price range set forth on the cover page of this prospectus) would increase the pro forma as adjusted net tangible book value by $0.57 per share and the dilution to new investors by $0.57 per share, after deducting underwriting discounts and commissions and any estimated offering expenses payable by us.

Conversely, each 1,000,000 share decrease in the number of shares offered by us together with a concomitant $1.00 decrease in the assumed initial public offering price of $7.00 per share (the midpoint of the estimated price range set forth on the cover page of this prospectus) would decrease the pro forma as adjusted net tangible book value by $0.52 per share and the dilution to new investors by $0.52 per share, after deducting underwriting discounts and commissions and any estimated offering expenses payable by us.

The pro forma as adjusted information presented in the discussion above is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their option to purchase additional shares of our common stock in full, the pro forma as adjusted net tangible book value after this offering would be approximately $26.3 million, the increase in pro forma net tangible book value per share would be approximately $1.45 and the dilution per share to new investors would be approximately $5.28 per share, in each case assuming an initial public offering price of $7.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

The following table summarizes, as of September 30, 2021, on the pro forma as adjusted basis described above, the differences between the number of shares purchased from us, the total consideration paid to us in cash and the average price per share that existing stockholders and new investors paid for such shares. The calculation below is based on an assumed initial public offering price of $7.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per Share
Existing stockholder	11,115,780	76%	$ 38,765,190	61%	$ 3.49
New investors	3,571,428	24%	$ 25,000,000	39%	$ 7.00
Total	14,687,208	100%	$ 63,765,189.61	100%	$ 4.34

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to 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 prospectus 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 clinical stage biopharmaceutical company using our proprietary Precision Timed Release, or 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. We are initially focusing our efforts on the treatment of Attention Deficit/Hyperactivity Disorder, or ADHD. Our PTR platform incorporates a proprietary Erosion Barrier Layer, or 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 initially targeting the ADHD stimulant-based treatment market, with an estimated US market size of $15.3 billion in 2020. Stimulants are the most commonly prescribed class of medications for ADHD and account for more than 90% of all ADHD medication prescriptions in the United States, where approximately 70 million stimulant prescriptions were written last year alone. By contrast, non-stimulant medications are typically employed only in the second-line or adjunctive therapy setting and account for 9-10% of all ADHD medication prescriptions. Extended-release, or long-acting, dosage forms of stimulant medications are most frequently deployed as the first-line treatment for ADHD and constitute approximately 60% of ADHD stimulant prescriptions by volume and nearly 85% of the dollars. 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 entire active-day coverage and suffer from a multitude of unwanted side effects as a result. We believe there remains a significant, unmet need within the current treatment paradigm for true once-daily ADHD stimulant medications with lasting duration and a superior side effect profile to better serve the needs of patients throughout their entire active-day.

Since inception in 2013, our operations have focused on developing our product candidates, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials. We do not have any product candidates approved for sale and have not generated any revenue. We have funded our operations through private capital raised. Cumulative capital raised from all financing rounds, was approximately $38.8 million as of September 30, 2021.

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 $7.2 million and $11.5 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $31.0 million. Our net losses were $18.0 million and $6.0 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $49.1 million.

We expect to continue to incur significant expenses and increasing operating losses in the near term. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- seek regulatory approval for our product candidates;
- continue research and development activities for our existing and new product candidates;

- manufacture supplies for our preclinical studies and clinical trials;
- operate as a public company; and
- build commercial infrastructure to support sales and marketing for our product candidates.

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.

Trends and Uncertainties – COVID-19

We are subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the impact of the COVID-19 pandemic on our business is highly uncertain and difficult to predict, as the responses that we, other businesses and governments are taking continue to evolve. Furthermore, capital markets and economies worldwide have also been negatively impacted by the COVID-19 pandemic, and it is possible that it could cause a local and/or global economic recession. Policymakers around the globe have responded with fiscal policy actions to support the healthcare industry and economy as a whole. The magnitude and overall effectiveness of these actions remain uncertain.

The severity of the impact of the COVID-19 pandemic on our business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on our service providers, suppliers, contract research organizations and our preclinical and clinical trials, all of which are uncertain and cannot be predicted.

As of the date of this prospectus, the extent to which the COVID-19 pandemic may in the future materially impact our financial condition, liquidity or results of operations is uncertain.

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, or 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 facilities, depreciation and other allocated expenses; and
- fees paid for contracted regulatory services as well as fees paid to regulatory authorities including the US Food and Drug Administration 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. Excluding the current period noncash expense relating to profits interest units as described below, 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 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. As we advance both CTx-1301, CTx-1302, and CTx-2103, as well as identify any other potential project candidates, we will continue to allocate our direct external research and development costs to the products. We expect to fund our research and development expenses from our current cash and cash equivalents, the net proceeds from this offering and any future debt financings, or other capital sources, including potential collaborations with other companies or other strategic transactions.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for our employees in administrative, executive and finance functions. General and administrative expenses also include professional fees for legal, accounting, audit, tax and consulting services, insurance, office, and travel expenses.

Excluding the current period noncash expense relating to profits interest units as described below, we expect that our general and administrative expenses will increase in the future as we increase our general and administrative headcount to support our continued research and development and potential commercialization of our product candidates. We also expect to incur 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.

Interest and other income (expense), net

Interest and other income (expense), net consists of interest earned on our short-term investments. The primary objective of our investment policy is liquidity and capital preservation.

Interest expense to date has consisted primarily of interest expense on notes payable to related parties, interest charged by certain vendors, and credit card interest.

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 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 financial statements appearing at the end of this prospectus, we believe that the following accounting policies are those most critical to the judgements and estimates used in the preparation of our 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 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.

Profits Interest Units

CTx established and adopted the Cingulate Therapeutics LLC Equity Incentive Plan to provide for issuance of Class C Profits Interest Units (PIU's) to employees, equity Members, Board members and service providers of the Company, as defined in the Plan, eligible to receive PIU's as an incentive under the Plan. As defined in the Company's Operating Agreement, all PIU's issued under the Plan entitle the holder to participate pro rata in the profits, if any, of the Company over the stated Distribution Threshold, assuming a cash distribution is generally made to all Members, subject to any preference or priorities of the other classes of Units. The Class C PIU's also hold voting rights on a one-for-one basis.

The Company accounted for these awards under *ASC Topic 718, Compensation – Stock Compensation, Share Based Payment Awards*, as equity classified thus recording compensation expense during the period in which the future achievement of the thresholds and targets to achieve payout is deemed probable. In connection with the Reorganization Merger, 8.5 million PIUs were exchanged for 1,158,008 shares of Cingulate common stock. The exchange of PIUs for common stock created a modification of the terms, character and rights of the PIUs and achievement of performance was considered probable. This resulted in the the Company recognizing a noncash modification charge equal to $12,738,088, which charge was calculated based on the Company's assessment of the the fair value of the shares of Cingulate common stock on the date of the modification. No compensation expense had been recognized relating to the PIUs prior to the Reorganization Merger.

Results of Operations

Comparison of the nine months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine-month periods ended September 30, 2021 and 2020:

(in thousands)	Nine months ended September 30, 2021	Nine months ended September 30, 2020	Increase (Decrease)	% Increase (Decrease)
Operating expenses:				
Research and development	$ 7,147	$ 4,463	$ 2,684	60.1%
General and administrative	10,885	1,467	9,418	642.0%
Loss from operations	(18,032)	(5,930)	12,102	204.1%
Interest and other income (expense)	(24)	(60)	(36)	(60.0)%
Loss before income taxes	(18,056)	(5,990)	12,066	201.4%
Income tax benefit (expense)	-	-	-	-
Net loss	$ (18,056)	(5,990)	12,066	201.4%

Research and development expenses

The following table summarizes our research and development expenses for the nine-month periods ended September 30, 2021 and 2020:

(in thousands)	Nine months ended September 30, 2021	Nine months ended September 30, 2020	Increase (Decrease)	% Increase (Decrease)
Clinical operations	$ 35	$ 2,265	$ (2,230)	(98.5)%
Drug manufacturing and formulation	1,271	923	348	37.7%
Personnel expenses	5,591	1,028	4,563	443.8%
Product development	225		225	
Regulatory costs	25	247	(222)	(89.9)%
Total research and development expenses	$ 7,147	$ 4,463	$ (2,684)	60.1%

Research and development (R&D) expenses were $7.1 million for the nine months ended September 30, 2021, an increase of $2.7 million or 60.1%, from the nine months ended September 30, 2020. This increase was related to an allocation of $4.6 million to R&D personnel expenses of a one-time noncash compensation charge for the modification of PIUs which occurred in the third quarter of 2021, offset by a decrease in clinical operations expenses of $2.2 million due to a decrease in clinical activity. In early 2020, we incurred significant clinical costs relating to the completion of the phase 1/2 comparative bioavailability study for CTx-1301. During the first nine months of 2021, we incurred little clinical activity due to constraints in capital funding; however, manufacturing activity has occurred relating to the preparation of Phase 3 clinical supply for CTx-1301.

General and administrative expenses

The following table summarizes our general and administrative (G&A) expenses for the nine-month periods ended September 30, 2021 and 2020:

(in thousands)	Nine months ended September 30, 2021	Nine months ended September 30, 2020	Increase (Decrease)	% Increase (Decrease)
Personnel expenses	$ 9,132	$ 825	$ 8,307	1006.9%
Legal and professional fees	1,056	277	779	281.2%
Occupancy	322	268	54	20.1%
Marketing and branding	49	-	49	
Other	326	97	229	236.0%
Total general and administrative expenses	$ 10,885	$ 1,467	$ 9,418	642.0%

Total G&A expenses were $10.9 million for the nine months ended September 30, 2021, an increase of $9.4 million or 642.0% from the nine months ended September 30, 2020. This increase was primarily related to an allocation of $8.1 million to G&A personnel expenses of a one-time noncash compensation charge relating to the modification of PIUs which occurred in the third quarter of 2021. In addition, legal and professional fees increased $0.8 million due to legal, consulting and audit fees relating to transactional work in 2021.

Comparison of the years ended December 31, 2020 and December 31, 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

(in thousands)	Years ended December 31, 2020	Years ended December 31, 2019	Increase (Decrease)	% Increase (Decrease)
Operating expenses:				
Research and development	$ 5,093	$ 9,095	$ (4,002)	(44.0)%
General and administrative	1,991	2,552	(561)	(21.9)%
Loss from operations	(7,084)	(11,647)	(4,563)	(39.2)%
Interest and other income (expense), net	(100)	101	201	199%
Net loss	$ (7,184)	$ (11,546)	$ (4,362)	37.8%

Research and development expenses

The following table summarizes our research and development expenses for the years ended December 31, 2020 and 2019:

(in thousands)	Years ended December 31, 2020	Years ended December 31, 2019	Increase (Decrease)	% Increase (Decrease)
Clinical operations	$ 2,277	$ 1,353	$ 924	68.3%
Drug manufacturing and formulation	1,177	6,049	(4,872)	(80.5)%
Personnel expenses	1,293	1,516	(223)	(14.7)%
Regulatory costs	346	177	169	95.4%
Total research and development expenses	$ 5,093	$ 9,095	$ (4,002)	(44.0)%

Research and development (R&D) expenses were $5.1 million for the year ended December 31, 2020, a decrease of $4.0 million or 44.0% from the year ended December 31, 2019. This decrease was primarily due to a decrease in overall R&D activity due to constraints in capital funding as well as the timing of the COVID-19 pandemic. Costs incurred relating to clinical operations increased from 2019 to 2020 due to the completion of the phase 1/2 comparative bioavailability study for CTx-1301 in early 2020. Manufacturing costs decreased significantly from 2019 to 2020 as the manufacturing of product to be used for the bioavailability study occurred in 2019 and very little manufacturing activity occurred in 2020.

General and administrative expenses

The following table summarizes our general and administrative (G&A) expenses for the years ended December 31, 2020 and 2019:

(in thousands)	Years ended December 31, 2020	Years ended December 31, 2019	Increase (Decrease)	% Increase (Decrease)
Personnel expenses	$ 917	$ 1,023	$ (106)	(10.4)%
Legal and professional fees	511	536	(25)	(4.7)%
Occupancy	371	321	50	15.6%
Marketing and branding	-	250	(NM)	-
Other	192	422	(230)	(54.5)%
Total general and administrative expenses	$ 1,991	$ 2,552	$ (561)	(22.0)%

Total G&A expenses were $2.0 million for the year ended December 31, 2020, a decrease of $0.6 million or 22.0% from the year ended December 31, 2019. This decrease was due to a decrease in market research and brand management activity from 2019 to 2020 as well as an overall decrease in certain operating costs including travel, meals, conferences, etc. from 2019 to 2020 due to the COVID-19 pandemic. Personnel expenses declined from 2019 to 2020 primarily due to a Paycheck Protection Program (PPP) loan obtained in 2020 which offsets certain payroll costs.

Interest and other income (expense)

The following table summarizes interest and other income (expense) for the years ended December 31, 2020 and 2019:

(in thousands)	Years ended December 31, 2020	Years ended December 31, 2019	Increase (Decrease)	% Increase (Decrease)
Interest and other income (expense), net	$ (100)	$ 101	$ 201	199%

Total interest and other income (expense), net in 2020 primarily relates to interest incurred on outstanding notes payable as well as interest charged by certain development vendors on outstanding balances. Other income in 2019 relates to interest and dividends earned on short-term investment balances as well as realized gains on the sale of short-term investments.

Cash Flows

(in thousands)	Year ended December 31, 2020	Year ended December 31, 2019	Increase (decrease)	Nine months ended September 30, 2021	Nine months ended September 30, 2020	Increase (decrease)
Net cash (used in) operating activities	$ (6,811)	$ (9,533)	$ 2,722	$ (5,810)	$ (4,146)	$ 1,664
Net cash (used in) investing activities	(384)	2,743	(3,127)	(104)	(671)	(567)
Net cash provided by financing activities	7,974	6,145	1,829	6,632	4,674	1,958
Net increase (decrease) in cash and cash equivalents	$ 779	$ (645)	$ 1,424	$ 718	$ (143)	$ 861

Cash Flows from Operating Activities

Net cash used in operating activities was $6.8 million for the year ended December 31, 2020. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of $7.2 million, offset by depreciation. Changes in operating assets and liabilities included a decrease in accounts payable and accrued expenses of $0.4 million mainly due to the timing of payments to our service providers.

Net cash used in operating activities was $9.5 million for the year ended December 31, 2019. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of $11.5 million, offset by depreciation. Changes in operating assets and liabilities included an increase in trade accounts payable and accrued expenses of $1.7 million, due to increased amounts owed to development vendors in relation to development activity occurring at the time including the bioavailability study for CTx-1301.

Net cash used in operating activities was $5.8 million for the nine months ended September 30, 2021. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates. Changes in operating assets and liabilities included an increase in accounts payable and accrued expenses of $2.1 million due to an increase in accrued payroll and accrued transaction costs as well as an increase in prepaid expenses and other current assets of $2.8 million due to deferred costs relating to our potential equity financing transaction totaling $1.9 million and prepaid costs for clinical study start-up fees totaling $0.6 million.

Net cash used in operating activities was $4.1 million for the nine months ended September 30, 2020. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of $6.0 million, offset by depreciation. Other changes in operating assets and liabilities included an increase in trade accounts payable of $1.3 million, primarily due to an increase in the amounts due to the Company's contract research organization for the completion of the bioavailability study for CTx-1301.

Cash Flows from Investing Activities

Net cash used in investing activities in the year ended December 31, 2020 was primarily related to the purchase of equipment to support our research and development, as well as leasehold improvements to our headquarters.

Net cash provided by investing activities for the year ended December 31, 2019 was primarily related to the net sale of short-term investments as funds were needed to pay for development activity occurring at that time, offset by the purchase of property, plant and equipment including certain manufacturing equipment and leasehold improvements to the Company's Kansas City office space.

Net cash used in investing activities in the nine months ended September 30, 2021 was related to the purchase of ancillary equipment to support our primary piece of manufacturing equipment.

Net cash used in investing activities for the nine months ended September 30, 2020 was primarily related to installment payments on the purchase of manufacturing equipment to be used in development activity.

Cash Flows from Financing Activities

Net cash provided by financing activities in the year ended December 31, 2020 was primarily related to proceeds of the issuance of 5,050,141 of equity units of Cingulate Therapeutics LLC totaling $7.5 million. In addition, we received $0.95 million in proceeds from notes payable to related parties, of which $0.4 million was converted to members' capital, and $0.1 million was repaid during 2020.

Net cash provided by financing activities for the year ended December 31, 2019 was related to proceeds of the issuance of 4,102,210 equity units of Cingulate Therapeutics LLC totalling $6.1 million.

Net cash provided by financing activities for the nine months ended September 30, 2021 was primarily related to the proceeds of the issuance of 3,243,174 equity units of Cingulate Therapeutics LLC totaling $7.1 million. In addition, principal payments of $0.3 million were made on a financing lease for a piece of manufacturing equipment and payments were made on a related party note payable totaling $0.2 million.

Net cash provided by financing activities for the nine months ended September 30, 2020 was related to the issuance of 2,833,591 equity units of Cingulate Therapeutics LLC totalling $3.9 million. In addition, the Company received cash of $0.9 million for the issuance of two related party notes and made payments of $0.2 million on finance lease obligations.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2013 through September 30, 2021, we have not generated any revenue and have incurred significant operating losses and negative cash flow from our operations. We expect our existing cash and cash equivalents of $1.9 million as of September 30, 2021 together with the proceeds from the net proceeds of this offering, will be sufficient to fund our operating expenses and capital expenditure requirements through the next 12 months. However, it is difficult to predict our spending for our product candidates prior to obtaining FDA approval. Moreover, 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 at least the next several years as we continue to develop our product candidates and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of our product candidates. If we obtain marketing approval for our product candidates, 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 following the closing of this offering.

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

- 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 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 of establishing, or outsourcing, 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 on our own.

To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, 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. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could be structured as a collaboration or partnering arrangement. We have no arrangements, agreements, or understandings in place at the present time to enter into any acquisition, in-licensing or similar strategic business transaction.

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. 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 stockholder. 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.

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 and 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 12 months after the issuance date of our financial statements. The accompanying financial statements have been prepared on a going concern basis. The 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, 2020 and 2019 and had accumulated losses of $31.0 million since inception to December 31, 2020. We anticipate incurring additional losses until such time, if ever, that we can generate significant revenue from our product candidates currently in development. Our primary source of capital has been the issuance of equity securities. Additional financings will be needed by us to fund our operations, to complete development of and to commercially develop our product candidates. There is no assurance that such financing will be available when needed or on acceptable terms.

Global Pandemic Outbreak

In March 2020, the World Health Organization declared COVID-19 a global pandemic. The outbreak has become increasingly widespread in the United States, impacting the markets in which we operate. While the full impact of the pandemic continues to evolve, the financial markets have been subject to significant volatility that adversely impacts our ability to enter into, modify, and negotiate favorable terms and conditions relative to equity and debt financing initiatives. The uncertain financial markets, disruptions in supply chains, mobility restraints, and changing priorities as well as volatile asset values also affect our ability to enter into collaborations, joint ventures, and license and royalty agreements. The outbreak and government measures taken in response to the pandemic have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, have spiked, while demand for other goods and services, such as travel, have fallen. The future progression of the pandemic and its effects on our business and operations are uncertain. We may face difficulties recruiting or retaining patients in our ongoing and planned preclinical and clinical trials if patients are affected by the virus or are fearful of traveling to our clinical trial sites because of the outbreak. We and our third-party contract manufacturers, CROs, and clinical sites may also face disruptions in procuring items that are essential to our research and development activities, including, for example, medical and laboratory supplies used in our clinical trials or preclinical studies, in each case, that are sourced from abroad or for which there are shortages because of ongoing efforts to address the outbreak. While expected to be temporary, these disruptions may negatively impact our results of operations, financial condition, and liquidity in 2021, and potentially beyond.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Recently Issued Accounting Standards

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments* which significantly changes the way entities recognize impairment of many financial assets by requiring immediate recognition of estimated credit losses expected to occur over their remaining life, instead of when incurred. In November 2018, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments–Credit Losses*, which amends Subtopic 326-20 (created by ASU 2016-13) to explicitly state that operating lease receivables are not in the scope of Subtopic 326-20. Additionally, in April 2019, the FASB issued ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*; in May 2019, the FASB issued ASU 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief*; in November 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, and ASU 2019-11, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*; and in March 2020, the FASB issued ASU 2020-03, *Codification Improvements to Financial Instruments*, to provide further clarifications on certain aspects of ASU 2016-13. The changes (as amended) are effective for the Company for annual and interim periods in fiscal years beginning after December 15, 2022. The Company does not expect the adoption of ASU 2016-13 to have a material effect on its consolidated financial statements.

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 initial public offering or until we no longer meet the requirements for being an “emerging growth company,” whichever occurs first.

BUSINESS

Overview

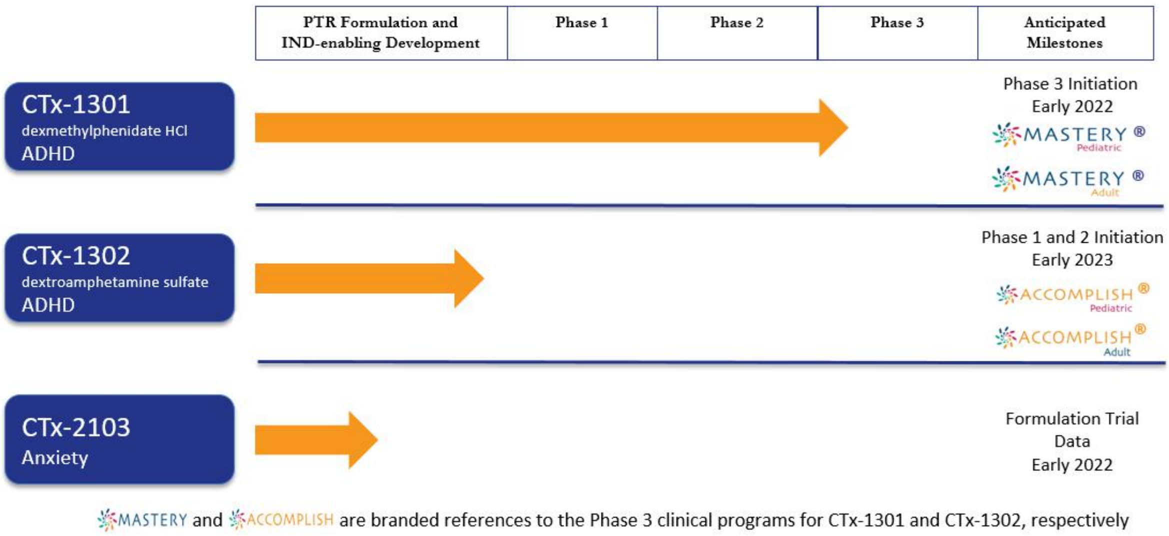
We are a clinical stage biopharmaceutical company using our proprietary Precision Timed Release, or PTR, drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. We are initially focusing our efforts on the treatment of Attention Deficit/Hyperactivity Disorder, or ADHD. Our PTR platform incorporates a proprietary Erosion Barrier Layer, or 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 initially targeting the ADHD stimulant-based treatment market, with an estimated US market size of $15.3 billion in 2020. Stimulants are the most commonly prescribed class of medications for ADHD and account for more than 90% of all ADHD medication prescriptions in the United States, where approximately 70 million stimulant prescriptions were written last year alone. By contrast, non-stimulant medications are typically employed only in the second-line or adjunctive therapy setting and account for 9-10% of all ADHD medication prescriptions. Extended-release, or long-acting, dosage forms of stimulant medications are most frequently deployed as the first-line treatment for ADHD and constitute approximately 60% of ADHD stimulant prescriptions by volume and nearly 85% of the dollars. 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 entire active-day coverage and suffer from a multitude of unwanted side effects as a result. We believe there remains a significant, unmet need within the current treatment paradigm for true once-daily ADHD stimulant medications with lasting duration and a superior side effect profile to better serve the needs of patients throughout their 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, in the three main patient segments: children (ages 6 -12), adolescents (ages 13-17), and adults (ages18+). Both CTx-1301 and CTx-1302 are designed to address the key shortcomings of currently approved stimulant therapies: to provide an immediate onset of action (within 30 minutes); offer 'entire active-day' duration; eliminate the need for a 'booster/recovery' dose of short-acting stimulant medications; minimize or eliminate the rebound/crash symptoms associated with early medication 'wear-off;' and provide favorable tolerability with a controlled descent of drug blood levels. Furthermore, by eliminating the 'booster' dose used by up to 60% of ADHD patients in conjunction with their primary medication, 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 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. We plan to initiate Phase 3 trials in early 2022 for CTx-1301 with results expected in early 2023. Assuming we receive positive clinical results from our pivotal Phase 3 trials for CTx-1301, we plan to submit an NDA for CTx-1301 using an accelerated approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act in late 2023. In addition, we plan to initiate a Phase 1/2 bioavailability study in ADHD patients for CTx-1302 in early 2023 and, if the results from this study are successful, we plan to initiate pivotal Phase 3 clinical trials in all patient segments for CTx-1302 in late 2023 with results expected in late 2024.

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 two or more active pharmaceutical ingredients (API) 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 to overcome unmet medical needs. We plan to initiate a formulation trial in human subjects for our third candidate, CTx-2103, to treat anxiety disorders in late 2021. CTx-2103 contains one of the most widely prescribed anxiolytic agents which must be taken several times a day. In 2020, United States sales for this API accounted for over $2 billion of sales in the $5.2 billion anxiety market. CTx-2103 will be designed as a once-daily, multi-dose tablet with clear differentiation and compelling advantages over standard treatment options. Further indications we intend to evaluate include insomnia, non-opioid pain, eating disorders, post-traumatic stress disorder, epilepsy, Alzheimer's, hypothyroidism, psychosis, depression, cardiovascular disorders, Parkinson's disease, migraine, oral oncology, and bipolar disorder, among others.

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:

- ***Complete development and obtain regulatory approval for CTx-1301 for the treatment of ADHD.*** We recently completed a Phase 1/2 bioavailability study in ADHD patients for CTx-1301. We plan to initiate Phase 3 clinical trials in all patient segments for CTx-1301 in early 2022 with results expected in early 2023. Assuming we receive positive clinical results from our pivotal Phase 3 trials and additional planned supplementary trials, we plan to submit an NDA for CTx-1301 in the late 2023 under the Section 505(b)(2) pathway.

- ***Advance development of CTx-1302 for the treatment of ADHD.*** We plan to initiate a Phase 1/2 bioavailability study in ADHD patients for CTx-1302 in early 2023 and, if the results from this study are successful, we plan to initiate pivotal Phase 3 clinical trials in all patient segments for CTx-1302 in late 2023 with results expected in late 2024.

- ***Successfully commercialize CTx-1301 and CTx-1302 ADHD product candidates.*** If we receive FDA approval for our CTx-1301 and CTx-1302 product candidates, we plan to commercialize our lead candidates either independently or via strategic partners with resources to address the pediatric and family practice markets in addition to the critical neurology and psychiatry practices.

- ***Advance clinical trials for CTx-2103 for the treatment of anxiety.*** We plan to initiate a clinical trial for our anxiety program, CTx-2103, in late 2021 to broaden the potential of our platform technology and provide a solution for patients in another indication where multiple daily doses are required. CTx-2103 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.

- ***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 expedited 505(b)(2) development pathway to develop additional therapeutic assets in other therapeutic areas where two 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, eating disorders, post-traumatic stress disorder, epilepsy, Alzheimer’s, hypothyroidism, psychosis, depression, cardiovascular disorders, Parkinson’s disease, migraine, oral oncology, and bipolar disorder, among others.

- ***Acquire or in-license additional assets or programs complement our portfolio 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.

- ***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.

- ***Capitalize on our existing cGMP Manufacturing Expertise***. We have developed a proprietary, reliable, high output, specialized manufacturing equipment train with the potential for real-time testing and release that is employed by our third-party manufacturing partner. Our process has been designed to allow for the creation of a platform that can incorporate other drug substances thus permitting expansion into additional indications and therapeutic areas. We expect that our investment in these manufacturing capabilities and equipment will substantially reduce our development timelines and overall development costs for current and future assets. We currently utilize commercial manufacturing equipment and will not require technology transfer or large scale-up processes to meet clinical or commercial manufacturing needs.

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, DuPont de Nemours, Inc. 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, Chairman 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. Laurie A. Myers, our Chief Operating Officer, has held leadership positions for leading global pharmaceutical companies, including Pfizer Inc., Novartis International AG, DuPont de Nemours, Inc. and Sanofi S.A. and has over 25 years of experience in drug development, marketing and commercialization.

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, approximately 6.4 million, or 11%, of children and adolescents aged 4-17 have been diagnosed with ADHD. Among this group, 80% receive treatment and 65% demonstrate clinical ADHD symptoms that persist into adulthood. Adult ADHD prevalence in the United States is estimated at approximately 11 million patients, or 4.4%, of the population, almost double the size of the child and adolescent segment combined. Currently, approximately 20% of the adult ADHD population receives treatment, however an increasing number of adult patients are being diagnosed and seeking treatment causing the adult ADHD market to grow approximately 10% year over year. Total ADHD medication sales in the United States have grown approximately 8% each year since 2010 with sales of all ADHD medications reaching approximately $18.3 billion in 2020.

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

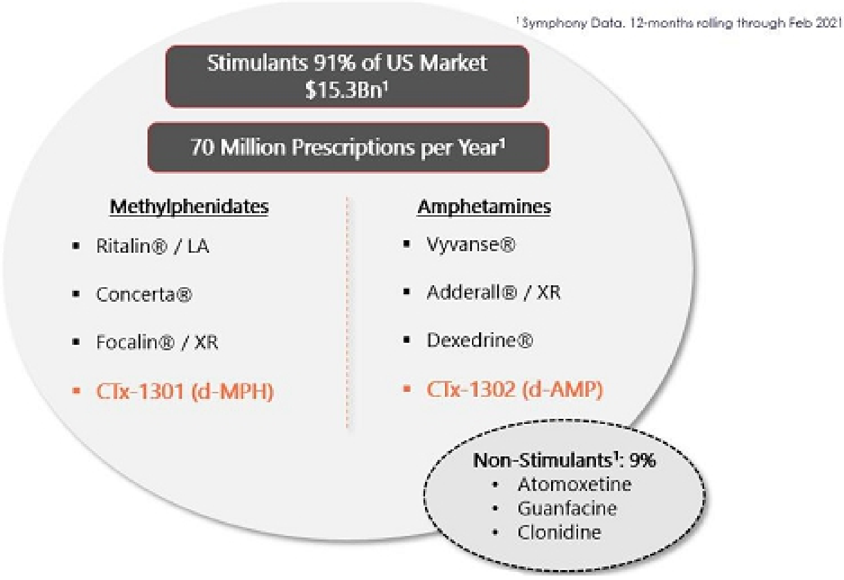
Adult ADHD patients typically suffer from restlessness, impulsivity, difficulty with time management, trouble regulating emotions and difficulty managing finances. Adults with ADHD report experiencing an internal sense of fidgetiness and restlessness and experience greater difficulty communicating with 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. Adults with ADHD earn approximately 30% less and are 10% less likely to be employed versus their unaffected peers. 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 experience a greater than 40% higher rate of vehicle accidents, 2x greater divorce rate, have a 2-fold greater incidence of accidental death, and research from prospective studies indicates that children and adults with ADHD have approximately twice the incarceration rate. On an economic level, in the United States alone, national annual incremental cost of ADHD ranged from $143 to $266 billion.

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 the most commonly prescribed class of medications for ADHD accounting for more than 90% of all ADHD medication prescriptions. Stimulants are Schedule II controlled substances and are believed to work by enhancing the effects of dopamine and norepinephrine neurotransmitters in the brain. Approximately 70 million stimulant prescriptions were written in 2020. In contrast, non-stimulant medications are typically deployed as second line or adjunctive therapies and account for 9-10% of all ADHD medication prescriptions. Currently, the ADHD market is dominated by four main stimulant medications: Vyvanse®, Adderall® XR, Concerta®, and Focalin® XR. These products were approved and became available between 2000 and 2007 and were believed to revolutionize the ADHD treatment paradigm by finally providing a solution to avoid the late morning second dose of stimulant medication then required by ADHD patients. These four medications today account for nearly $12 billion or 75% of the spending in the stimulant category and 54% of all stimulant prescriptions.

$18 Billion US ADHD Market Dominated by Stimulants



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 still require additional medication to cover the remainder of their active day. Currently, 60% of ADHD patients require 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 (14-16 hours); 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 Market Currently Dominated by 4 Stimulant Products

Major Unmet Medical Needs Persist

ADHD BRANDS	Approved	ATTRIBUTES		UNMET NEEDS			
		Onset	Duration (less onset)	Fast Onset of Action ≤ 30 min	Entire Active-Day Efficacy*	Minimize Crash/Rebound	Avoid Booster
Vyvanse®	2007	2 hours	12 hours	✗	✗	Data Not Available	✗
Adderall® XR	2001	1½ hours	10½ hours	✗	✗	Data Not Available	✗
Concerta®	2000	2 hours	10 hours	✗	✗	Data Not Available	✗
Focalin® XR	2005	30 mins	11½ hours	✓	✗	Data Not Available	✗

* 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

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		RELEASE PROFILES		
	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)	1½ hours	10½ 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

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, 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 a combined 2.0% of the total ADHD prescriptions written in the United States in 2020. 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 Have Also Failed to Overcome ALL Unmet Needs

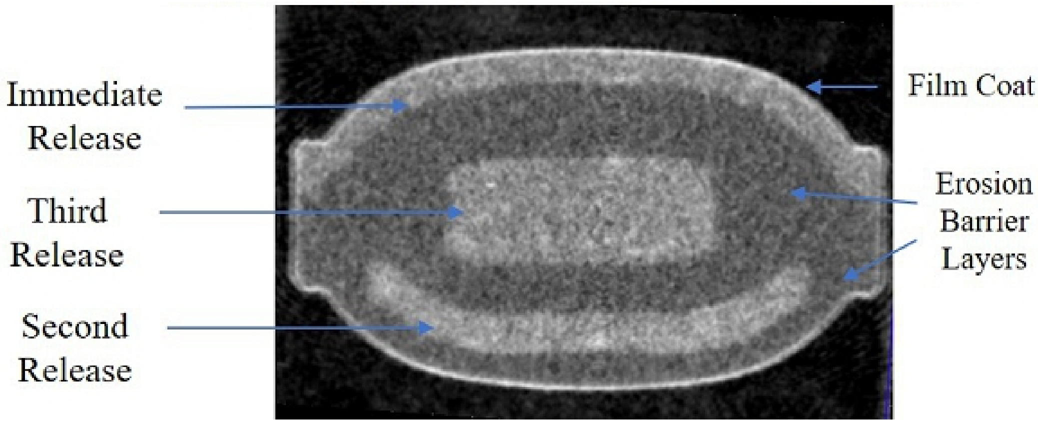
ADHD BRANDS	ATTRIBUTES		UNMET NEEDS			
Product	Onset	Duration	Fast Acting (≤ 30 min)	Entire Active-Day Efficacy	Avoid Crash/Rebound	Avoid Booster
Quillivant / Chew® XR	60 mins	8 hours	✖	✖	✖	✖
Mydayis®	2 or 4 hrs	16+ hours	✖	✖	✖	Potentially
Adzenys® ER/ODT	60 mins	8-9 hours	✖	✖	✖	✖
Cotempla® XR/ODT	60 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	60 mins	12-13 hours	✖	✖	✖	✖
Azstarys® (summer 2021)	Failed Endpoint	Failed Endpoint	✖	✖	✖	✖

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 ADHD medications capable of achieving true once-daily dosing using our internally developed, Precision Timed Release (PTR) drug delivery platform technology. Our CTx-1301 and CTx-1302 drug candidates both 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 Erosion Barrier Layer (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 target efficacious period of up to 16 hours.

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.

Elimination of Need For Short-Acting Stimulant Boosters. With entire active-day coverage up to a 16-hour period, we believe our technology will eliminate the need for patients to take afternoon booster doses when their currently prescribed therapies wear off. By eliminating 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.

Elimination 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, eliminating 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% the cost of their brand counterparts. We believe, if approved, our drug candidates will offer a much more cost-effective solution to patients.

Significantly Improved Tolerability. Because of the PK and PD profile of our drug, we believe patients will experience fewer treatment related adverse events associated with existing stimulant therapies including insomnia, appetite suppression, and feelings of extreme restlessness, dysphoria, irritability, fatigue, and flattening of affect.

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 at launch, practitioners will not have to constantly switch their patients to other medications or supplement patients with more short-acting booster medications. Medications that have launched with three dosage strengths are often ignored or avoided until at least six or seven strengths are available. Both CTx-1301 and CTx-1302 contain active pharmaceutical ingredients (APIs) that are Schedule II controlled substances. The APIs of both product candidates utilize 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

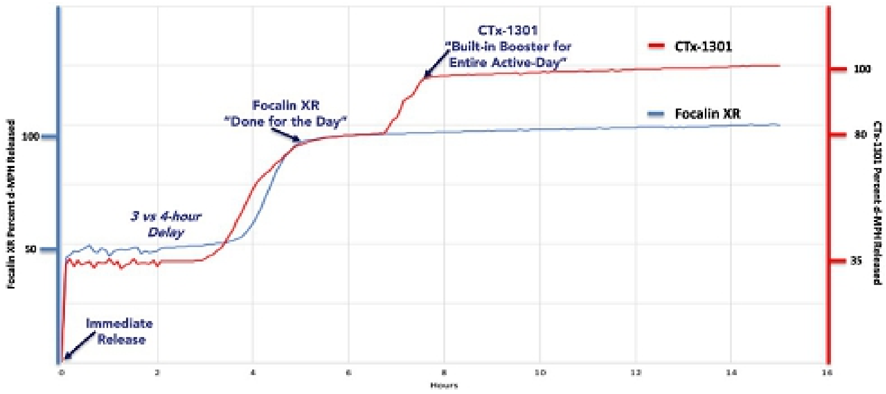
We believe our most advanced drug product candidate, CTx-1301, will be the first true once-daily dexmethylphenidate tablet for the treatment of ADHD, providing onset-of-action within 30 minutes and efficacy for the entire active day (14 to 16 hours versus placebo). CTx-1301 is a trimodal extended-release tablet, based on tablet-in-tablet technology, which provides three 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 demonstrate a more favorable tolerability profile that results from this specialized design and unique 35%-45%-20% release profile, compared to the currently available 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 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 8 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 three Phase 1 clinical pharmacology studies and our Phase 3 Mastery clinical efficacy and safety trials.

Our Phase 1/2 Bioavailability Trial Results

We recently completed a Phase 1/2 comparative bioavailability study in ADHD subjects, under fasted conditions, and demonstrated similar bioavailability to our Reference Listed Drug (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

<u>Bridged to Focalin® XR</u>

- 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 at 16 hours versus Focalin® XR at 12 hours

- CTx-1301 blood levels demonstrated the potential for an extended duration of action, up to 16 hours
- 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 Plasma Levels Equal to Focalin® XR at 30 and 60 Minutes

- Confirmed similar Fast Onset of Action to Focalin XR

Demonstrated Controlled Descent of Plasma Levels versus Focalin® XR

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

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)

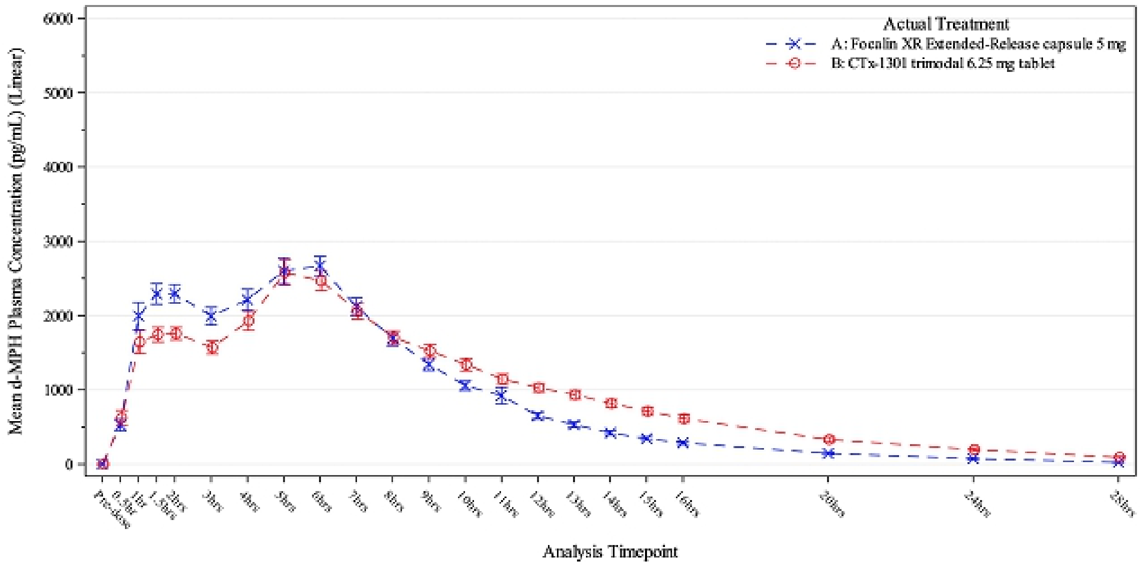


Figure 2: Comparative Bioavailability Study of CTx-1301 versus Focalin XR in Adult ADHD subjects under Fasted Conditions (high dose)

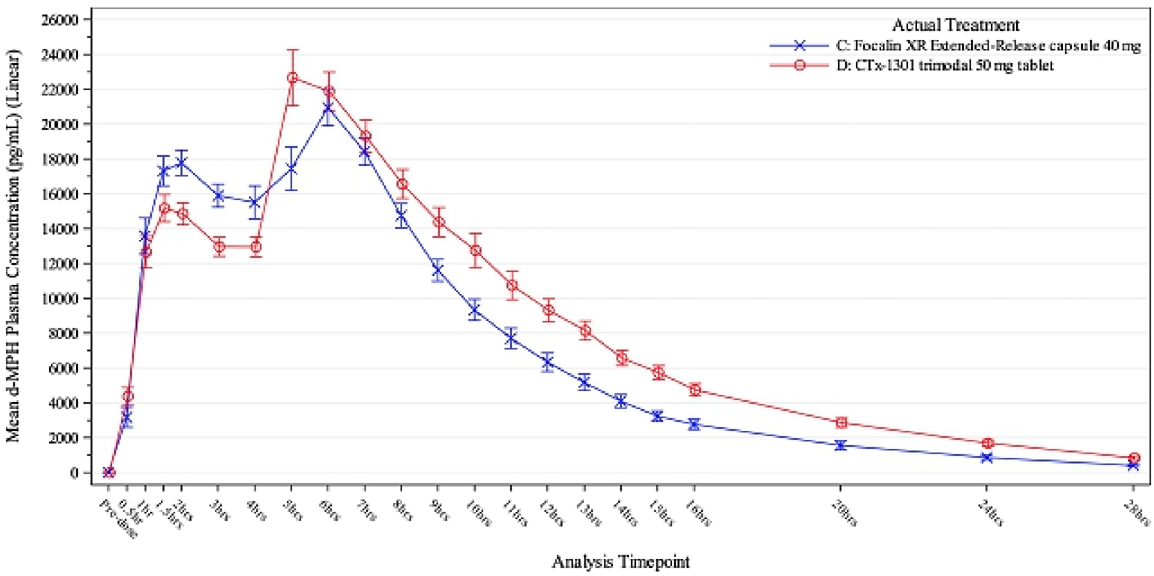
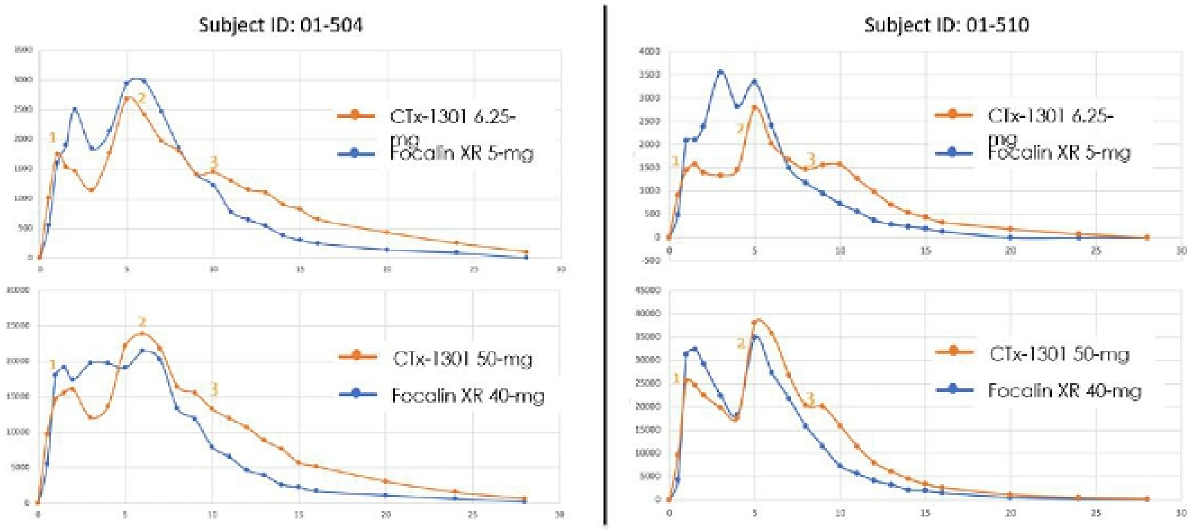


Figure 3: Comparative Bioavailability Study of CTx-1301 versus Focalin XR in individual Adult ADHD subjects under Fasted Conditions (low and high dose)



Our Additional Planned Phase 1 Studies

We plan to initiate the additional Phase 1 studies concurrently with our Phase 3 Mastery studies.

Fast-Fed Study

- *A Phase 1, 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 the absorption and bioavailability of CTx-1301*. The objectives of this study are to assess the effect of food on the rate and extent of absorption and the overall bioavailability, to provide pharmacokinetic data on blood plasma levels of CTx-1301 in both a fasted and fed state, and evaluate the safety of a single dose of CTx-1301 50 mg.

Pediatric PK Study

- *A Phase 1, Single-dose, Pharmacokinetic (PK) Study of CTx-1301 in Children (6 to 12) and Adolescent (13-17) Subjects with ADHD under Fasted Conditions.* The objectives of this study are to characterize the pharmacokinetic and concentration-time profiles in child and adolescent subjects under fasted conditions and evaluate the safety of CTx-1301 (37.5 mg).

Our Planned Phase 3 MASTERY Trials

We plan to initiate Phase 3 trials in the first quarter of 2022 and to file an NDA in late 2023. Our entire Phase 3 clinical plan will include approximately 600 patients. Based on the results of our Phase 1/2 clinical trial and communications with the FDA, we expect the 505(b)(2) NDA filing for CTx-1301 will use Focalin XR 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-1301 clinical program.

The Proposed Phase 3 CTx-1301 safety and efficacy studies will utilize diagnostic tools and ADHD evaluations including the ADHD-RS-5, the CGI-S, the SKAMP, and the PERMP. These tools and evaluations are commonly used as study endpoints in support of an NDA filing.

- The ADHD-RS, 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. 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 ADHD-RS-5 scores range from zero to 54.

- The CGI-S is the Clinical Global Impressions (Severity) Scale, a single-item scale that measures the severity of psychopathology from 1-7.

- The SKAMP, or Swanson, Kotkin, Agler, M-Flynn and Pelham Scale, measures the manifestations of ADHD using an independent observer rating of a subject's impairment in the classroom-observed behaviors. The SKAMP combined score is comprised of 13 items (including subscales: attention with items 1-4, deportment with items 5-8, quality of work with items 9-11, and compliance with items 12-13. Each item is rated on a 7-point impairment scale (0=normal to 6=maximal impairment). The SKAMP composite score is obtained by summing up each item score for a total possible combined score of 0-78, where a higher score indicates worse impairment.

- The PERMP, or Permanent Product Measure of Performance, is a skill-adjusted math test. 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.

Our Proposed Phase 3 CTx-1301 clinical safety and efficacy studies include:

- *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 classroom efficacy and safety study in children (6-12 y/o*): The primary efficacy endpoint is the SKAMP Combined Score. Time to onset and duration of effect will also be evaluated as key secondary endpoints.

- *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 one year.* 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-1301 against prior therapies using patient reported outcomes (PRO). The PRO evaluation will include:

- 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 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 provide critical information allowing us to gain important market access.

Additionally, we will conduct a Phase 1 Food Effect study to evaluate the pharmacokinetic profile of CTx-1301 under fed and fasted conditions in adults and a Phase 1 Pediatric and Adolescent PK Study to evaluate the pharmacokinetic profile of CTx-1301 in pediatrics and adolescents.

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

We believe our second 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, up to 16 hours. 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 first delayed, sustained release (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 second delayed, immediate release (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 8 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 inactive ingredient database (IID).

Our CTx-1302 Clinical Development Program

Our proposed clinical program for CTx-1302 consists of multiple Phase 1 clinical pharmacology studies and multiple Phase 3 clinical efficacy and safety trials. We plan to initiate a Phase 1/2 bioavailability study in ADHD patients for CTx-1302 in early 2023 and, if the results from this study are successful, we plan to initiate pivotal Phase 3 clinical trials, the branded ACCOMPLISH trials, in all patient segments for CTx-1302 in late 2023 with results expected in late 2024. Our Phase 1 trials will include approximately 100 patients and 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 Reference Listed Drug, 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 Pediatric PK and Safety Study:* To evaluate the pharmacokinetic profile and safety of CTx-1302 in children and adolescents (6-17 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 Reference Listed Drug, Dexedrine Spansule in adults (18+ y/o).

The Proposed Phase 3 CTx-1302 safety and efficacy studies will utilize diagnostic tools and ADHD evaluations including the ADHD-RS-5, the CGI-S, the SKAMP, and the PERMP. These tools and evaluations are commonly used and described above.

Our Planned Phase 3 ACCOMPLISH 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 classroom efficacy and safety study in children (6-12 y/o):* The primary efficacy endpoint is the SKAMP Combined Score. Time to onset and duration of effect will also be evaluated as key secondary endpoints.

- *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 one year.* 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 patient reported outcomes (PRO) are 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.

Commercialization

Given our stage of development, we do not currently have any internal sales, marketing, or distribution infrastructure or capabilities. If approved, we plan to pursue one of two courses of action for commercialization of our product candidates in the United States, which we expect will be the first country in which we receive market authorization. We may seek out a commercial collaboration or strategic relationship with an established pharmaceutical company to provide us with more immediate access to marketing, sales, market access and distribution infrastructure. Alternatively, we may build our own internal commercial infrastructure. In the United States, we believe a scientifically oriented, specialty sales force of 125-150 sales professionals could communicate with the majority of the high-volume neurology and psychiatry prescribers of ADHD medications. Additionally, we believe that another 125-150 sales professionals will be required, especially at launch, to communicate with high prescribing ADHD pediatricians and family practice providers.

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. The period from initial diagnosis to symptom control is difficult, and caregivers actively seek and pass on useful information. 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. We utilize a contract development and manufacturing organization, Pharmaceutical Manufacturing Research Services, Inc., or PMRS, for the manufacture of our products used in pre-clinical research and clinical trials and we will continue to utilize PMRS for the near term for the commercial manufacturing of our drug product, if our drug product candidates are approved.

Currently, we do not have a commercial supply agreement with our contract manufacturer. We intend to enter into an agreement with such manufacturer prior to commercialization. Under the supply agreement, we retain sole ownership of our product assets. In addition, we are responsible for product development, including formulation, clinical trials, regulatory approval, and commercialization.

Any current and future 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 current good manufacturing practices (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 current and future 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 DEA.

Drug Substance

We currently purchase the APIs used in CTx-1301 (Dexmethylphenidate) and CTx-1302 (Dextroamphetamine) and excipients from USA based third-party manufacturers. We anticipate entering into commercial supply agreements with many of these manufacturers in the future. Both drug substances are classified as controlled under U.S. 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 prospectus.

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 Precision Timed Release, or PTR drug delivery platform technology, our and our technology platform. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. 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 five patents and three patent applications in the United States and 85 patents and 17 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.

We have and will continue to actively protect our intellectual property, including filing patent applications for our innovations, prosecuting our pending patent applications, and maintaining and enforcing our issued patents. No assurances can be given that pending patent applications will result in the issuance of a patent or that the examination process will not require us to narrow our claims. In addition, issued patents may be circumvented by third parties, or found unenforceable or invalid if contested before a court or administrative agency. Thus, we may not be able to successfully enforce our patent rights against third parties. No assurance can be given that others will not independently develop a similar or competing technology or design around any patents that may be issued to us.

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 2036.

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
WO2011107755	"Immediate Delayed Release" (A press-coated tablet formulation for a delayed, followed by a	DRUG DELIVERY INTERNATIONAL LTD	United States	Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany,	March 2031

	pulsed release of an active agent)			Great Britain, Greece, Hungary, Ireland, Italy, Japan, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United States	
WO2016075496	"Pharmaceutical Processing" (A method for making a controlled release material)	DRUG DELIVERY INTERNATIONAL LTD	Europe, United States		November 2035 (when issued)
WO2016075495	"Compositions" (A press coated tablet for delayed release of an active ingredient)	DRUG DELIVERY INTERNATIONAL LTD	Brazil, Canada, China, Egypt, India, South Korea	Australia, Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Greece, Hong Kong Hungary, Ireland, Italy, Japan Mexico, Netherlands, Norway, Poland, Portugal, Romania, Russia, Saudi Arabia Slovakia, Slovenia 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	Australia, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea, United States		February 2036 (when issued)
US PROVISIONAL 63/187,037	"Trimodal, Precision-Timed Pulsatile Release Tablet"	CINGULATE THERAPEUTICS LLC	United States		May 2042 (when 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. We have filed for trademark protection for the Cingulate, Cingulate Therapeutics trade dress and mark, which we use with our pharmaceutical research and development as well as products, as well as trade names that could be used with our potential products. We currently have registered trademarks for Cingulate Therapeutics in the United States as well as for our PTR technology.

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, which will lose exclusivity in 2023.

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 these niche areas including Aytu, Tris, Corium, Ironshore, Arbor, and Rhodes. However, we do not consider most of these companies to be significant competitors as they are seeking to capture 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 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.

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, or 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 require 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 U.S. 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, or GLP, regulations or other applicable regulations;

- Submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials involving humans may begin;

- Approval by an independent institutional review board, or 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, or GCPs, and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational product for each proposed indication;

- 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 approved and listed drug.

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 NIH's 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 U.S. 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 reference listed drug. 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 $2.8 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 over $330,000. 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 PDUFA, the agency seeks to review applications for standard review drug products within ten months from the filing date, and applications for priority review drugs within six months from the 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, or 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, or 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, or 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 application, or 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 reference listed drug. Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the Listed Drug 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 Listed Drug 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 Listed Drug, 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 Listed Drug; (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 Listed Drug'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 Listed Drug 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 Listed Drug 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, or 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, or FDASIA, 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, or PSP, 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 initial PSP 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 PSP, but the sponsor can submit amendments to an agreed-upon initial PSP 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 are currently in discussions with the FDA regarding our PREA obligations.

The Best Pharmaceuticals for Children Act, or BPCA, 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.

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, or 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 (DSCA) 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 U.S. Drug Enforcement Administration, or DEA, as controlled substances under the Controlled Substances Act of 1970, or 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 U.S. and lack accepted safety for use under medical supervision. They may not be marketed or sold for dispensing to patients in the U.S. 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 and CTx-1302, 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, or 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, or the OBRA, and the Veterans Health Care Act of 1992, or the VHCA, 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 U.S. government, continue to apply downward pressure on the reimbursement of pharmaceutical products. 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, including various provisions of the recent health reform legislation that affect reimbursement of these products. 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 U.S. 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 U.S. government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. 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 U.S., for example, in connection with the promotion of products for unapproved uses and other allegedly unlawful sales and marketing practices;

- The U.S. federal Health Insurance Portability and Accountability Act of 1996, or 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 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 the Centers for Medicare & Medicaid Services, or 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, or 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 attorney's 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, HHS 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, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA, was enacted in March 2010 and has had a significant impact on the health care industry in the United States. The PPACA expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to biopharmaceutical products, the 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, or ASP, to the Department of Health and Human Services ("DHHS") beginning on January 1, 2022, subject to enforcement via civil money penalties.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the PPACA and we expect there will be additional challenges and amendments to the PPACA in the future. Members of the U.S. Congress have indicated that they may continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the PPACA. For example, the Tax Cuts and Jobs Act, or TCJA, was enacted in 2017 and, among other things, removed penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, commonly referred to as the "individual mandate." In December 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate was a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA were invalid and the law in its entirety was unconstitutional. In December 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether other reforms enacted as part of the ACA but not specifically related to the individual mandate or health insurance could be severed from the rest of the ACA so as not to be declared invalid as well. In March 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and allocated one hour for oral arguments, which occurred on November 10, 2020. A decision from the Supreme Court is expected to be issued in Spring 2021. It is unclear how this litigation and other efforts to repeal and replace the PPACA will impact the implementation of the PPACA, the pharmaceutical industry more generally, and our business. Complying with any new legislation or reversing changes implemented under the PPACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

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, or 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 President Biden 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.

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 U.S. 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, or 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. In addition, the next cycle of Congressional reauthorization for FDA's prescription drug, biologic, and medical device user fee programs must be completed by mid-2022 and that periodic must-pass legislation is typically used as a vehicle to implement federal policy changes or other substantive amendments to the FDCA. 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 subject to laws and regulations governing data privacy and the protection of personal information including health information. 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 which will continue to affect our business. In the United States, we may be subject to state security breach notification laws, state laws protecting the privacy 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 overlap and often conflict 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 laws and regulations we could be subject to penalties or sanctions, including criminal penalties. Our future customers and research partners must comply with laws governing the privacy and security of health information, including the Health Insurance Portability and Accountability Act of 1996 as amended ("HIPAA") and state health information privacy laws. If we knowingly obtain health information that is protected under HIPAA, called "protected health information," our customers or research collaborators may be subject to enforcement 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 that imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information, and California has recently adopted the California Consumer Privacy Act of 2018 ("CCPA"). The CCPA mirrors a number of the key provisions of the EU 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. Additionally, a new privacy law, the California Privacy Rights Act ("CPRA"), was approved by California voters in the election on November 3, 2020. The CPRA will modify the CCPA significantly, potentially resulting in further uncertainty, additional costs and expenses in an effort to comply and additional potential for harm and liability for failure to comply. Other states in the U.S. are considering privacy laws similar to CCPA, with Virginia enacting its own such law in early 2021.

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

Master Services Agreement with Pharmaceutical Manufacturing Research Services, Inc.

Effective August 20, 2019, we entered into a master services agreement with PMRS (the "Manufacturing Agreement"). Pursuant to the Manufacturing Agreement, PMRS performs manufacturing services for our clinical supply of both CTx-1301 and CTx-1302. Such services are performed under agreed statements of work. Under the terms of the Manufacturing Agreement, we have agreed to pay fees for PMRS' performance of services as provided in each applicable statement of work.

The Manufacturing Agreement terminates in August 2024, unless terminated earlier. The term of each statement of work terminates upon completion of the services under such statement of work, unless terminated earlier. The term of the Manufacturing Agreement is automatically extended to conform to the term of any statement of work and may be extended by mutual consent. We may terminate the Manufacturing Agreement or any statement of work upon prior written notice to PMRS. The Manufacturing Agreement may be terminated by either party for breach, unless the breaching party has remedied such breach within thirty (30) days from the receipt by it of written notice thereof from the non-breaching party.

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 Limited

We entered into a patent and know-how license agreement with BDD Pharma Limited, or 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. We may be required to pay BDD Pharma aggregate milestone payments $750,000 for each product in connection with clinical trial and regulatory milestones, 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.

Employees

As of September 30, 2021, we employed 13 full-time employees. Of these, six are engaged in full-time research and development and manufacturing activities, and seven in full-time general and administrative functions. All of our employees are located in the United States. We have never had a work stoppage, and 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.

Facilities

Our corporate headquarters is located in Kansas City, Kansas, where we lease approximately 14,205 square feet of office space. Our lease expires on May 2025, with an option to extend. Our manufacturing activities take place at PMRS our outsourced manufacturing organization in Horsham, Pennsylvania. 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 relating to commercialization. We believe that appropriate alternative space is readily available on commercially reasonable terms.

Legal Proceedings

We are not a party to any material pending legal proceedings. From time to time, we may be subject to legal proceedings and claims arising in the ordinary course of business.

MANAGEMENT

Executive Officers and Directors

The following table provides information regarding our executive officers and directors:

Name	Age	Position
Executive Officers:		
Shane J. Schaffer, PharmD	47	Chief Executive Officer and Chairman of the Board
Louis G. Van Horn, MBA	63	Executive Vice President and Chief Financial Officer
Laurie A. Myers, PhD	65	Executive Vice President and Chief Operating Officer
Craig S. Gilgallon, Esq.	49	Executive Vice President and General Counsel
Raul R. Silva, MD	64	Executive Vice President and Chief Science Officer
Matthew Brams, MD	58	Executive Vice President and Chief Medical Officer
Directors:		
Jeff Hargroves	55	Director
Peter J. Werth	83	Director
Jeff Conroy	56	Director
Patrick Gallagher, MBA	56	Director
Gregg Givens	61	Director
Curt Medeiros, MBA	46	Director

Management

Shane J. Schaffer, PharmD co-founded Cingulate in 2013 and has since served as its Chief Executive Officer and Chairman of the Board of Directors. 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 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 of Directors.

Louis G. Van Horn, MBA has served as our Executive Vice President and Chief Financial Officer since May 2017. He previously served as a consultant with Tarsus CFO Services, LLC from December 2016 to May 2017. From December 2004 through June 2016, Mr. Van Horn served as Executive Vice President and Chief Financial Officer of Store Financial Services, LLC. Previously, Mr. Van Horn served as Vice President and Comptroller of Kansas City Southern (NYSE: KSU) from June 1988 to December 2003. He previously held financial positions at Yellow Freight Systems and PricewaterhouseCoopers. Mr. Van Horn received his Master of Business Administration from the University of Missouri – Kansas City, and a Bachelor of Arts in Accounting from Westminster College. Mr. Van Horn is a Certified Public Accountant.

Laurie A. Myers, PhD, MBA has served as our Executive Vice President and Chief Operating Officer since April 2017 and previously served as a member of our Board of Directors from June 2013 through April 2018 and as our Senior Vice President of operations from November 2017 to April 2018. Dr. Myers also serves as a Member of the Board of Advisors of Linea System, LLC, a position she has held since September 2020. Dr. Myers previously served as the Head of Marketing of Fidia Pharma USA Inc., a wholly owned subsidiary of Fidia Farmaceutici from September 2014 through November 2017. Dr. Myers was an Adjunct Professor at the College of New Jersey School of Business from January 2012 through December 2014, and served as President and a Member of the Board of the Hallett David Strategic Group from January 2010 through September 2014. Dr. Myers received her Doctor of Philosophy in Toxicology from Rutgers Medical School and Rutgers School of Pharmacy, her Masters in Business Administration from St. Joseph's University and her Master of Science and Bachelor of Science from the University of Scranton.

Craig S. Gilgallon, Esq. co-founded Cingulate in 2013 and has served as our Executive Vice President, General Counsel and Board Secretary since our inception. Previously, he served as our Director of Operations from March 2017 through November 2017. Since 2012, Mr. Gilgallon has served as a partner at the law firm of Pawar Gilgallon & Rudy, LLC. Prior to that, he served as the owner of the Law Office of Craig S. Gilgallon from October 2004 through August 2012. Mr. Gilgallon received his Juris Doctor from the Thomas Jefferson School of Law and his Bachelor of Science from Ithaca College.

Raul R. Silva, MD co-founded Cingulate in 2013 and has served as our Executive Vice President and Chief Science Officer since January 2018. He has been in private practice 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 2013 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. We believe that Dr. Bram's background in both adult, adolescent and child psychiatry and neurology, uniquely qualifies him to serve on our Board of Directors because of his and extensive research and clinical experience over the past 30 years.

Jeff Hargroves has served as a member of our board of directors since June 2018. 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.

Peter J. Werth has served on our board of directors since June 2018. Mr. Werth is Founder and Chief Executive Officer of ChemWerth Inc., a full-service generic drug development and supply company providing Active Pharmaceutical Ingredients to regulated markets worldwide. 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 serves on the Board of Directors of VM Pharma LLC since December 2010, VM Therapeutics LLC since May 2012, Alopexx Vaccines LLC since June 2012, Altos Therapeutics LLC since December 2012, VM Oncology LLC since August 2014, Nuance Designs of CT LLC since January 2015, Perseus Science Group LLC since January 2015, Alzeca Biosciences, Inc. since July 2017, Likarda LLC since August 2017, Techtona LLC since September 2017, Bright Path Pharma/Labs since November 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 of Directors.

Jeff Conroy has served on our board of directors since May 2018. Mr. Conroy currently serves as the Chairman and Chief Executive Officer of Embody, Inc., a medical device company he co-founded in April 2014. He also has served as a Director of Odyssey Group International, Inc. (OTC: ODYY) since January 2020. Mr. Conroy was the Managing Director of Windward Investments from May 2012 through December 2019. Previously, he was the Managing Director of Adjuvant Partners from January 2000 through May 2012. Mr. Conroy is a Director and Past Chairman of the Virginia Biotechnology Association and serves on the Virginia Bioscience Healthcare Research Corporation's (VBHRC) Board of Directors. Mr. Conroy holds a Bachelor of Science in Business Administration from Providence College. We believe that Mr. Conroy's experience in the life sciences industry and his knowledge in financial and corporate development qualifies him to serve on our Board of Directors.

Patrick Gallagher, MBA, CFA has served as a member of our board of directors since January 2014. Mr. Gallagher has served as Senior Managing Director at Laidlaw & Co., and as Managing Partner at Laidlaw Venture Partners, since September 2014. Since January 2018, he has also served as the Chief Executive Officer and as a member of the Board of Directors of Voltron Therapeutics, a privately held biotechnology company. Mr. Gallagher also serves as the Chief Executive Officer and a member of the Board of Directors at PD Theranostics, Inc. positions he has held since April 2018, and has served as Treasurer of Aerwave Medical, Inc. since November 2020. Prior to his current roles, Mr. Gallagher was a founding partner and Chief Executive Officer of BDR Research Group, LLC, from July 2001 through October 2010. Previously, he served as a Management Consultant for CHD Bioscience, Inc. from July 2012 through August 2014. He has served a member of the Board of Directors of BioSig Technologies, Inc. (NASDAQ: BSGM) since July 2014, Evermore Global since June 2015, and Algorithm Sciences, Inc. since May 2019. Mr. Gallagher earned his Master in Business Administration from Penn State University and his Bachelor of Science in Finance from the University of Vermont. We believe that Mr. Gallagher's extensive experience in the life sciences industry qualifies him to serve on our Board of Directors.

Gregg Givens has served on our board of directors since July 2021. Mr. Givens currently serves as the Chief Financial Officer at Park University, a position he has held since March 2020. Since November 2018, Mr. Givens has also served as a member of the Board of Directors of Excel Industries, Inc. Previously, Mr. Givens served as a member of the Board of Directors at Asurion, Inc. from January 2006 to July 2007. From May 1996 through April 2018, Mr. Givens served in various positions at DST Systems, Inc. (NYSE: DST), including as Senior Vice President, Chief Financial Officer and Treasurer. Mr. Givens received his Bachelor of Science in Accountancy from the University of Missouri and is a Certified Public Accountant. We believe Mr. Givens' extensive financial and accounting experience qualifies him to serve on our Board of Directors.

Curt Medeiros, MBA has served on our board of directors since July 2021. Mr. Medeiros currently serves as a Strategic Advisor to HealthRhythms and DermTech, positions he has held since June 2021. Prior to his current roles, Mr. Medeiros served as the President and Chief Operating Officer at Ontrak, Inc., from December 2019 through June 2021 (NASDAQ: OTRK). From June 2010 to November 2019, he served in various positions at UnitedHealth Group, including President of UnitedHealth Group subsidiaries OPTUM Analytics and OPTUM Life Sciences. Mr. Medeiros received his Bachelor of Science in Chemical Engineering from Massachusetts Institute of Technology and his Master in Business Administration from Harvard Business School. We believe Mr. Medeiros' extensive experience in the life sciences industry qualifies him to serve on our Board of Directors.

Board Composition

Our board of directors currently consists of seven 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 that will become effective upon the completion of this offering, our board of directors will be 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 will be divided among the three classes as follows:

- The Class I directors will be Patrick Gallagher and Peter J. Werth; their terms will expire at the annual meeting of stockholders to be held in 2022.
- The Class II directors will be Jeff Conroy, Curt Medeiros, and Gregg Givens; their terms will expire at the annual meeting of stockholders to be held in 2023.
- The Class III directors will be Shane J. Schaffer and Jeff Hargroves; their terms will expire at the annual meeting of stockholders to be held in 2024.

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

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

Director Independence

Upon the completion of this offering, we anticipate that our common stock will be listed on the Nasdaq Capital Market (or Nasdaq). Under the listing requirements and rules of Nasdaq, independent directors must constitute a majority of a listed company's board of directors within 12 months after its initial public offering. Under 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 of directors has determined that Jeff Conroy, Patrick Gallagher, Gregg Givens, Jeff Hargroves, Curt Medeiros, and Peter J. Werth are "independent directors" as such term is defined by Nasdaq Marketplace Rule 5605(a)(2). We have established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee.

Committees of the Board of Directors

Our board of directors has established an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each of these committees operate under a charter that has been approved by our board of directors, which will be available on our website.

Audit Committee. Our Audit Committee consists of Gregg Givens, Patrick Gallagher, and Jeff Hargroves, with Gregg Givens serving as the Chairman of the Audit Committee. Our board of directors has determined that the three 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 of directors has determined that Gregg Givens qualifies as an audit committee financial expert within the meaning of SEC regulations and the Nasdaq Marketplace Rules.

The Audit Committee oversees and monitors our financial reporting process and internal control system, reviews and evaluates the audit performed by our registered independent public accountants and reports to the board of directors any substantive issues found during the audit. The Audit Committee is directly responsible for the appointment, compensation and oversight of the work of our registered independent public accountants. The Audit Committee reviews and approves all transactions with affiliated parties.

Compensation Committee. Our Compensation Committee consists of Jeff Conroy, Gregg Givens, and Peter J. Werth, with Jeff Conroy serving as the Chairman of the Compensation Committee. Our board of directors has determined that the three directors currently serving on our Compensation Committee are independent under the listing standards, are “non-employee directors” as defined in rule 16b-3 promulgated under the Exchange Act and are “outside directors” as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended.

The Compensation Committee provides advice and makes recommendations to the board of directors in the areas of employee salaries, benefit programs and director compensation. The Compensation Committee also reviews and approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other officers and makes recommendations in that regard to the board of directors as a whole.

Nominating and Corporate Governance Committee. Our Nominating and Corporate Governance Committee consists of Jeff Hargroves, Jeff Conroy, and Curt Medeiros, with Jeff Hargroves serving as the Chairman of the Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee nominates individuals to be elected to the board of directors by our stockholders. The Nominating and Corporate Governance Committee considers recommendations from stockholders if submitted in a timely manner in accordance with the procedures set forth in our bylaws and will apply the same criteria to all persons being considered. All members of the Nominating and Corporate Governance Committee are independent directors as defined under the Nasdaq listing standards.

Role of Board in Risk Oversight Process

The chief executive officer and chairman of the board of directors positions are held by Shane J. Schaffer. Dr. Schaffer currently beneficially owns approximately 11.31% of the voting power of our common stock, or 8.56% after the closing of this offering. Periodically, our Board of directors assesses these roles and the board of directors leadership structure to ensure the interests of Cingulate and our stockholders are best served. Our board of directors has determined that its current leadership structure is appropriate. Dr. Schaffer, as one of our founders and as our chief executive officer and chairman, has extensive knowledge of all aspects of Cingulate, our business and risks.

While management is responsible for assessing and managing risks to Cingulate, our board of directors is responsible for overseeing management’s efforts to assess and manage risk. This oversight is conducted primarily by our full board of directors, which has responsibility for general oversight of risks, and standing committees of our board of directors. Our board of directors satisfies this responsibility through full reports by each committee chair regarding the committee’s considerations and actions, as well as through regular reports directly from officers responsible for oversight of particular risks within our company. Our board of directors believes that full and open communication between management and the board of directors is essential for effective risk management and oversight.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves, or in the past has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of our board of directors or our compensation committee. None of the members of our compensation committee is, or has ever been, an officer or employee of our company.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our employees, officers and directors. A current copy of the code will be posted on the Corporate Governance section of our website, which will be located at www.cingulate.com. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, 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 filings with the SEC.

Limitation of Directors Liability and Indemnification

The Delaware General Corporation Law authorizes corporations to limit or eliminate, subject to certain conditions, the personal liability of directors to corporations and their stockholders for monetary damages for breach of their fiduciary duties. Our amended and restated certificate of incorporation, which will become effective upon the completion of this offering, limits the liability of our directors to the fullest extent permitted by Delaware law. In addition, upon the closing of this offering, we will enter into indemnification agreements with all of our directors and named executive officers whereby we will agree to indemnify those directors and officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee or agent of ours, provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, our best interests.

We have director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us, including matters arising under the Securities Act. Our certificate of incorporation and bylaws also provide that we will indemnify our directors and officers who, by reason of the fact that he or she is or was one of our officers or directors of our Company, is involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative related to their board role with us.

There is no pending litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

Indemnification Agreements

At the closing of this offering, we plan on entering into Indemnification Agreements with each of our current directors and executive officers. The Indemnification Agreements will provide for indemnification against expenses, judgments, fines and penalties actually and reasonably incurred by an indemnitee in connection with threatened, pending or completed actions, suits or other proceedings, subject to certain limitations. The Indemnification Agreements will also provide for the advancement of expenses in connection with a proceeding prior to a final, nonappealable judgment or other adjudication, provided that the indemnitee provides an undertaking to repay to us any amounts advanced if the indemnitee is ultimately found not to be entitled to indemnification by us. The Indemnification Agreements will set forth procedures for making and responding to a request for indemnification or advancement of expenses, as well as dispute resolution procedures that will apply to any dispute between us and an indemnitee arising under the Indemnification Agreements.

EXECUTIVE COMPENSATION

The following tables and accompanying narrative disclosure set forth information about the compensation earned by our named executive officers during the year ended December 31, 2020. Our named executive officers, who are our principal executive officer and the two most highly-compensated executive officers (other than our principal executive officer) serving as executive officers as of December 31, 2020, were:

- Shane J. Schaffer, Chief Executive Officer and Chairman of the Board;
- Louis G. Van Horn, Executive Vice President and Chief Financial Officer; and
- Craig S. Gilgallon, Esq., Executive Vice President and General Counsel.

Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by or paid to each of our named executive officers during the fiscal years ended December 31, 2020.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards (1)	Total ($)
Shane J. Schaffer, *Chief Executive Officer and Chairman of the Board*	2020	275,000	-	-	275,000
Louis G. Van Horn, *Executive Vice President and Chief Financial Officer*	2020	238,499	-	-	238,499
Craig S. Gilgallon, Esq., *Executive Vice President, General Counsel and Board Secretary*	2020	235,000	-	-	235,000

(1) During 2020, we granted awards of Class C profits interests pursuant subject to the terms of the Limited Liability Company Agreement of CTx. These Class C profits interests were intended to constitute profits interests for U.S. federal income tax purposes to our employees (including our Named Executive Officers), non-employee consultants and non-employee directors and those of our affiliates. All of the Class C profits interests in 2020 represent a profits interest, as that term is defined in Revenue Procedure 93-27, 1993-2 C.B. 343, as clarified by Revenue Procedure 2001-43, 2001-2 C.B. 191. As the future achievement of the thresholds and targets to achieve payout of the Class C profits interests is not deemed probable, the Class C profits interest are determined to have zero value as of December 31, 2020**.** See Note 8 to our financial statements for more information.

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 and receives a base salary of $475,000 annually. 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 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 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 without cause 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 half (1 ½) times Dr. Schaffer's base salary, 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 two (2) times Dr. Schaffer'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 Dr. Schaffer shall become vested and exercisable as of the date of termination for the remainder of their full term.

Louis G. Van Horn

On September 23, 2021, we entered into an employment agreement with Mr. Van Horn. Under the terms of Mr. Van Horn's employment agreement, he holds the positions of Executive Vice President and Chief Financial Officer and receives a base salary of $380,000 annually. In addition, Mr. Van Horn is eligible to receive an annual bonus, with a target amount equal to twenty-five percent (25%) of Mr. Van Horn'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 Mr. Van Horn's individual performance, as recommended by the Chief Executive Officer. Pursuant to the terms of his employment agreement, Mr. Van Horn 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. Van Horn's employment at any time without cause upon providing written notice to Mr. Van Horn, and Mr. Van Horn may terminate his employment at any time for any reason, including for Good Reason (as that term is defined in Mr. Van Horn's employment agreement).

If Mr. Van Horn's employment is terminated by the Company without cause or by Mr. Van Horn for Good Reason, Mr. Van Horn 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. Van Horn's base salary, within 60 days following the date of termination. In addition, all stock options and stock appreciation rights held by Mr. Van Horn, 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. Van Horn'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, Mr. Van Horn 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. Van Horn'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. Van Horn shall become vested and exercisable as of the date of termination for the remainder of their full term.

Craig S. Gilgallon, Esq.

On September 23, 2021, we entered into an employment agreement with Mr. Gilgallon. Under the terms of Mr. Gilgallon's employment agreement, he holds the positions of Executive Vice President and General Counsel and receives a base salary of $380,000 annually. In addition, Mr. Gilgallon is eligible to receive an annual bonus, with a target amount equal to twenty-five percent (25%) of Mr. Gilgallon'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 Mr. Gilgallon's individual performance, as recommended by the Chief Executive Officer. Pursuant to the terms of his employment agreement, Mr. Gilgallon is also eligible to participate in all incentive and deferred compensation programs, and other executive retirement plans 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. Gilgallon's employment at any time without cause upon providing written notice to Mr. Gilgallon, and Mr. Gilgallon may terminate his employment at any time for any reason, including for Good Reason (as that term is defined in Mr. Gilgallon's employment agreement).

If Mr. Gilgallon's employment is terminated by the Company without cause or by Mr. Gilgallon for Good Reason, Mr. Gilgallon 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. Gilgallon's base salary, within 60 days following the date of termination. In addition, all stock options and stock appreciation rights held by Mr. Gilgallon, 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. Gilgallon's employment is terminated by the Company without cause or by Mr. Gilgallon for Good Reason within twelve (12) months of a Change of Control, Mr. Gilgallon 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. Gilgallon'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. Gilgallon shall become vested and exercisable as of the date of termination for the remainder of their full term.

Outstanding Equity Awards at Fiscal Year-End Table

There were no outstanding equity awards at December 31, 2020.

Equity Grants

Pursuant to the 2021 Plan, effective as of the date of this prospectus, our board of directors will grant options to purchase shares of common stock to our executive officers and directors in the following amounts: Dr. Schaffer (279,600), Dr. Myers (104,850), Mr. Van Horn (104,850), Mr. Gilgallon (104,850), Dr. Brams (6,990), Dr. Silva (6,990), Mr. Conroy (13,980), Mr. Hargroves (13,980), Mr. Givens (13,980), Mr. Werth (13,980), Mr. Gallagher (13,980) and Mr. Medeiros (13,980) (the "IPO Grants"). The IPO Grants will have an exercise price equal to the offering price of our common stock in this offering and will vest in four equal annual installments beginning on the one-year anniversary of the date of grant.

Director Compensation

In 2020, we did not maintain any standard fee arrangements for the non-employee members of our board of directors for their service as a director other than for reimbursement of expenses. Our policy has been and will continue to be to reimburse our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of our board of directors and committees of the board of directors. We intend to put in place a formal director compensation policy for all of our non-employee directors following the completion of this offering.

Employee Benefits 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 (or, 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.

Limitation of Directors Liability and Indemnification

The Delaware General Corporation Law authorizes corporations to limit or eliminate, subject to certain conditions, the personal liability of directors to corporations and their stockholder for monetary damages for breach of their fiduciary duties. The amended and restated certificate of incorporation to be adopted upon the closing of this offering limits the liability of our directors to the fullest extent permitted by Delaware law. In addition, upon closing of this offering we will enter into indemnification agreements with all of our directors and named executive officers whereby we will agreed to indemnify those directors and officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee or agent of ours, provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, our best interests.

We have director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us, including matters arising under the Securities Act. The amended and restated certificate of incorporation and amended and restated bylaws that will be adopted upon closing of this offering will also provide that we will indemnify our directors and officers who, by reason of the fact that he or she is or was one of our officers or directors of our Company, is involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative related to their board role with us.

There is no pending litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

Indemnification Agreements

Upon the closing of this offering, we will enter into Indemnification Agreements with each of our current directors and executive officers. The Indemnification Agreements provide for indemnification against expenses, judgments, fines and penalties actually and reasonably incurred by an indemnitee in connection with threatened, pending or completed actions, suits or other proceedings, subject to certain limitations. The Indemnification Agreements also provide for the advancement of expenses in connection with a proceeding prior to a final, nonappealable judgment or other adjudication, provided that the indemnitee provides an undertaking to repay to us any amounts advanced if the indemnitee is ultimately found not to be entitled to indemnification by us. The Indemnification Agreement sets forth procedures for making and responding to a request for indemnification or advancement of expenses, as well as dispute resolution procedures that will apply to any dispute between us and an indemnitee arising under the Indemnification Agreements.

2021 Equity Incentive Plan

General

In September 2021, our board of directors and stockholders adopted the 2021 Plan which provides for the grant of incentive stock options and non-qualified stock options to purchase shares of our common stock and other types of awards. The general purpose of the 2021 Plan is to provide a means whereby eligible employees, officers, non-employee directors and other individual service providers 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. By means of the 2021 Plan, we seek to retain the services of such eligible persons and to provide incentives for such persons to exert maximum efforts for our success and the success of our subsidiaries.

Description of the 2021 Omnibus Equity Incentive Plan

The following description of the principal terms of the 2021 Plan is a summary and is qualified in its entirety by the full text of the 2021 Plan.

Administration. In general, the 2021 Plan will be administered by the Compensation Committee of the board of directors. The Compensation Committee will determine the persons to whom options to purchase shares of common stock, stock appreciation rights (or SARs), 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 may be granted. The Compensation Committee may also establish rules and regulations for the administration of the 2021 Plan and amendments or modifications of outstanding awards. The Compensation Committee may delegate authority to the Chief Executive Officer and/or other executive officers to grant options and other awards to employees (other than themselves), subject to applicable law and the 2021 Plan. No options, stock purchase rights or awards may be made under the 2021 Plan on or after September 24, 2031 (or, the expiration date), but the 2021 Plan will continue thereafter while previously granted options, SARs or other awards remain outstanding.

Eligibility. Persons eligible to receive options, SARs or other awards under the 2021 Plan are those employees, officers, directors, consultants, advisors and other individual service providers of our Company and our subsidiaries who, in the opinion of the Compensation Committee, are in a position to contribute to our success, or any person who is determined by the Compensation Committee to be a prospective employee, officer, director, consultant, advisor or other individual service provider of the Company or any subsidiary. As of the date of this prospectus, we had 13 full-time employees, of which three are executive officers. As awards under the 2021 Plan are within the discretion of the Compensation Committee, we cannot determine how many individuals in each of the categories described above will receive awards.

Shares Subject to the 2021 Plan. The aggregate number of shares of common stock available for issuance in connection with options and other awards granted under the 2021 Plan is 1,690,286.

The number of shares of common stock available for issuance under the 2021 Plan will automatically increase on January 1st of each year commencing with January 1, 2022 and on each January 1 thereafter until the expiration date, 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, 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.

“Incentive stock options”, or ISOs, that are intended to meet the requirements of Section 422 of the Internal Revenue Code of 1986, as amended (or, the Code) may be granted under the 2021 Plan with respect to all of the 1,690,286 shares of common stock authorized for issuance under the 2021 Plan. None of the additional shares of common stock available for issuance pursuant to the previous paragraph may be subject to ISOs.

If any option or SAR granted under the 2021 Plan terminates without having been exercised in full or if any award is forfeited, the number of shares of common stock as to which such option or award was forfeited will be available for future grants under the 2021 Plan. Awards settled in cash will not count against the number of shares available for issuance under the 2021 Plan.

No non-employee director may receive awards in any calendar year having an accounting value in excess of $750,000 (inclusive of any cash awards to the non-employee director for such year that are not made pursuant to the 2021 Plan); provided that in the case of a new non-employee director, such amount is increased to $(1,000,000 for the initial year of the non-employee director’s term.

The number of shares authorized for issuance under the 2021 Plan and the foregoing share limitations are subject to customary adjustments for stock splits, stock dividends or similar transactions.

We intend to file with the SEC a registration statement on Form S-8 covering the shares of our common stock issuable under the 2021 Plan.

Terms and Conditions of Options. Options granted under the 2021 Plan may be either ISOs or “nonstatutory stock options” that do not meet the requirements of Section 422 of the Code. The Compensation Committee will determine the exercise price of options granted under the 2021 Plan. The exercise price of stock options may not be less than the fair market value per share of our common stock on the date of grant (or 110% of fair market value in the case of ISOs granted to a ten-percent stockholder).

If on the date of grant the common stock is listed on a stock exchange or is quoted on the automated quotation system of the Nasdaq Stock Market, the fair market value will generally be the closing sale price on the date of grant (or the last trading day before the date of grant if no trades occurred on the date of grant). If no such prices are available, the fair market value will be determined in good faith by the Compensation Committee based on the reasonable application of a reasonable valuation method.

No option may be exercisable for more than ten years (five years in the case of an ISO granted to a ten-percent stockholder) from the date of grant. Options granted under the 2021 Plan will be exercisable at such time or times as the Compensation Committee prescribes at the time of grant. No employee may receive ISOs that first become exercisable in any calendar year in an amount exceeding $100,000. The Compensation Committee may, in its discretion, permit a holder of an option to exercise the option before it has otherwise become exercisable, in which case the shares of our common stock issued to the recipient will continue to be subject to the vesting requirements that applied to the option before exercise.

Generally, the option price may be paid in cash or by certified check, bank draft or money order. The Compensation Committee may permit other methods of payment, including (a) through delivery of shares of our common stock having a fair market value equal to the purchase price, (b) by a full recourse, interest bearing promissory note having such terms as the Compensation Committee may permit, or (c) a combination of these methods, as set forth in an award agreement or as otherwise determined by the Compensation Committee. The Compensation Committee is authorized to establish a cashless exercise program and to permit the exercise price (and/or tax withholding obligations) to be satisfied by reducing from the shares otherwise issuable upon exercise a number of shares having a fair market value equal to the exercise price.

No option may be transferred other than by will or by the laws of descent and distribution, and during a recipient’s lifetime an option may be exercised only by the recipient. However, the Compensation Committee may permit the holder of an option, SAR or other award to transfer the option, right or other award to immediate family members or a family trust for estate planning purposes. The Compensation Committee will determine the extent to which a holder of a stock option may exercise the option following termination of service with us.

Stock Appreciation Rights. The Compensation Committee may grant SARs under the 2021 Plan. The Compensation Committee will determine the other terms applicable to SARs. The exercise price per share of a SAR will not be less than 100% of the fair market value of a share of our common stock on the date of grant, as determined by the Compensation Committee. The maximum term of any SAR granted under the 2021 Plan is ten years from the date of grant. Generally, each SAR will entitle a participant upon exercise to an amount equal to:

- the excess of the fair market value on the exercise date of one share of our common stock over the exercise price, multiplied by

- the number of shares of common stock covered by the SAR.

Payment may be made in shares of our common stock, in cash, or partly in common stock and partly in cash, all as determined by the Compensation Committee.

Restricted Stock and Restricted Stock Units. The Compensation Committee may award restricted common stock and/or restricted stock units under the 2021 Plan. Restricted stock awards consist of shares of stock that are transferred to a participant subject to restrictions that may result in forfeiture if specified conditions are not satisfied. Restricted stock units confer the right to receive shares of our common stock, cash, or a combination of shares and cash, at a future date upon or following the attainment of certain conditions specified by the Compensation Committee. The restrictions and conditions applicable to each award of restricted stock or restricted stock units may include performance-based conditions. Dividends with respect to restricted stock may be paid to the holder of the shares as and when dividends are paid to stockholders or at the time that the restricted stock vests, as determined by the Compensation Committee. Dividend equivalent amounts may be paid with respect to restricted stock units either when cash dividends are paid to stockholders or when the units vest. Unless the Compensation Committee determines otherwise, holders of restricted stock will have the right to vote the shares.

Performance Shares and Performance Units. The Compensation Committee may award performance shares and/or performance units under the 2021 Plan. Performance shares and performance units are awards, denominated in either shares or U.S. dollars, which are earned during a specified performance period subject to the attainment of performance criteria, as established by the Compensation Committee. The Compensation Committee will determine the restrictions and conditions applicable to each award of performance shares and performance units.

Incentive Bonuses. The Compensation Committee may grant incentive bonus awards under the 2021 Plan from time to time. The terms of incentive bonus awards will be set forth in award agreements. Each award agreement will have such terms and conditions as the Compensation Committee determines, including performance goals and amount of payment based on achievement of such goals. Incentive bonus awards are payable in cash and/or shares of our common stock.

Other Stock-Based and Cash-Based Awards. The Compensation Committee may award other types of equity-based or cash-based awards under the 2021 Plan, including the grant or offer for sale of shares of our common stock that do not have vesting requirements and the right to receive one or more cash payments subject to satisfaction of such conditions as the Compensation Committee may impose.

Effect of Certain Corporate Transactions. The Compensation Committee may, at the time of the grant of an award provide for the effect of a change in control (as defined in the 2021 Plan) on any award, including (i) accelerating or extending the time periods for exercising, vesting in, or realizing gain from any award, (ii) eliminating or modifying the performance or other conditions of an award, or (iii) providing for the cash settlement of an award for an equivalent cash value, as determined by the Compensation Committee. The Compensation Committee may, in its discretion and without the need for the consent of any recipient of an award, also take one or more of the following actions contingent upon the occurrence of a change in control: (a) cause any or all outstanding options and SARs to become immediately exercisable, in whole or in part; (b) cause any other awards to become non-forfeitable, in whole or in part; (c) cancel any option or SAR in exchange for a substitute option; (d) cancel any award of restricted stock, restricted stock units, performance shares or performance units in exchange for a similar award of the capital stock of any successor corporation; (e) cancel or terminate any award for cash and/or other substitute consideration in exchange for an amount of cash and/or property equal to the amount, if any, that would have been attained upon the exercise of such award or realization of the participant's rights as of the date of the occurrence of the change in control, but if the change in control consideration with respect to any option or SAR does not exceed its exercise price, the option or SAR may be canceled without payment of any consideration; or (f) make such other modifications, adjustments or amendments to outstanding awards as the Compensation Committee deems necessary or appropriate.

Amendment, Termination. The board of directors may at any time amend the 2021 Plan for the purpose of satisfying the requirements of the Code, or other applicable law or regulation or for any other legal purpose, provided that, without the consent of our stockholders, the board of directors may not (a) increase the number of shares of common stock available under the 2021 Plan, (b) change the group of individuals eligible to receive options, SARs and/or other awards, or (c) extend the term of the 2021 Plan.

U.S. Federal Income Tax Consequences

Following is a summary of the U.S. federal income tax consequences of option and other grants under the 2021 Plan. Optionees and recipients of other rights and awards granted under the 2021 Plan are advised to consult their personal tax advisors before exercising an option or SAR or disposing of any stock received pursuant to the exercise of an option or SAR or following the vesting and payment of any award. In addition, the following summary is based upon an analysis of the Code as currently in effect, existing laws, judicial decisions, administrative rulings, regulations and proposed regulations, all of which are subject to change and does not address state, local, foreign or other tax laws.

Treatment of Options

The Code treats incentive stock options and nonstatutory stock options differently. However, as to both types of options, no income will be recognized to the optionee at the time of the grant of the options under the 2021 Plan, nor will our Company be entitled to a tax deduction at that time.

Generally, upon exercise of a nonstatutory stock option (including an option intended to be an incentive stock option but which has not continued to so qualify at the time of exercise), an optionee will recognize ordinary income tax on the excess of the fair market value of the stock on the exercise date over the option price. Our Company will be entitled to a tax deduction in an amount equal to the ordinary income recognized by the optionee in the fiscal year which includes the end of the optionee's taxable year. We will be required to satisfy applicable withholding requirements in order to be entitled to a tax deduction. In general, if an optionee, in exercising a nonstatutory stock option, tenders shares of our common stock in partial or full payment of the option price, no gain or loss will be recognized on the tender. However, if the tendered shares were previously acquired upon the exercise of an incentive stock option and the tender is within two years from the date of grant or one year after the date of exercise of the incentive stock option, the tender will be a disqualifying disposition of the shares acquired upon exercise of the incentive stock option.

For incentive stock options, there is no taxable income to an optionee at the time of exercise. However, the excess of the fair market value of the stock on the date of exercise over the exercise price will be taken into account in determining whether the “alternative minimum tax” will apply for the year of exercise. If the shares acquired upon exercise are held until at least two years from the date of grant and more than one year from the date of exercise, any gain or loss upon the sale of such shares, if held as capital assets, will be long-term capital gain or loss (measured by the difference between the sales price of the stock and the exercise price). Under current federal income tax law, a long-term capital gain will be taxed at a rate which is less than the maximum rate of tax on ordinary income. If the two-year and one year holding period requirements are not met (a “disqualifying disposition”), an optionee will recognize ordinary income in the year of disposition in an amount equal to the lesser of (i) the fair market value of the stock on the date of exercise minus the exercise price or (ii) the amount realized on disposition minus the exercise price. The remainder of the gain will be treated as long-term capital gain, depending upon whether the stock has been held for more than a year. If an optionee makes a disqualifying disposition, our Company will be entitled to a tax deduction equal to the amount of ordinary income recognized by the optionee.

In general, if an optionee, in exercising an incentive stock option, tenders shares of common stock in partial or full payment of the option price, no gain or loss will be recognized on the tender. However, if the tendered shares were previously acquired upon the exercise of another incentive stock option and the tender is within two years from the date of grant or one year after the date of exercise of the other option, the tender will be a disqualifying disposition of the shares acquired upon exercise of the other option.

As noted above, the exercise of an incentive stock option could subject an optionee to the alternative minimum tax. The application of the alternative minimum tax to any particular optionee depends upon the particular facts and circumstances which exist with respect to the optionee in the year of exercise. However, as a general rule, the amount by which the fair market value of the common stock on the date of exercise of an option exceeds the exercise price of the option will constitute an item of “adjustment” for purposes of determining the alternative minimum taxable income on which the alternative tax may be imposed. As such, this item will enter into the tax base on which the alternative minimum tax is computed, and may therefore cause the alternative minimum tax to become applicable in any given year.

Treatment of Stock Appreciation Rights

Generally, the recipient of a SAR will not recognize any income upon grant of the SAR, nor will our Company be entitled to a deduction at that time. Upon exercise of a SAR, the holder will recognize ordinary income, and our Company generally will be entitled to a corresponding deduction, equal to the excess of fair market value of our common stock at that time over the exercise price.

Treatment of Stock Awards

Generally, absent an election to be taxed currently under Section 83(b) of the Code (or, a Section 83(b) Election), there will be no federal income tax consequences to either the recipient or our Company upon the grant of a restricted stock award or award of performance shares. At the expiration of the restriction period and the satisfaction of any other restrictions applicable to the restricted shares, the recipient will recognize ordinary income and our Company generally will be entitled to a corresponding deduction equal to the fair market value of the common stock at that time. If a Section 83(b) Election is made within 30 days after the date the restricted stock award is granted, the recipient will recognize an amount of ordinary income at the time of the receipt of the restricted shares, and our Company generally will be entitled to a corresponding deduction, equal to the fair market value (determined without regard to applicable restrictions) of the shares at such time, less any amount paid by the recipient for the shares. If a Section 83(b) Election is made, no additional income will be recognized by the recipient upon the lapse of restrictions on the shares (and prior to the sale of such shares), but, if the shares are subsequently forfeited, the recipient may not deduct the income that was recognized pursuant to the Section 83(b) Election at the time of the receipt of the shares.

The recipient of an unrestricted stock award, including a performance unit award, will recognize ordinary income, and our Company generally will be entitled to a corresponding deduction, equal to the fair market value of our common stock that is the subject of the award when the Award is made.

The recipient of a restricted stock unit generally will recognize ordinary income as and when the units vest and are settled. The amount of the income will be equal to the fair market value of the shares of our common stock issued at that time, and our Company will be entitled to a corresponding deduction. The recipient of a restricted stock unit will not be permitted to make a Section 83(b) Election with respect to such award.

Treatment of Incentive Bonus Awards and Other Stock or Cash Based Awards

Generally, the recipient of an incentive bonus or other stock or cash based award will not recognize any income upon grant of the award, nor will our Company be entitled to a deduction at that time. Upon payment with respect to such an award, the recipient will recognize ordinary income, and our Company generally will be entitled to a corresponding deduction, equal to the amount of cash paid and/or the fair market value of our common stock issued at that time.

Potential Limitation on Company Deductions

Section 162(m) of the Code generally disallows a tax deduction for compensation in excess of $1 million paid in a taxable year by a publicly held corporation to its chief executive officer and certain other "covered employees." Our Board and the Compensation Committee intend to consider the potential impact of Section 162(m) on grants made under the 2021 Plan, but reserve the right to approve grants of options and other awards for an executive officer that exceed the deduction limit of Section 162(m).

Tax Withholding

As and when appropriate, we shall have the right to require each optionee purchasing shares of common stock and each grantee receiving an award of shares of common stock under the 2021 Plan to pay any federal, state, or local taxes required by law to be withheld.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2018 to which we have been a participant in which the amount involved exceeded or will exceed the lesser of (i) $120,000 or (ii) 1% of the average total assets of the Company at year end for the last two completed fiscal years and 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 which are described under “Executive Compensation.”

Office Lease

On January 1, 2018, CTx entered into a lease agreement (the “Lease Agreement”) for our office space in Morristown, New Jersey with Pawar Gilgallon & Rudy, LLC, a law firm of which Mr. Gilgallon, our Executive Vice President and General Counsel, is a partner. The original term of the Lease Agreement expired on January 1, 2021 and was extended, pursuant to its terms, for three years, until January 1, 2024. The monthly lease payment is $3,000 for the duration of the lease. Payments under the Lease Agreement totaled approximately $18,000 and $24,000 during fiscal 2020 and fiscal 2019, respectively. As of September 30, 2021, the unpaid rent was $0.

Related Party Notes

On February 26, 2020, CTx issued a $314,000 promissory note (the “February Note”) to Matthew Brams, our Chief Medical Officer. On September 30, 2020, we issued a $40,000 promissory note (the “September Note”, and together with the February Note, the “Brams Notes”) to Mr. Brams. The Brams Notes accrue interest at the rate of 8% per annum. The principal of the Brams Notes and accrued interest thereon may convert, at Dr. Brams’ option into preferred units of CTx at a Twenty-Five (25%) Percent discount to the offered unit price at the time of conversion. We have the right to prepay this note without penalty or premium. On each of December 30, 2020 and July 1, 2020, we made a $100,000 repayment of the February Note. The February Note, which initially matured on February 24, 2021 was extended for an additional 12 months to February 24, 2022. The September Note, which initially matured on September 30, 2021 was extended to February 24, 2022. On July 1, 2021 we made a $100,000 payment on the February Note and on August 17, 2021, we made a $50,000 payment on the February Note. As of September 30, 2021, we owed $104,000 and $35,238 in principal and interest, respectively, on the Brams Notes.

On July 25, 2020, CTx issued a $100,000 promissory note (the “July Note”) to Raul R. Silva, our Executive Vice President and Chief Science Officer. The July Note accrues interest at the rate of 8% per annum. The principal of the July Note and accrued interest thereon may convert, at Dr. Silva’s option into preferred units of CTx at a Twenty-Five (25%) Percent discount to the offered unit price at the time of conversion. We have the right to prepay this note without penalty or premium. The July Note, which initially matured on July 24, 2021, was extended for an additional seven months to February 24, 2022. As of September 30, 2021, we owed $100,000 and $9,380 in principal and interest, respectively, on the July Note.

On February 1, 2020, CTx issued a $500,000 promissory note to Dresch, Inc., a Former Member CTx (the “Member Note”, and together with the Brams Notes and the July Note, the “Related Party Notes”). Principal and interest of the Member Note is convertible upon lender’s notice into preferred units of CTx at the offered unit prices at the time of conversion. On September 30, 2020, $353,665 was converted to 246,096 Preferred Units of CTx at the current unit price in accordance with the terms of the Member Note leaving a note payable amount of $146,335. The Member Note, which initially matured on February 1, 2021 was extended for an additional 12 months to February 1, 2022. As of September 30, 2021, we owed $146,335 and $37,425 in principal and interest, respectively, on the Member Note.

We intend to repay all outstanding principal and interest on the Related Party Notes with the proceeds of this offering.

Indemnification of Officers and Directors

Upon closing of this offering, we will enter into indemnification agreements with each of our current directors and executive officers. These agreements will 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. We also intend to enter into indemnification agreements with our future directors and executive officers.

Policies and Procedures for Related Party Transactions

In anticipation of becoming a public company upon completion this offering, we plan to adopt a policy that 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, are not permitted to enter into a transaction with us without the prior consent of our board of directors 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 exceeds $120,000 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.

PRINCIPAL STOCKHOLDERS

The following table sets forth information about the beneficial ownership of our common stock as of November 5, 2021 by:

- each person or group known to us who beneficially owns more than 5% of our common stock prior to this offering;
- each of our directors;
- each of our Named Executive Officers; and
- all of our directors and 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 held by such person that are currently exercisable or will become exercisable within 60 days of the date of this prospectus are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. The following table does not reflect the IPO Grants.

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.

Name of Beneficial Owner (1)	Number of Shares Beneficially Owned Prior to Offering	Percentage of Shares Beneficially Owned (2) (3) Prior to Offering	After Offering
5% or Greater Stockholders			
Matthew Brams, MD (4)	1,011,906	9.10	6.89%
Raul Silva, MD (5)	727,108	6.54	4.95%
Named Executive Officers and Directors Other Than 5% or Greater Stockholders			
Shane J. Schaffer, Pharm.D.	1,257,145(6)	11.31	8.56%
Louis G. Van Horn, MBA	220,368(7)	1.98	1.50%
Craig S. Gilgallon, Esq.	288,359(8)	2.59	1.96%
Jeff Hargroves	58,426(9)	*	* %
Peter J. Werth	1,335,658(10)	12.02	9.09%
Jeff Conroy	7,702	*	* %
Patrick Gallagher, MBA	106,379	*	* %
Gregg Givens	26,173	*	* %
Curt Medeiros	—	—	—%
All Directors and Officers as a Group (12 persons)	5,110,753	45.98%	34.80%

* 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 stockholder 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. Unless otherwise noted, the shares of common stock listed above are owned as of the date of this prospectus, and are owned of record by each individual named as beneficial owner and such individual has sole voting and dispositive power with respect to the shares of common stock owned by each of them.

(3) Percentage ownership after this offering is based on 14,687,208 shares of common stock issued and outstanding immediately after the closing of this offering.

(4) Dr. Brams is our Chief Medical Officer.

(5) Dr. Silva is our Chief Science Officer.

(6) Includes 1,257,145 shares of 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.

(7) Includes 220,368 shares of common stock held by Louis G. Van Horn Trust, 12/23/19. Mr. Van Horn is the Trustee of Louis G. Van Horn Trust, 12/23/19 and has voting and investment power over the securities held by Louis G. Van Horn Trust, 12/23/19.

(8) Includes 288,359 shares of common stock held by The Limerick Group, LLC. Mr. Gilgallon is the sole member of The Limerick Group, LLC and has voting and investment power over the securities held by Limerick Group, LLC.

(9) Includes 58,426 shares of common stock held by Hargroves Family Investments, LLC. Mr. Hargroves is the manager of Hargroves Family Investments, LLC and has voting and investment power over the securities held by Hargroves Family Investments, LLC.

(10) Includes 1,301,656 shares of common stock held by Werth Family Investment Associates. Mr. Werth is the manager of Werth Family Investment Associates LLC and has voting and investment power over the securities held by Werth Family Investment Associates LLC.

DESCRIPTION OF CAPITAL STOCK

The following description summarizes the most important terms of our capital stock, as they will be in effect following this offering. Because it is only a summary, it does not contain all the information that may be important to you. We expect to adopt an amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering, and this description summarizes provisions that are expected to be included in these documents. For a complete description, you should refer to our amended and restated certificate of incorporation and restated bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of Delaware law.

Authorized Capitalization

Upon completion of this offering, we will have 250,000,000 shares of capital stock authorized under our amended and restated certificate of incorporation, consisting of 240,000,000 shares of common stock with a par value of $0.0001 per share and 10,000,000 shares of preferred stock with a par value of $0.0001 per share.

We are selling 3,571,428 shares of common stock in this offering (4,107,142 shares if the underwriters exercise in full their option to purchase additional shares). All shares of our common stock outstanding upon consummation of this offering will be fully paid and non-assessable. Upon completion of this offering, we expect to have 14,687,208 shares of common stock outstanding (15,222,922 shares if the underwriters exercise in full their option to purchase additional shares).

Common Stock

Holders of our common stock are entitled to such dividends as may be declared by our board of directors out of funds legally available for such purpose. The shares of common stock are neither redeemable nor convertible. Holders of common stock have no preemptive or subscription rights to purchase any of our securities.

Each holder of our common stock is entitled to one vote for each such share outstanding in the holder’s name. No holder of common stock is entitled to cumulate votes in voting for directors.

In the event of our liquidation, dissolution or winding up, the holders of our common stock are entitled to receive a pro rata share of our assets, which are legally available for distribution, after payments of all debts and other liabilities. All of the outstanding shares of our common stock are fully paid and non-assessable. The shares of common stock offered by this prospectus will also be fully paid and non-assessable.

Preferred Stock

Upon completion of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more classes or series and to fix the designations, rights, preferences, privileges and restrictions thereof, without further vote or action by the stockholders. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such class or series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after completion of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Stock Options

As of the date of this prospectus, we had reserved the following shares of common stock for issuance pursuant to stock options under the 2021 Plan described below:

- 817,830 shares of our common stock issuable upon exercise of stock options to be issued to certain of our officers, directors and employees, effective as of the date of this prospectus, which options shall have an exercise price equal to the offering price of our common stock in this offering; and

- 872,456 shares of our common stock reserved for future issuance under the 2021 Plan.

Underwriter Warrants

We have agreed to sell to the representative of the underwriters of this offering, or its permitted designees, for nominal consideration, warrants to purchase 178,571 shares of our common stock as additional consideration to the underwriters in this offering, based on an assumed initial public offering price of $7.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus. The underwriter warrants will have an exercise price equal to 125% of the public offering price in this offering and shall be exercisable for a period of five years following the commencement of sales in this offering and will contain customary “cashless” exercise and registration rights provisions. The warrants shall not be exercisable for a period of 180 days from the date of commencement of sales in the offering. See “Underwriting.”

Anti-Takeover Effects of Delaware law and Our Certificate of Incorporation and Bylaws

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws described below may have the effect of delaying, deferring or discouraging another party from acquiring control of us.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation and amended and restated bylaws, to become effective upon completion of the offering, provide for:

- classifying our board of directors into three classes;

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

- limiting the removal of directors by the stockholders;

- requiring a supermajority vote of stockholders to amend our bylaws or certain provisions our certificate of incorporation;

- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

- eliminating the ability of stockholders to call a special meeting of stockholders;

- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and

- establishing Delaware as the exclusive jurisdiction for certain stockholder litigation against us.

Potential Effects of Authorized but Unissued Stock

Pursuant to our amended and restated certificate of incorporation which will become effective upon the closing of this offering, we will have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the Delaware General Corporation Law and subject to any limitations set forth in our certificate of incorporation. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

Choice of Forum

Unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any stockholder to bring (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Company or the Company's stockholders, (iii) any action asserting a claim against the Company or any director or officer of the Company arising pursuant to, or a claim against the Company or any director or officer of the Company, with respect to the interpretation or application of any provision of the DGCL, our certificate of incorporation or bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine, except for, in each of the aforementioned actions, any claims to which the Court of Chancery of the State of Delaware determines it lacks jurisdiction. This provision will not apply to claims arising under the Exchange Act, or for any other federal securities laws which provide for exclusive federal jurisdiction. However, the exclusive forum provision provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Therefore, this provision could apply to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and that asserts claims under the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. There is uncertainty as to whether a court would enforce such an exclusive forum provision with respect to claims under the Securities Act.

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.

Transfer Agent

The name, address and telephone number of our stock transfer agent is Computershare Trust Company, N.A.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, or the perception that such sales could occur, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through the sale of our equity securities. Furthermore, because only a limited number of shares will be available for sale shortly after this offering due to existing contractual and legal restrictions on resale as described below, there may be sales of substantial amounts of our common stock in the public market after the restrictions lapse. This may adversely affect the prevailing market prices for our shares of common stock, and our ability to raise equity capital in the future. Although we have applied to have our common stock approved for listing on the Nasdaq Capital Market under the symbol "CING," we cannot assure you that there will be an active public market for our common stock.

Based on the number of shares outstanding as of the date of this prospectus, upon completion of this offering, 14,687,208 shares of common stock will be outstanding, or 15,222,922 if the over-allotment option is exercised in full. Of the shares to be outstanding immediately after the completion of this offering, the 3,571,428 shares of common stock sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act.

The remaining shares of common stock will be "restricted securities" under Rule 144.

Subject to the lock-up agreements described below and the provisions of Rule 144 and 701 under the Securities Act, these restricted securities will be available for sale in the public market as follows:

Date Available for Sale	Shares Eligible for Sale	Description
Date of Prospectus	3,571,428	Shares sold in the offering that are not subject to a lock-up
90 Days after Date of Prospectus	–*	Shares saleable under Rules 144 and 701 that are not subject to a lock-up
180 Days after the closing of the offering of shares	5,249,678	Lock-up released; shares saleable under Rules 144 and 701

* On March 29, 2021 (the sixth month anniversary of the closing of the Reorganization Merger), 5,866,102 shares of common stock that are not subject to a lock-up will be eligible for sale under Rules 144 and 701.

In addition, of the shares of our common stock that are issuable upon the exercise of stock options outstanding as of the date of this prospectus, options to purchase 817,830 shares of common stock are outstanding, and upon exercise these shares will be eligible for sale subject to the lock-up agreements described below and/or Rules 144 and 701 under the Securities Act.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to the reporting requirements under the Exchange Act for at least 90 days, a person (or persons whose shares are aggregated) who is not deemed to have been an affiliate of ours at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, would be entitled to sell those shares, subject only to the availability of current public information about us. A non-affiliated person who has beneficially owned restricted securities within the meaning of Rule 144 for at least one year would be entitled to sell those shares without regard to the provisions of Rule 144.

An affiliate of ours who has beneficially owned restricted shares of our common stock for at least one year (or six months, provided that such sale occurs after we have been subject to the reporting requirements under the Exchange Act for at least 90 days) would be entitled to sell, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of shares of our common stock then outstanding; or
- the average weekly trading volume of shares of our common stock on the Nasdaq during the four calendar weeks preceding the date on which notice of the sale is filed with the SEC.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to manner of sale provisions, notice requirements and the availability of current public information about us.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under the section entitled "Underwriting" and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Lock-up Agreements

All of our directors and executive officers, employees and 5% holders of our common stock or securities exercisable for or convertible into our common stock outstanding immediately prior to this offering have entered into lock-up agreements with respect to the disposition of their shares. See "Underwriting" for additional information.

Equity Incentive Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of the shares of common stock issued pursuant to this offering but does not purport to be a complete analysis of all potential tax consequences. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or foreign tax laws are not discussed. This discussion is based on the Code, Treasury regulations promulgated thereunder (the "Treasury Regulations"), judicial decisions, and published rulings and administrative pronouncements of the United States Internal Revenue Service (the "IRS"), in effect as of the date of this offering. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a non-U.S. holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to non-U.S. holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a non-U.S. holder's particular circumstances, including the impact of the alternative minimum tax or the unearned income Medicare contribution tax. In addition, it does not address consequences relevant to holders subject to particular rules, including, without limitation:

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- regulated investment companies or real estate investment trusts;
- brokers, dealers or traders in securities or currencies;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons for whom our common stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code or as "Section 1244 stock" for purposes of Section 1244 of the Code;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an "applicable financial statement" (as defined in the Code);
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;

- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities, all of the interests of which are held by qualified foreign pension funds.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT INTENDED AS LEGAL OR TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "non-U.S. holder" is any beneficial owner of our common stock that is not a "United States person," a partnership or an entity disregarded as separate from its owner, each for United States federal income tax purposes. A United States person is any person that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has made a valid election under applicable Treasury Regulations to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions on our common stock, such distributions of cash or property on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will first constitute a return of capital and be applied against and reduce a non-U.S. holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "Sale or Other Taxable Disposition of Common Stock." Because we may not know the extent to which a distribution is a dividend for U.S. federal income tax purposes at the time it is made, for purposes of the withholding rules discussed below we or the applicable withholding agent may treat the entire distribution as a dividend. Subject to the discussions below on backup withholding and foreign accounts, dividends paid to a non-U.S. holder of our common stock that are not effectively connected with the non-U.S. holder's conduct of a trade or business within the United States will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty).

Non-U.S. holders may be entitled to a reduction in or an exemption from withholding on dividends as a result of either (a) an applicable income tax treaty or (b) the dividends being effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and if required by an applicable income tax treaty, the non-U.S. holder's maintaining a permanent establishment in the United States to which such dividends are attributable). To claim such a reduction in or exemption from withholding, the non-U.S. holder must provide the applicable withholding agent with a properly executed (a) IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) claiming an exemption from or reduction of the withholding tax under the benefit of an income tax treaty between the United States and the country in which the non-U.S. holder resides or is established, or (b) IRS Form W-8ECI stating that the dividends are not subject to withholding tax because they are effectively connected with the conduct by the non-U.S. holder of a trade or business within the United States, as may be applicable. These certifications must be provided to the applicable withholding agent prior to the payment of dividends and must be updated periodically. Non-U.S. holders that do not timely provide the applicable withholding agent with the required certification, but that qualify for a reduced rate under an applicable income tax treaty, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such dividends are attributable), then, although exempt from U.S. federal withholding tax (provided the non-U.S. holder provides appropriate certification, as described above), the non-U.S. holder will be subject to U.S. federal income tax on such dividends on a net income basis at the regular rates. In addition, a non-U.S. holder that is a corporation may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits for the taxable year that are attributable to such dividends, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty that may provide for different rules.

Sale or Other Taxable Disposition of Common Stock

Subject to the discussions below on backup withholding and foreign accounts, a non-U.S. holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable);

- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or

- our common stock constitutes a U.S. real property interest (a "USRPI"), by reason of our status as a U.S. real property holding corporation (a "USRPHC") for U.S. federal income tax purposes.

Gain described in the first bullet point above will generally be subject to U.S. federal income tax on a net income basis at the regular rates. A non-U.S. holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on any gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder (even though the individual non-U.S. holder is not considered a resident of the United States) provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we are not currently and do not anticipate becoming a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our other business assets and our non-U.S. real property interests and our other business assets, however, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder of our common stock will not be subject to U.S. federal income tax if our common stock is “regularly traded on an established securities market,” as defined by applicable Treasury Regulations, during the calendar year in which the disposition occurs, and such non-U.S. holder has owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the non-U.S. holder’s holding period. If we are a USRPHC and either our common stock is not regularly traded on an established securities market during the calendar year in which the relevant disposition occurred, or a non-U.S. holder holds, or is treated as holding, more than 5% of our outstanding common stock, directly or indirectly, during the applicable testing period, such non-U.S. holder’s gain on the disposition of shares of our common stock generally will be taxed in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply, and a 15% withholding tax would apply to the gross proceeds from such disposition. Prospective investors are encouraged to consult their tax advisors regarding the possible consequences to them if we are, or were to become, a USRPHC.

Non-U.S. holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Subject to the discussion below on foreign accounts, a non-U.S. holder will not be subject to backup withholding (currently at a rate of 24%) with respect to distributions on our common stock we make to the non-U.S. holder, provided the applicable withholding agent does not have actual knowledge or reason to know such holder is a United States person and the holder certifies its non-U.S. status, such as by providing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns generally will be filed with the IRS in connection with any distributions (including deemed distributions) made on our common stock to the non-U.S. holder, regardless of whether any tax was actually withheld.

In addition, proceeds of a sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that the beneficial owner is a United States person, or such holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the non-U.S. holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder’s U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 through 1474 of the Code (such sections are commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends (including deemed dividends) paid on our common stock to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends (including deemed dividends) paid on our common stock. While withholding under FATCA would also have applied to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued. Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

We entered into an underwriting agreement with the underwriters named below on , 2021. Aegis Capital Corp. is acting as the representative of the underwriters. The underwriting agreement provides for the purchase of a specific number of shares of common stock by each of the underwriters. The underwriters' obligations are several, which means that each underwriter is required to purchase a specified number of shares of common stock, but is not responsible for the commitment of any other underwriter to purchase shares of common stock. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase the number of shares of common stock set forth opposite its name below:

Underwriter	Number of Shares of Common Stock
Aegis Capital Corp	
Laidlaw & Company (UK) Ltd.	
Total	

The underwriters have agreed to purchase all of the shares of common stock offered by this prospectus (other than those covered by the over-allotment option described below), if any are purchased.

The shares of common stock offered hereby are expected to be ready for delivery on or about , 2021 against payment in immediately available funds.

The underwriters are offering the shares of common stock subject to various conditions and may reject all or part of any order. The representative of the underwriters has advised us that the underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus and to dealers at a price less a concession not in excess of $ per share of common stock to brokers and dealers. After the shares of common stock are released for sale to the public, the representative of the underwriters may change the offering price, the concession, and other selling terms at various times.

We have granted an option to the underwriters, exercisable for up to 45 days after the date of this prospectus, to purchase up to 535,714 additional shares of common stock at the public offering price from us to cover over-allotments, if any, less underwriting discounts and commissions. If the underwriters exercise all or part of this option, they will purchase shares of our common stock covered by the option at the public offering price that appears on the cover page of this prospectus, less applicable underwriting discounts and commissions. If this option is exercised in full, the total price to the public will be $, and the total proceeds to us, before expenses, will be $. If the underwriters exercise this option, each underwriter will be obligated, subject to the conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's amount reflected in the above table.

The following table provides information regarding the amount of the discounts and commissions to be paid to the underwriters by us, before expenses. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to 535,714 additional shares from us:

	Per Share	Total Without Exercise of Over-Allotment Option	Total With Full Exercise of Over-Allotment Option
Initial public offering price	$	$	$
Underwriting discounts and commissions payable by us (8%)	$	$	$
Non-accountable expense allowance (1%)	$		
Proceeds to us, before other expenses	$	$	$

We have also agreed to pay Aegis Capital Corp. (a) a non-accountable expense allowance equal to 1.0% of the gross proceeds raised in the offering and (b) $150,000 for fees and expenses of legal counsel and other out-of-pocket expenses. We estimate the total expenses payable by us for this offering will be approximately $3.0 million, which amount excludes underwriting discounts and commissions and the non-accountable expense allowance.

The Company has agreed to issue to Aegis Capitol Corp. or its designees warrants to purchase up to a total of 5.0% of the shares of common stock sold in this offering (excluding the shares sold through the exercise of the over-allotment option). Such warrants and underlying shares of common stock are included in this prospectus. The warrants are exercisable at $ per share (125% of the public offering price) commencing on a date which is 180 days from the commencement of sales in the offering and expiring on a date which is no more than five (5) years from the commencement of sales in the offering in compliance with FINRA Rule 5110. The warrants have been deemed compensation by FINRA and are therefore subject to a 180 day lock-up pursuant to Rule 5110 of FINRA. The underwriters (or their permitted assignees under the Rule) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will it engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from effectiveness. The warrants may be exercised as to all, or a lesser number of shares of common stock, and will provide for cashless exercise and will contain provisions for "piggyback" registration rights, for a period of no greater than seven (7) years from the commencement of sales in the offering in compliance with FINRA Rule 5110. The Company will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or the Company's recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant exercise price.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

In connection with our initial public offering, our directors, executive officers, employees and 5% stockholders have agreed not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any of our common stock or securities convertible into or exchangeable for, or that represent the right to receive, shares of common stock, for a period of 180 days following the closing of the offering of the shares. This means that, subject to certain exceptions, for a period of 180 days following the closing of the offering of the shares, such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of Aegis Capital Corp.

We have agreed, for a period of 365 days following the date of the closing of the offering of the shares, that we will not, without the prior written consent of Aegis Capital Corp., issue, enter into any agreement to issue or announce the issuance or proposed issuance of any common stock, shares or share equivalents except for the issuance of shares of common stock or options to employees, consultants, officers or directors of our Company pursuant to any stock or option plan duly adopted for such purpose, approved by the Company's stockholders and issued for bona fide services permissible under Form S-8.

Prior to the offering, there has been no public market for our shares of common stock. The initial public offering price for the shares of common stock will be negotiated among us and the underwriters. Among the factors to be considered in determining the initial public offering price of the shares of common stock, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We have applied to list our common stock on Nasdaq under the symbol "CING."

Conflict of Interest

Patrick Gallagher is a member of our board of directors. He is also a Managing Director at Laidlaw & Company (UK) Ltd. Because of this relationship, Laidlaw & Company (UK) Ltd. is deemed to have a conflict of interest under FINRA Rule 5121. Accordingly, this offering is being conducted in accordance with the applicable provisions of Rule 5121. Pursuant to FINRA Rule 5121, a "qualified independent underwriter" is not required to participate in the offering because the underwriter primarily responsible for managing the offering, Aegis Capital Corp., does not have a conflict of interest, is not an affiliate of Laidlaw & Company (UK) Ltd. and meets the requirements of FINRA Rule 5121(f)(12)(E). In accordance with the requirements of FINRA Rule 5121, Laidlaw & Company (UK) Ltd. will not confirm sales of the shares to any account over which it exercises discretionary authority without the prior written approval of the account holder.

Rules of the SEC may limit the ability of the underwriters to bid for or purchase shares of common stock before the distribution of the shares of common stock is completed. However, the underwriters may engage in the following activities in accordance with the rules:

- Stabilizing transactions – The representative may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares of common stock, so long as stabilizing bids do not exceed a specified maximum.

- Over-allotments and syndicate covering transactions – The underwriters may sell more shares of common stock in connection with the offering than the number of shares of common stock that they have committed to purchase. This over-allotment creates a short position for the underwriters. This short sales position may involve either "covered" short sales or "naked" short sales. Covered short sales are short sales made in an amount not greater than the underwriters' over-allotment option to purchase shares of common stock in the offering described above. The underwriters may close out any covered short position either by exercising its over-allotment option or by purchasing shares of common stock in the open market. To determine how they will close the covered short position, the underwriters will consider, among other things, the price of the shares of common stock available for purchase in the open market, as compared to the price at which they may purchase shares of common stock through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that, in the open market after pricing, there may be downward pressure on the price of the shares of common stock that could adversely affect investors who purchase shares of common stock in the offering.

- Penalty bids – If the representative purchases shares of common stock in the open market in a stabilizing transaction or syndicate covering transaction, it may reclaim a selling concession from the underwriters and selling group members who sold those shares of common stock as part of the offering.

- Passive market making – Market makers in the shares of common stock who are underwriters or prospective underwriters may make bids for or purchases of shares of common stock, subject to limitations, until the time, if ever, at which a stabilizing bid is made.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales or to stabilize the market price of the shares of common stock may have the effect of raising or maintaining the market price of the shares of common stock or preventing or mitigating a decline in the market price of the shares of common stock. As a result, the price of the shares of common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the shares of common stock if it discourages resales of the shares of common stock.

Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares of common stock. These transactions may occur on the Nasdaq Capital Market or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

Electronic Delivery of Preliminary Prospectus

A prospectus in electronic format may be delivered to potential investors by one or more of the underwriters participating in the offering. The prospectus in electronic format will be identical to the paper version of such prospectus. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part.

Notice to Non-U.S. Investors

Belgium

The offering is exclusively conducted under applicable private placement exemptions and therefore it has not been and will not be notified to, and this document or any other offering material relating to the shares of common stock has not been and will not be approved by, the Belgian Banking, Finance and Insurance Commission ("Commission bancaire, financière et des assurances/Commissie voor het Bank, Financie en Assurantiewezen"). Any representation to the contrary is unlawful.

Each underwriter has undertaken not to offer sell, resell, transfer or deliver directly or indirectly, any shares of common stock, or to take any steps relating/ancillary thereto, and not to distribute or publish this document or any other material relating to the shares of common stock or to the offering in a manner which would be construed as: (a) a public offering under the Belgian Royal Decree of 7 July 1999 on the public character of financial transactions; or (b) an offering of securities to the public under Directive 2003/71/EC which triggers an obligation to publish a prospectus in Belgium. Any action contrary to these restrictions will cause the recipient and the company to be in violation of the Belgian securities laws.

Canada

This document constitutes an "exempt offering document" as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the securities described herein, or the Securities. No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this document or on the merits of the Securities and any representation to the contrary is an offence.

Canadian investors are advised that this document has been prepared in reliance on section 3A.3 of National Instrument 33-105 Underwriting Conflicts ("NI 33-105"). Pursuant to section 3A.3 of NI 33-105, this document is exempt from the requirement to provide investors with certain conflicts of interest disclosure pertaining to "connected issuer" and/or "related issuer" relationships as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

Resale Restrictions

The offer and sale of the securities in Canada is being made on a private placement basis only and is exempt from the requirement to prepare and file a prospectus under applicable Canadian securities laws. Any resale of Securities acquired by a Canadian investor in the offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the securities outside of Canada.

Representations of Purchasers

Each Canadian investor who purchases the securities will be deemed to have represented to the issuer and to each dealer from whom a purchase confirmation is received, as applicable, that the investor (i) is purchasing as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) is an "accredited investor" as such term is defined in section 1.1 of National Instrument 45-106 *Prospectus Exemptions*, or NI-45-106 or, in Ontario, as such term is defined in section 73.3(1) of the *Securities Act* (Ontario); and (iii) is a "permitted client" as such term is defined in section 1.1 of National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*.

Taxation and Eligibility for Investment

Any discussion of taxation and related matters contained in this document does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the securities and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the securities or with respect to the eligibility of the securities for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

Rights of Action for Damages or Rescission

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum, including where the distribution involves an "eligible foreign security" as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration Exemptions* and in Multilateral Instrument 45-107 *Listing Representation and Statutory Rights of Action Disclosure Exemptions*, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a "misrepresentation" as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defences under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

Language of Documents

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

France

Neither this prospectus nor any other offering material relating to the shares of common stock has been submitted to the clearance procedures of the Autorité des marchés financiers in France. The shares of common stock have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the shares of common stock has been or will be: (a) released, issued, distributed or caused to be released, issued or distributed to the public in France; or (b) used in connection with any offer for subscription or sale of the shares of common stock to the public in France. Such offers, sales and distributions will be made in France only: (i) to qualified investors (investisseurs qualifiés) and/or to a restricted circle of investors (cercle restreint d'investisseurs), in each case investing for their own account, all as defined in and in accordance with Articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code monétaire et financier; (ii) to investment services providers authorised to engage in portfolio management on behalf of third parties; or (iii) in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French Code monétaire et financier and article 211-2 of the General Regulations (Règlement Général) of the Autorité des marchés financiers, does not constitute a public offer (appel public à l'épargne). Such shares of common stock may be resold only in compliance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code monétaire et financier.

Israel

This prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares of common stock is directed only at, investors listed in the first addendum to the Israeli Securities Law, or the Addendum, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Italy

The offering of the shares of common stock offered hereby in Italy has not been registered with the Commissione Nazionale per la Società e la Borsa, or CONSOB, pursuant to Italian securities legislation and, accordingly, the shares of common stock offered hereby cannot be offered, sold or delivered in the Republic of Italy, or Italy, nor may any copy of this prospectus or any other document relating to the shares of common stock offered hereby be distributed in Italy other than to professional investors (operatori qualificati) as defined in Article 31, second paragraph, of CONSOB Regulation No. 11522 of 1 July, 1998 as subsequently amended. Any offer, sale or delivery of the shares of common stock offered hereby or distribution of copies of this prospectus or any other document relating to the shares of common stock offered hereby in Italy must be made:

(a) by an investment firm, bank or intermediary permitted to conduct such activities in Italy in accordance with Legislative Decree No. 58 of 24 February 1998 and Legislative Decree No. 385 of 1 September 1993, or the Banking Act;

(b) in compliance with Article 129 of the Banking Act and the implementing guidelines of the Bank of Italy; and

(c) in compliance with any other applicable laws and regulations and other possible requirements or limitations which may be imposed by Italian authorities.

Sweden

This prospectus has not been nor will it be registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this prospectus may not be made available, nor may the shares of common stock offered hereunder be marketed and offered for sale in Sweden, other than under circumstances which are deemed not to require a prospectus under the Financial Instruments Trading Act (1991: 980).

Switzerland

The shares of common stock offered pursuant to this prospectus will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to art. 652a or art. 1156 of the Swiss Federal Code of Obligations. The company has not applied for a listing of the shares of common stock being offered pursuant to this prospectus on the SWX Swiss Exchange or on any other regulated securities market, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the relevant listing rules. The shares of common stock being offered pursuant to this prospectus have not been registered with the Swiss Federal Banking Commission as foreign investment funds, and the investor protection afforded to acquirers of investment fund certificates does not extend to acquirers of shares of common stock.

Investors are advised to contact their legal, financial or tax advisers to obtain an independent assessment of the financial and tax consequences of an investment in shares of common stock.

European Economic Area and the United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom, each referred to as a Relevant State, no shares of common stock have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares of common stock which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation), except that offers of shares of common stock may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares of common stock shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any shares of common stock or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with us and the underwriters that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares of common stock being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares of common stock acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

We, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of common stock in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of common stock, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

References to the Prospectus Regulation includes, in relation to the United Kingdom, the Prospectus Regulation as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018.

The above selling restriction is in addition to any other selling restrictions set out below.

United Kingdom

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the Financial Promotion Order), (ii) are persons falling within Article 49(2)(a) to (d), or high net worth companies, unincorporated associations etc., of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended, or FSMA,) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as "relevant persons"). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Lowenstein Sandler LLP, New York, New York. Certain legal matters relating to the offering will be passed upon for the underwriters by Sichenzia Ross Ference LLP, New York, New York.

EXPERTS

The consolidated financial statements of Cingulate Therapeutics LLC as of December 31, 2020 and 2019, and for each of the years in the two-year period ended December 31, 2020, have been included herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2020 consolidated financial statements contains an explanatory paragraph that states that the Company's recurring losses from operations and net capital deficiency raise substantial doubt about the entity's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-1 under the Securities Act of 1933, as amended, with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits filed therewith. For further information about us and the common stock offered hereby, reference is made to the registration statement and the exhibits filed therewith. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete, please see the copy of the contract or document that has been filed for the complete contents of that contract or document. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The exhibits to the registration statement should be reviewed for the complete contents of these contracts and documents.

We currently do not file periodic reports with the SEC. Upon the completion of this offering, we will be required to file periodic reports, proxy statements and other information with the SEC pursuant to the Securities Exchange Act of 1934, as amended. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the website is www.sec.gov.

We also maintain a website at www.cingulate.com. Upon completion of this offering, you may access these materials at our website free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained in, or that can be accessed through, our website is not a part of, and is not incorporated into, this prospectus.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Members and Board of Managers

Cingulate Therapeutics LLC:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cingulate Therapeutics LLC and its subsidiary (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and other comprehensive loss, changes in members' capital, and cash flows for each of the years in the two-year period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, 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 suffered losses and negative cash flows from operations since inception and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. 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. 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.

/s/ KPMG LLP

We have served as the Company's auditor since 2020.

Kansas City, Missouri
May 21, 2021

Cingulate Therapeutics LLC
Consolidated Balance Sheets
December 31, 2020 and 2019

	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,197,672	$ 418,470
Short-term investments	933	18,723
Miscellaneous receivables	151,772	113,240
Prepaid expenses and other current assets	439,496	427,884
Total current assets	1,789,873	978,317
Property and equipment, net	3,038,959	3,024,391
Operating lease right-of-use assets	958,724	1,135,048
Other assets	-	143,016
Total assets	**5,787,556**	**5,280,772**
LIABILITIES AND MEMBERS' CAPITAL		
Current liabilities:		
Accounts payable	975,114	1,895,886
Accrued expenses	1,215,559	524,029
Current installments of obligations under finance leases	436,259	375,818
Other current liabilities	234,168	155,492
Notes payable	500,335	-
Total current liabilities	3,361,435	2,951,225
Long-term liabilities:		
Obligations under finance leases	52,630	422,058
Operating lease liabilities	1,057,441	1,291,609
Other liabilities	23,615	-
Total liabilities	**4,495,121**	**4,664,892**
Members' capital:		
Members' capital	1,292,270	615,848
Accumulated other comprehensive income	165	32
Total members' capital	**1,292,435**	**615,880**
Total liabilities and members' capital	**$ 5,787,556**	**$ 5,280,772**

See notes to consolidated financial statements

Cingulate Therapeutics LLC
Consolidated Statements of Operations and Other Comprehensive Loss
Years Ended December 31, 2020 and 2019

	2020	2019
Operating expenses:		
Research and development	$ 5,093,277	$ 9,094,826
General and administrative	1,990,086	2,552,434
Operating loss	**(7,083,363)**	**(11,647,260)**
Interest and other income (expense), net	(100,252)	100,962
Net loss	**$ (7,183,615)**	**$ (11,546,298)**
Other comprehensive income (loss):		
Change in unrealized (gain) loss on short-term investments	(133)	1,459
Comprehensive loss	**$ (7,183,748)**	**$ (11,544,839)**

See notes to consolidated financial statements

Cingulate Therapeutics LLC
Consolidated Statements of Changes in Members' Capital
Years Ended December 31, 2020 and 2019

	Members' Capital	Accumulated Other Comprehensive (Loss) Income	Total Members' Capital
Balance, January 1, 2019	**$ 6,018,735**	**$ 1,491**	**$ 6,020,226**
Members' capital contributions	6,144,841	-	6,144,841
Unrealized gains on short-term investments	-	(1,459)	(1,459)
Exchange offer	(1,430)	-	(1,430)
Net loss	(11,546,298)	-	(11,546,298)
Balance, December 31, 2019	**615,848**	**32**	**615,880**
Members' capital contributions	7,860,037	-	7,860,037
Unrealized losses on short-term investments	-	133	133
Net loss	(7,183,615)	-	(7,183,615)
Balance, December 31, 2020	**$ 1,292,270**	**$ 165**	**$ 1,292,435**

See notes to consolidated financial statements

Cingulate Therapeutics LLC
Consolidated Statements of Cash Flows
Years Ended December 31, 2020 and 2019

	2020	2019
Operating activities:		
Net loss	$ (7,183,615)	$ (11,546,298)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	666,029	178,912
Other, net	-	(48,052)
Changes in operating assets and liabilities:		
Miscellaneous receivables	(38,532)	(71,835)
Prepaid expenses and other current assets	(11,612)	157,821
Operating lease right-of-use assets	176,324	845,062
Other noncurrent assets	143,016	(20,698)
Trade accounts payable and accrued expenses	(448,812)	1,698,090
Operating lease liabilities	(137,492)	(725,612)
Other liabilities	23,615	-
Net cash used in operating activities	**(6,811,079)**	**(9,532,610)**
Investing activities:		
Purchase of property and equipment	(402,096)	(1,015,814)
Purchase of short-term investments	(78)	(1,546,445)
Proceeds from sale of short-term investments	18,000	5,305,287
Net cash (used in) provided by investing activities	**(384,174)**	**2,743,028**
Financing Activities:		
Members' capital contributions	7,506,372	6,144,841
Proceeds from notes payable	954,000	-
Payment on notes payable	(100,000)	-
Principal payments on finance lease obligations	(385,917)	-
Net cash provided by financing activities	**7,974,455**	**6,144,841**
Cash and cash equivalents:		
Net increase (decrease) in cash and cash equivalents	779,202	(644,741)
Cash and cash equivalents at beginning of year	418,470	1,063,211
Cash and cash equivalents at end of year	**$ 1,197,672**	**$ 418,470**
Supplemental information:		
Non-cash investing activity:		
Property and equipment accrued but not yet paid at end of year	$ 201,570	$ 252,012
Cash payments:		
Interest paid	$ 50,229	$ -

See notes to consolidated financial statements

(1) Nature of the Business and Liquidity

Cingulate Therapeutics LLC (the "Company") is a Delaware limited liability company ("LLC") that was formed on November 14, 2012. The Company's form of organization is that of an LLC; accordingly, its equity owners are referred to as "Members." Effective May 1, 2019, Cingulate Inc., a wholly-owned subsidiary of Cingulate Therapeutics LLC was formed to provide employee services to Cingulate Therapeutics LLC. The consolidated financial statements and notes represent the full consolidation of Cingulate Inc. and Cingulate Therapeutics LLC and all references to the Company represent this full consolidation.

The Company is a clinical stage 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"). 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 a 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. The Company completed a Proof of Concept Phase I clinical trial and a Phase I Pharmacokinetic clinical trial by June 2017 and filed its Investigative New Drug ("IND") applications with the U.S. Food and Drug Administration ("FDA") in August 2019. In March 2020 the Company completed its Phase 1/2 bioavailability clinical trial in ADHD patients. The Company has offices in Kansas City, Kansas and Morristown, New Jersey.

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. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to additional private investment, potential strategic research and development partners, licensing and/or marketing arrangements with pharmaceutical companies and public offerings of securities through an Initial Public Offering or Alternative Public Offering. 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 Therapeutics LLC and its wholly-owned subsidiary, Cingulate Inc. 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. At December 31, 2020 and 2019, the Company had no bank balances on deposit with any banks which exceeded federally insured limits.

(d) **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, 2020 and 2019 consisted of bank deposits and a short-term money market fund. Cash and cash equivalents are carried at cost which is indicative of fair value.

(e) **Short-term Investments**

Short-term investments are recorded at fair value with unrealized gains and losses recorded in other comprehensive income in the period in which they arise. Short-term investments are comprised of short-term bond funds and are classified by the Company as available for sale securities. Gains and losses on the sale of securities, determined using the specific identification method, are recorded on the date of trade. Unrealized gains and losses for the years ended December 31, 2020 and 2019 were ($133) and $1,459, respectively.

(f) **Miscellaneous Receivables**

Miscellaneous receivables consist of payroll tax credits generated from the Company’s 2020 and 2019 federal income tax returns which had not yet been received as of December 31, 2020 and 2019. As of December 31, 2020 and 2019, the Company determined that there is no allowance necessary relating to these receivables.

(g) **Property and Equipment**

Property and equipment are stated at cost, less accumulated depreciation and amortization. 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.

(h) **Leases**

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)* and subsequently has issued additional guidance (collectively "ASC 842"), which requires companies to generally recognize operating and finance lease liabilities and corresponding right-of-use (ROU) assets on the balance sheet. The Company elected to adopt ASC 842 on January 1, 2019 using a modified retrospective transition approach as of the effective date. The Company has elected to adopt the package of transition practical expedients and, therefore, has not reassessed (1) whether existing or expired contracts contain a lease, and 2) lease classification for existing or expired leases. The Company did not elect the practical expedient to use hindsight for leases existing at the adoption date.

The adoption of ASC 842 had a material effect on both the Company's consolidated balance sheet and consolidated statements of operations and other comprehensive loss. The most significant changes to the consolidated balance sheet relate to the recognition of the new ROU assets and lease liabilities for operating leases. The most significant changes to the consolidated statements of operations and other comprehensive loss related to the timing of the commencement date of one of the office space leases under ASC 842 which in effect began straight-lining the lease cost starting at an earlier date, thus increasing rent expense in 2019 and 2020. The Company's accounting for finance leases was modified due to the ASC 842 definition of a financing lease including lessees of an asset in which the lessor has no future use of the asset being considered a financing lease. The adoption of ASC 842 also had no material effect on operating, investing, or financing cash flows in the consolidated statements of cash flows. However, ASC 842 has significantly affected the Company's disclosures about noncash investing and financing activities. Additionally, the Company's lease-related disclosures have significantly increased as of and for the year ended December 31, 2020 and 2019 as compared to prior years. See Note 9.

As a result of adopting ASC 842, the Company recognized additional operating liabilities of $969,321 (of which $818,561 was current and $150,760 was noncurrent) with corresponding ROU assets of the same amount as of January 1, 2019.

The Company is a lessee in two noncancellable operating leases, relating to office space at the Kansas City headquarters office and the New Jersey office and two finance leases, for certain furniture and equipment.

The Company determines if an arrangement is or contains a lease at contract inception. The Company recognizes a 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. 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 developmental 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.

Variable lease payments associated with the Company's leases are recognized when the event, activity, or circumstance in the lease agreement on which those payments are assessed occurs. Variable lease payments are presented as general and administrative expense in the Company's consolidated statements of operations and other comprehensive loss in the same line item as expense arising from fixed lease payments (operating leases) or amortization of the ROU asset (finance leases).

ROU assets for operating and finance leases are evaluated for impairment losses. The Company uses 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 portion of operating lease liabilities is included in other current liabilities and the long-term portion is presented separately as operating lease liabilities on the consolidated balance sheet. Finance lease ROU assets are included in property, plant, and equipment. The current portion of finance lease liabilities is included in current installments of obligations under finance leases on the consolidated balance sheets.

(i) **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, 2020 or 2019.

(j) **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 two 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.

(k) **Paycheck Protection Program**

On March 27, 2020, the U.S. federal government enacted the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). The CARES Act includes a provision for a Paycheck Protection Program ("PPP") administered by the U.S. Small Business Administration ("SBA") and further amended by the Paycheck Protection Program Flexibility Act of 2020 ("PPP Flexibility Act"), which was enacted on June 5, 2020. In April 2020, the Company received a PPP Loan of $312,500. In accordance with the requirements of the CARES Act, as amended by the PPP Flexibility Act, the PPP Loan may be fully forgiven if proceeds are used to pay eligible payroll costs, rent, mortgage interest and utilities. The Company believes that all of the requirements of the CARES Act have been met and that it is probable that the entire balance of the PPP Loan will be forgiven. As such, there is no liability for the PPP Loan reflected in the consolidated financial statements as the relevant expense accounts were adjusted to reflect the amounts covered under the loan.

(l) **Segments**

Operating segments are components of a Company for which separate financial information is available and is evaluated regularly by the Company's chief operating decision-maker in deciding how to allocate resources and in assessing performance. The Company currently operates in one operating business segment- drug development.

(m) **Income Taxes**

The Company is organized as an LLC, but is treated as a partnership for tax purposes. Thus, its taxable income or loss for federal and state income tax purposes is reported by and taxed on the tax returns of its Members. The Company's wholly-owned subsidiary, Cingulate Inc., is treated as a corporation for federal income tax purposes.

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. The Company is no longer subject to U.S. federal income tax examinations by tax authorities for years before 2016.

(3) Fair Value of Assets and Liabilities

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair values based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

Level 1—Inputs represent unadjusted quoted prices for identical assets exchanged in active markets.

Level 2—Inputs include directly or indirectly observable inputs other than Level 1 inputs such as quoted prices for similar assets exchanged in active or inactive markets; quoted prices for identical assets exchanged in inactive markets; other inputs that are considered in fair value determinations of the assets, such as interest rates and yield curves that are observable at commonly quoted intervals.

Level 3—Inputs include unobservable inputs used in the measurement of assets. Management is required to use its own assumptions regarding unobservable inputs because there is little, if any, market activity in the assets or related observable inputs that can be corroborated at the measurement date. Measurements of certain investments carried at fair value are based primarily on valuation models, discounted cash flow models or other valuation techniques that are believed to be used by market participants. Unobservable inputs require management to make certain projections and assumptions about the information that would be used by market participants in pricing assets.

The categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The Company's policy is to recognize significant transfers between the levels at the actual date of the event. For the year ended December 31, 2020 and 2019, there were no transfers in or out of Levels 1, 2, or 3.

The Company has no Level 2 or Level 3 investments. The short-term investments held by the Company are categorized as Level 1 investments as quoted market prices are readily available for these investments.

Assets measured and carried at fair value on a recurring basis are summarized below:

	December 31, 2020					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value of Current Assets	Fair Value of Non-Current Assets	Fair Value of Total Assets
Equity investments						
Mutual funds	$ 920	$ 13	$ -	$ 933	$ -	$ 933

	December 31, 2019					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value of Current Assets	Fair Value of Non-Current Assets	Fair Value of Total Assets
Equity investments						
Mutual Funds	$ 18,750	$ -	$ (27)	$ 18,723	$ -	$ 18,723

(4) Property and Equipment

Property and equipment, net consists of the following at December 31, 2020 and 2019:

	Estimated Useful Life (in years)	2020	2019
Equipment	2-7	$ 1,988,598	$ 1,988,598
Furniture and fixtures	7	131,278	82,258
Computer equipment	5	41,898	41,897
Leasehold improvements	5	471,505	333,022
Construction-in-process	-	1,363,418	870,325
		3,996,697	3,316,100
Less: accumulated depreciation		(957,738)	(291,709)
		$ 3,038,959	$ 3,024,391

Depreciation expense was $666,029 and $178,912 for the years ended December 31, 2020 and 2019, respectively.

(5) Accrued Expenses

Accrued expenses consisted of the following at December 31, 2020 and 2019:

	2020	2019
Payroll and related costs	$ 1,082,643	$ 294,483
Professional and consulting fees	15,000	2,500
Research and development	18,944	172,607
Interest	64,105	-
Other	34,867	54,439
	$ 1,215,559	$ 524,029

Payroll was deferred for a number of the Company's employees in 2020 and to a lesser extent in 2019 resulting in accrued payroll and related costs at the end of each year.

(6) Notes Payable

Notes payable consisted of the following as of December 31, 2020 and 2019:

	2020	2019
$100,000, unsecured note payable to a member, principal and interest of 8% due in full on July 24, 2021 (1)	$ 100,000	$ -
$354,000, unsecured note payable to a member, principal and interest of 8% due in full on February 25, 2021 (1)	254,000	-
$500,000, unsecured note payable to a member, principal and interest of 8% due in full on February 1, 2021 (2)	146,335	-
	$ 500,335	$ -

(1) Principal and interest is convertible upon lenders' notice into Preferred Units of the Company at a 25% discount to the offered unit prices at the time of conversion.

(2) Principal and interest is convertible upon lender's notice into Preferred Units of the Company at the offered unit prices at the time of conversion. $353,665 was converted to 246,096 Preferred Units of the Company at the current unit price in accordance with the terms of the note payable agreement in 2020.

Interest expense for these notes payable for the year ended December 31, 2020 was $54,605.

(7) Members' Capital

As of December 31, 2020, the Company had multiple classes of members' capital, comprised of Founders Units, Class B, D, E and F Preferred Units, and Class C Profits Interests. Class B, E and F Preferred Units have similar rights specifically related to cash distributions as a return of invested capital. Class D Preferred Units hold all the rights of Founders and the other Classes of Preferred Units plus some additional rights noted below. All classes of members' capital hold voting rights. The Company maintains capital accounts for each member.

Founders Units

At inception the Company authorized, through the Operating Agreement, 34,595,000 Founders Units for issuance to early members of the Company with no cash consideration. All authorized Founders Units have been issued. In accordance with the Operating Agreement, the Founders Units hold certain preemptive rights with respect to operations of the Company including liquidation of the Company, amendment of the Operating Agreement, entering into strategic partnerships, alliances or acquisitions, creation or issuance of new Units, increasing or decreasing the size of the Board of Managers (the "Board") and entering in to related party transactions.

Class A Convertible Preferred Units

With the 2nd Amended and Restated Operating Agreement dated June 30, 2017 the Company authorized 7,287,236 Class A Convertible Preferred Units; all have been issued. Holders of Class A Preferred Units were entitled to an eight percent annual return ("Class A Preferred Interest") as defined in the Agreement. On March 31, 2018, all Class A Preferred unitholders accepted an exchange offer to convert their Class A Preferred Units into Class B Preferred Units in an amount equal to the capital balance of the Class A Preferred Units, plus accrued interest, thus eliminating this class of members' capital going forward. The Company raised a total of $4.4 million from issuance of Class A Units.

Class B Preferred Units

The Board authorized 11,843,242 Class B Preferred Units on August 18, 2017, including the Class A Units converted as mentioned above; all have been issued. The Company raised a total of $3.7 million from issuance of Class B Units.

Class C Profits Interest Units

The Board authorized 8,500,000 Class C Profits Interest Units on November 1, 2017, 8,142,461 have been issued as described in Note 8. Profits Interest Units are issued at no cost to the holder and are used as an incentive for management and others.

Class D Preferred Units

The Board authorized 6,104,249 Class D Preferred Units; all have been issued. The Company raised a total of $7.5 million from issuance of Class D Units. In addition to their Preferred status, the Class D Units hold similar rights as Founders Units and provide for additional preemptive rights including entering into new lines of business, changes in the Company's independent accountants, a sale or disposition of Company property, commitment to capital expenditures, acquisitions and mergers, investment in subsidiaries or joint ventures and changes in compensation, bonuses or issuance of Profits Interest Units to Company officers.

Class E Preferred Units

The Board authorized 3,997,438 Class E Preferred Units; all have been issued. The Company raised a total of $5.2 million from issuance of Class E Units. The newly created Class E Units as authorized by the Board and as reflected in the 3rd Amended and Restated Operating Agreement was effective on July 24, 2018.

Class F Preferred Units

The Board authorized 6,958,458 Class F Preferred Units in two tranches; 6,739,968 have been issued as of December 31, 2020. The Company raised a total of $10.8 million from issuance of Class F Units as of December 31, 2020. The newly created Class F Units as authorized by the Board and as reflected in the 3rd Amended and Restated Operating Agreement to reflect the creation of the Class F Units became effective on December 14, 2018.

Distributions, if any, from the Company are made first to the holders of Class B, D, E and F Preferred Units, pro rata in proportion to each such member's unreturned capital contributions. Distributions are then made to all members including Founders Units, pro rata in proportion to the number of units held by each member, with consideration given to the applicable distribution thresholds for Class C Profits Interests at which each was issued and as disclosed in each Profits Interest Unit agreement, as further described in Note 8.

Costs associated with issuance of the Units is immaterial.

(8) Profits Interest Plan

During 2017, the Board established and adopted the Cingulate Therapeutics LLC Equity Incentive Plan (the Plan) to provide for issuance of Class C Profits Interest Units (PIU's) to employees, equity Members, Board members and service providers of the Company, as defined in the Plan, eligible to receive PIU's as an incentive under the Plan. PIU's are granted at the discretion of the Board of Managers of the Company and in some cases at the discretion of the Chief Executive Officer of the Company based upon Board authorization. The PIU's are issued at a Distribution Threshold equal to the pre-money fair market valuation of the Company at the date of issuance. The Distribution Threshold is the amount by which a cash distribution, made pro rata to all Members, if any, must be exceeded in order for a particular PIU holder to participate in the allocated distribution. The PIU's vesting period with respect to the service condition is defined in the PIU award agreement and can range from 30 days to three years with an average vesting period for all PIU's granted of 107 days. As defined in the Company's Operating Agreement, all PIU's issued under the Plan entitle the holder to participate pro rata in the profits, if any, of the Company over the stated Distribution Threshold, assuming a cash distribution is generally made to all Members, subject to any preference or priorities of the other classes of Units. The Class C PIU's also hold voting rights on a one-for-one basis.

At December 31, 2020 and 2019, the Company had granted and issued 8,142,461 and 6,616,781 PIU's, net of forfeitures, respectively. The Company accounts for these awards under *ASC Topic 718, Compensation – Stock Compensation, Share Based Payment Awards*, as equity classified awards. No compensation expense was recorded during the years ended December 31, 2020 and 2019 related to the PIU's as the future achievement of the thresholds and targets (the performance condition) to achieve payout was not deemed probable. This assessment was made based on the Company's history of operating losses and continued challenges in raising necessary equity capital to fund operations. Based on the terms of the PIU's, a future event impacting the awards other than a liquidation event would result in a modification to the terms of the arrangement, and the fair value of the awards would be assessed at that point in time for potential recognition in the consolidated financial statements. Such potential impact to the consolidated financial statements at that point in time could be material.

In accordance with the Company's Operating Agreement, the number of PIU's that may be granted is limited to a total of 8,500,000.

The following summarizes the activity of the Company's Plan during the years ended December 31, 2020 and 2019:

	Profits Interest Units		**Distribution Thresholds (in millions)**
Outstanding at January 1, 2019	5,780,333	$	25-$80
Issued	893,668	$	90-$120
Forfeited	(57,220)	$	90
Oustanding at December 31, 2019	6,616,781		
Issued	1,525,680	$	80-$120
Forfeited	-		
Outstanding at December 31, 2020	8,142,461		

At December 31, 2020 and 2019 there were 357,539 and 1,883,219, respectively, additional PIU's available to be granted under the plan. At December 31, 2020 and 2019, 8,136,955 and 6,138,533 PIU's, respectively, had vested based upon the vesting period as outlined in the PIU agreement.

PIU's issued and outstanding as of December 31, 2020 at the various distribution thresholds were as follows:

	Distribution Threshold $ (in millions):						
Year Granted	$25	$40	$75	$80	$90	$120	Total
2017	4,753,000	125,200	-	-	-	-	4,878,200
2018	-	661,525	217,725	22,883	-	-	902,133
2019	-	-	-	-	377,524	458,924	836,448
2020	-	-	-	1,476,126	-	49,554	1,525,680
Total	4,753,000	786,725	217,725	1,499,009	377,524	508,478	8,142,461

(9) Leases

In late December 2017, the Company entered into a 36-month noncancelable lease agreement for office space with rent commencing February 1, 2018. The base rent for this lease ranged from $9,479 to $9,625 per month. On June 4, 2019, this lease was superseded as a new lease for this office space was executed to expand the square footage leased by the Company. The term of the new lease is for a period of five years commencing on the date of receipt of a Certificate of Occupancy for the expanded space, which occurred on May 1, 2020. Under this new expanded lease, total rent ranges from $30,453 to $33,145 per month. The new lease provided for a lease incentive by the lessor of tenant improvements totaling $201,600.

The Company leases office space for its New Jersey based employees from a related party. The base rent for this lease was $3,000 per month in 2020 and 2019 and it was entered into in January 2018, for a three-year lease agreement which ended as of December 31, 2020.

In 2018, the Company entered into an 18-month operating lease for manufacturing equipment. Interim rent was incurred during installation of the equipment with the lease commencing in June 2018. Monthly lease payments for this leased equipment were $61,786. In December 2019, this lease was extended for a period of twenty-four months with a monthly lease payment of $37,072. At this date, this lease was modified for accounting purposes and its classification was assessed as a financing type lease as management determined the lessor to have no alternative future use of the leased asset. The ROU assets associated with the leased machinery is being amortized over the remaining 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 is March 2025.

The components of lease cost for the years ended December 31, 2020 and 2019 were as follows:

	2020	2019
Operating lease cost	$ 338,787	$ 1,001,323
Finance lease cost:		
Amortization of right-of-use assets	408,180	-
Interest on lease liabilities	72,374	-
Total finance lease cost	480,554	-
Total lease cost	$ 819,341	$ 1,001,323

Amounts reported in the consolidated balance sheets as of December 31, 2020 and 2019 were as follows:

	2020	2019
Operating Leases:		
Operating lease right-of-use assets	$ 958,724	$ 1,135,048
Other current liabilities	234,168	155,492
Operating lease liabilities	1,057,441	1,291,609
Total operating lease liabilities	1,291,609	1,447,101
Finance leases:		
Property and equipment	874,803	797,875
Accumulated amortization	(407,180)	-
Property and equipment, net	467,623	797,875
Current installments of obligations under finance leases	436,259	375,818
Long-term portion of obligations under finance leases	52,630	422,058
Total finance lease liabilities	$ 488,889	$ 797,876

Other information relating to leases as of December 31, 2020 and 2019 was as follows:

Supplemental cash flow information:	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flow from operating leases	$ 299,953	$ 881,698
Operating cash flow from finance leases	72,374	-
Financing cash flow from finance leases	385,914	-
ROU assets obtained in exchange for lease obligations:		
Operating leases	-	1,010,789
Finance leases	76,928	797,876
Reductions to ROU assets resulting from reductions to lease obligations:		
Operating leases	176,324	845,062
Finance leases	407,180	-
Weighted average remaining lease term:		
Operating leases	52 months	63 months
Finance leases	17 months	24 months
Weighted average discount rate:		
Operating leases	11.76%	11.79%
Finance leases	10.85%	11.66%

Maturities of lease liabilities under noncancellable leases as of December 31, 2020 are as follows:

	Operating leases	Finance leases
2021	$ 370,172	$ 462,764
2022	370,400	17,900
2023	378,800	17,900
2024	393,005	17,900
2025	132,580	4,473
Thereafter	-	-
Total undiscounted lease payments	1,644,957	520,937
Less imputed interest	(353,348)	(32,048)
Total lease liabilities	$ 1,291,609	$ 488,889

(10) 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 its products. 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 upon receipt of first marketing approval of each product in the field, payable on a per product basis.

The Company has not recorded any expense relating to the above milestones as it has not deemed them probable of occurring as of December 31, 2020 or December 31, 2019.

(11) Related Party Transactions

A member and general counsel of the Company is a partner with a law firm providing office facilities space that is leased by the Company. Rental expense incurred by the Company to the law firm was $36,000 in 2020 and 2019, which approximates fair value. As of December 31, 2020 and 2019, the Company owed $27,000 and $9,000, respectively on this lease.

The Company has three loans outstanding with related parties, all three members of Cingulate Therapeutics LLC and one also a Manager. (Note 6)

(12) Subsequent Events

Management evaluated events that occurred subsequent to December 31, 2020 through May 21, 2021, which is the date the financial statements were available to be issued.

In early 2021, the Company renewed the office lease with the related party for a term of three years, with an option to extend for an additional three-year term at a monthly lease rate of $3,000.

In February 2021, the Company received a second PPP loan of $236,457, which was available under the CARES Act as described in Note 2.

In early 2021, the two notes payable with the maturity dates in February 2021 were renewed with the same terms and a maturity date of February 2022.

In May 2021, the name of Cingulate Inc. was changed to Cingulate Works Inc.

Cingulate Inc.
Consolidated Balance Sheets (unaudited)

	September 30 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,915,415	$ 1,197,672
Short-term investments	933	933
Miscellaneous receivables	357,062	151,772
Prepaid expenses and other current assets	3,283,542	439,496
Total current assets	5,556,952	1,789,873
Property and equipment, net	2,614,879	3,038,959
Operating lease right-of-use assets	910,498	958,724
Total assets	**9,082,329**	**5,787,556**
LIABILITIES AND MEMBERS' CAPITAL		
Current liabilities:		
Accounts payable	914,588	975,114
Accrued expenses	3,354,728	1,215,559
Current installments of obligations under finance leases	125,016	436,259
Other current liabilities	322,130	234,168
Notes payable	350,335	500,335
Total current liabilities	5,066,797	3,361,435
Long-term liabilities:		
Obligations under finance leases	41,395	52,630
Operating lease liabilities	871,306	1,057,441
Other liabilities	23,615	23,615
Total liabilities	**6,003,113**	**4,495,121**
Stockholders' Equity		
Members' Capital	-	32,314,541
Common Stock, $0.0001 par value; 240,000,000 shares authorized and 11,115,780 shares issued and outstanding as of September 30, 2021	1,112	-
Preferred Stock, $0.0001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of September 30, 2021	-	-
Additional Paid-in-Capital	52,156,476	-
Accumulated deficit	(49,078,372)	(31,022,106)
Total stockholders' equity	**3,079,216**	**1,292,435**
Total liabilities and stockholders' equity	**$ 9,082,329**	**$ 5,787,556**

See notes to consolidated financial statements.

Cingulate Inc.
Consolidated Statements of Operations (unaudited)

	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Operating expenses:		
Research and development	$ 7,147,513	$ 4,463,411
General and administrative	10,884,759	1,466,933
Operating loss	**(18,032,272)**	**(5,930,344)**
Interest and other income (expense), net	(23,994)	(59,646)
Loss before income taxes	(18,056,266)	(5,989,990)
Income tax benefit (expense)	-	-
Net loss	$ (18,056,266)	$ (5,989,990)
Net loss per share of common stock, basic and diluted	$ (1.62)	$ -
Shares used in computing net loss per share of common stock, basic and diluted	11,115,780	-

See notes to consolidated financial statements.

Cingulate Inc.
Consolidated Statements of Stockholders' Equity (unaudited)

	Common Stock		Additional Paid-in-Capital	Members' Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2020				**$ 24,454,506**	**$ (23,838,626)**	**$ 615,880**
Activity for the nine months to September 30, 2020:						
Members' capital contributions				3,928,100	-	3,928,100
Net loss				-	(5,989,990)	(5,989,990)
Balance September 30, 2020				**$ 28,382,606**	**$ (29,828,616)**	**$ (1,446,010)**
Balance, January 1, 2021	-	-	-	**$ 32,314,541**	**$ (31,022,106)**	**$ 1,292,435**
Activity for the nine months to September 30, 2021:						
Members' capital contributions	-	-	-	7,104,959	-	7,104,959
Conversion of LLC units to common stock in connection with Reorganization Merger	11,115,780	1,112	39,418,388	(39,419,500)	-	-
Modification of profits interests units in connection with Reorganization Merger	-	-	12,738,088	-	-	12,738,088
Net loss	-	-	-	-	(18,056,266)	(18,056,266)
Balance September 30, 2021	**11,115,780**	**$ 1,112**	**$ 52,156,476**	**$ -**	**$ (49,078,372)**	**$ 3,079,216**

See notes to consolidated financial statements

Cingulate Inc.
Consolidated Statements of Cash Flows (unaudited)

	Nine Months Ended September 30,	
	2021	**2020**
Operating activities:		
Net loss	$ (18,056,266)	$ (5,989,990)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	528,809	486,661
Noncash compensation expense relating to modification of profits interest units	12,738,088	-
Other, net	-	(164)
Changes in operating assets and liabilities:		
Miscellaneous receivables	(205,290)	101
Prepaid expenses and other current assets	(2,844,046)	(71,733)
Operating lease right-of-use assets	48,226	129,853
Trade accounts payable and accrued expenses	2,078,643	1,361,173
Other current liabilities	87,962	-
Operating lease liabilities	(186,135)	(93,357)
Other liabilities	-	31,119
Net cash used in operating activities	**(5,810,009)**	**(4,146,337)**
Investing activities:		
Purchase of property and equipment	(104,729)	(689,062)
Purchase of short-term investments	-	(78)
Proceeds from sale of short-term investments	-	18,000
Net cash used in provided by investing activities	**(104,729)**	**(671,140)**
Financing Activities:		
Members’ capital contributions	7,104,959	3,928,100
Payments on notes payable	(150,000)	-
Proceeds from notes payable	-	954,000
Principal payments on finance lease obligations	(322,478)	(207,497)
Net cash provided by financing activities	**6,632,481**	**4,674,603**
Cash and cash equivalents:		
Net increase (decrease) in cash and cash equivalents	717,743	(142,874)
Cash and cash equivalents at beginning of period	1,197,672	418,470
Cash and cash equivalents at end of period	**$ 1,915,415**	**$ 275,596**
Supplemental information:		
Non-cash investing activity:		
Property and equipment accrued but not yet paid at end of period	$ -	$ 328,730
Cash payments:		
Interest paid	$ 8,090	$ 30,700

See notes to consolidated financial statements

(1) Nature of the Business and Liquidity

Organization

Cingulate Therapeutics LLC ("CTx") is a Delaware limited liability company that was formed on November 14, 2012. CTx's equity owners are referred to as "Members." On May 1, 2019, Cingulate Inc., a Delaware corporation and wholly-owned subsidiary of CTx, was formed to provide employee services to CTx. On May 6, 2021, Cingulate Inc. changed its name to Cingulate Works Inc.

On May 10, 2021, Cingulate Inc. ("Cingulate"), a Delaware corporation and wholly-owned subsidiary of CTx, was formed to serve as a holding company and, on August 16, 2021, Cingulate Pharma LLC ("Merger Sub"), a Delaware LLC and wholly-owned subsidiary of Cingulate was formed in connection with planned organizational transactions. Effective September 29, 2021, Cingulate acquired CTx through the merger of Merger Sub with and into CTx, with CTx as the surviving entity (the "Reorganization Merger"). After the Reorganization Merger, CTx remains the entity through which the Company conducts operations. As a result of the Reorganization Merger, CTx become a wholly-owned subsidiary of Cingulate and all outstanding Units of CTx immediately prior to the Reorganization Merger, including Profits Interest Units ("PIU"s), and after reflecting the stock dividend and reverse stock split described below, were converted into 11,115,780 shares of Cingulate common stock pursuant to the terms of the merger agreement. In addition, the Company recognized a noncash modification charge equal to $12,738,088 in connection with the conversion of the PIU's into shares of Cingulate common stock, as further described in Note 7. Prior to the consummation of the Reorganization Merger, the "Company" refers to CTx and on or following the consummation of Reorganization Merger, the "Company" refers to Cingulate.

CTx is the predecessor of Cingulate for financial reporting purposes. The consolidated financial statements and notes for the nine months ended September 30, 2021 represent the full consolidation of Cingulate and its subsidiaries, including CTx and all references to the Company represent this full consolidation. For periods prior to the nine months ended September 30, 2021, the consolidated financial statements and notes represent the full consolidation of CTx and its subsidiaries.

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. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to additional private investment, potential strategic research and development partners, licensing and/or marketing arrangements with pharmaceutical companies and public offerings of securities through an Initial Public Offering or Alternative Public Offering. 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) Unaudited Interim Financial Information

The accompanying consolidated balance sheet as of September 30, 2021, the consolidated statements of operations for the nine months ended September 30, 2021 and 2020, the consolidated statement of stockholders' equity for the nine-month periods ended September 30, 2021 and 2020, the consolidated statements of cash flows for the nine months ended September 30, 2021 and 2020, and the related interim disclosures are unaudited. These unaudited consolidated financial statements include all adjustments necessary, consisting of only normal recurring adjustments, to fairly state the financial position and the results of operations and cash flows for interim periods in accordance with U.S. GAAP. Interim period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period. The accompanying consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto.

(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) **Miscellaneous Receivables**

Miscellaneous receivables consist of payroll tax credits generated from the Company's 2020 and 2019 federal income tax returns which had not yet been received as well as employee retention tax credits for payroll costs incurred in the first three quarters of 2021. As of September 30, 2021 and December 31, 2020, the Company determined that there is no allowance necessary relating to these receivables.

(e) Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs will be recorded in stockholders' equity as a reduction of the proceeds generated as a result of the offering, if any. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. The Company had $1,853,275 of deferred offering costs as of September 30, 2021. These costs are included in prepaid expenses.

(f) **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 nine months ended September 30, 2021 or 2020.

(g) Paycheck Protection Program

On March 27, 2020, the U.S. federal government enacted the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). The CARES Act includes a provision for a Paycheck Protection Program ("PPP") administered by the U.S. Small Business Administration ("SBA") and further amended by the Paycheck Protection Program Flexibility Act of 2020 ("PPP Flexibility Act"), which was enacted on June 5, 2020. In April 2020, the Company received a PPP Loan of $312,500. In February 2021, the Company received a second PPP loan of $236,457. In accordance with the requirements of the CARES Act, as amended by the PPP Flexibility Act, the PPP Loans may be fully forgiven if proceeds are used to pay eligible payroll costs, rent, mortgage interest and utilities. As of September 30, 2021 and December 31, 2020, the Company believed that all of the requirements of the CARES Act had been met and that it was probable that the entire balance of the PPP Loans would be forgiven. As such, there is no liability for the PPP Loans reflected in the consolidated financial statements as the relevant expense accounts were adjusted to reflect the amounts covered under the loan.

In July 2021, the Company was notified that the first PPP loan was forgiven by the SBA and in October 2021, the Company was notified that the second PPP loan was forgiven by the SBA.

(3) Property and Equipment

Property and equipment, net consists of the following at September 30, 2021 and December 31, 2020:

	Estimated Useful Life (in years)	September 30, 2021	December 31, 2020
Equipment	2-7	$ 2,008,923	$ 1,988,598
Furniture and fixtures	7	131,278	131,278
Computer equipment	5	41,898	41,898
Leasehold improvements	5	471,505	471,505
Construction-in-process	-	1,447,820	1,363,418
		4,101,424	3,996,697
Less: accumulated depreciation		(1,486,545)	(957,738)
		$ 2,614,879	$ 3,038,959

Depreciation expense for the nine months ended September 30, 2021 was $528,809 and for the nine months ended September 30, 2020 was $486,660.

(4) Accrued Expenses

Accrued expenses consisted of the following at September 30, 2021 and December 31, 2020:

	September 30, 2021	December 31, 2020
Payroll and related costs	$ 1,625,467	$ 1,082,643
Professional and consulting fees	1,427,131	15,000
Research and development	193,944	18,944
Interest	82,044	64,105
Other	26,142	34,867
	$ 3,354,728	$ 1,215,559

Payroll was deferred for a number of the Company's employees in the nine months ended September 30, 2021 and the year ended December 31, 2020 resulting in accrued payroll and related costs at the end of each period.

(5) Notes Payable

Notes payable consisted of the following as of September 30, 2021 and December 31, 2020:

	September 30, 2021	December 31, 2020
$100,000, unsecured note payable to a member, principal and interest of 8% due in full on February 24, 2022 (1)	$ 100,000	$ 100,000
$354,000, unsecured note payable to a member, principal and interest of 8% due in full on February 24, 2022 (1)	104,000	254,000
$500,000, unsecured note payable to a member, principal and interest of 8% due in full on February 1, 2022 (2)	146,335	146,335
	$ 350,335	$ 500,335

(1) Prior to the Reorganization Merger, principal and interest was convertible upon lenders' notice into Preferred Units of CTx at a 25% discount to the offered unit prices at the time of conversion.

(2) Prior to the Reorganization Merger, principal and interest was convertible upon lender's notice into Preferred units of CTx at the offered unit prices at the time of conversion. $353,665 was converted to 246,096 Preferred Units of CTx at the current unit price in accordance with the terms of the note payable agreement in 2020.

Interest expense for these notes payable for the nine months ended September 30, 2021 was $27,439 and for the nine months ended September 30, 2020 was $42,244.

(6) Members' Capital

Prior to the Reorganization Merger, the Company had multiple classes of Members' capital, comprised of Founders Units, Class B, D, E, F and G Preferred Units, and Class C Profits Interests. Class B, E, F and G Preferred Units had similar rights specifically related to cash distributions as a return of invested capital. Class D Preferred Units had all the rights of Founders and the other Classes of Preferred Units plus some additional rights noted below. All classes of Members' capital had voting rights. The Company maintained capital accounts for each Member. 3,243,201 Units of Class F and Class G were issued during the nine months ended September 30, 2021.

Class F Preferred Units

The CTx Board authorized 6,984,985 Class F Preferred Units in two tranches; all authorized Class F Units were issued prior to the Reorganization Merger. The Company raised a total of $11.3 million from issuance of Class F Units. The newly created Class F Units as authorized by the CTx Board and as reflected in the 3rd Amended and Restated Operating Agreement to reflect the creation of the Class F Units became effective on December 14, 2018.

Class G Preferred Units

The CTx Board authorized 12,000,000 Class G Preferred Units; 2,998,184 were issued prior to the Reorganization Merger. The Company raised a total of $6.7 million from issuance of Class G Units . The newly created Class G Units as authorized by the CTx Board became effective on February 9, 2021.

Distributions, if any, from the Company were to be made first to the holders of Class B, D, E, F and G Preferred Units, pro rata in proportion to each such Member's unreturned capital contributions. Distributions were then to be made to all Members including Founders Units, pro rata in proportion to the number of units held by each Member, with consideration given to the applicable distribution thresholds for Class C Profits Interests at which each was issued and as disclosed in each Profits Interest Unit agreement, as further described in Note 8.

Costs associated with issuance of the Units is immaterial. Pursuant to the terms of the Reorganization Merger, all Units were converted into shares of common stock of Cingulate, as further described in Note 1.

(7) Profits Interest Plan

During 2017, the CTx Board established and adopted the Cingulate Therapeutics LLC Equity Incentive Plan (the "Plan") to provide for issuance of Class C PIU's to employees, CTx Members, Board members and service providers of the Company, as defined in the Plan, eligible to receive PIU's as an incentive under the Plan. PIU's were granted at the discretion of the Board of Managers of the Company and in some cases at the discretion of the Chief Executive Officer of the Company based upon Board authorization. The PIU's were issued at a Distribution Threshold equal to the pre-money fair market valuation of the Company at the date of issuance. The Distribution Threshold is the amount by which a cash distribution, made pro rata to all Members, if any, must be exceeded in order for a particular PIU holder to participate in the allocated distribution beyond that threshold. Based on the terms of the award, the Distribution Threshold is treated as a performance condition for purposes of financial statement recognition. The PIU's vesting period with respect to the service condition is defined in the PIU award agreement and ranged from 30 days to three years with an average vesting period for all PIU's granted of 107 days. As defined in the Company's Operating Agreement, all PIU's issued under the Plan entitled the holder to participate pro rata in the profits, if any, of the Company over the stated Distribution Threshold, assuming a cash distribution was generally made to all Members, subject to any preference or priorities of the other classes of Units. The Class C PIU's also held voting rights on a one-for-one basis.

Immediately prior to the Reorganization Merger and as of December 31, 2020, the Company had granted and issued 8,500,000 and 8,142,461 PIU's, net of forfeitures, respectively. The Company accounted for these awards under *ASC Topic 718, Compensation – Stock Compensation*, as equity classified awards. No compensation expense was recorded prior to the Reorganization Merger related to the PIU's as the future achievement of the thresholds and targets (the performance condition) to achieve payout was not deemed probable. This assessment was made based on the Company's history of operating losses and continued challenges in raising necessary equity capital to fund operations. In connection with the Reorganization Merger, as further described in Note 1, 8.5 million PIU's were exchanged for 1,158,008 shares of Cingulate common stock. The exchange of PIU's for common stock created a modification of the terms, character and rights of the PIU's and achievement of performance was considered probable. This resulted in the Company recognizing a noncash modification charge equal to $12,738,088, which charge was calculated based on the Company's assessment of the fair value of the shares of Cingulate common stock on the date of the modification. $8,241,624 of this charge was recorded to general and administrative expense and $4,496,464 was recorded to research and development expense.

The following summarizes the activity of the Company's Plan:

	Profits Interest Units	Distribution Thresholds (stated in millions)
Outstanding at January 1, 2020	6,616,781	$25-$120
Activity for nine months ended September 30, 2020:		
Issued	1,478,879	$80-$120
Forfeited	-	
Outstanding at September 30, 2020	8,095,660	

	Profits Interest Units	Distribution Thresholds (stated in millions)
Outstanding at January 1, 2021	8,142,461	$25-$160
Activity for nine months ended September 30, 2021:		
Issued	357,539	
Forfeited	-	
Converted to common shares upon Reorganization Merger	(8,500,000)	
Outstanding at September 30, 2021	-	

Prior to the Reorganization Merger, the Company had issued all units available under the Plan and all units had vested based upon the vesting period as outlined in the PIU agreement.

PIU's issued and outstanding prior to the Reorganization Merger, which was also the modification date, at the various distribution thresholds were as follows:

	Distribution Threshold $ (in millions):							
Year Granted	**$25**	**$40**	**$75**	**$80**	**$90**	**$120**	**$160**	**Total**
2017	4,753,000	125,200	-	-	-	-	-	4,878,200
2018	-	661,525	217,725	22,883	-	-	-	902,133
2019	-	-	-	-	377,524	458,924	-	836,448
2020	-	-	-	1,476,126	-	49,554	-	1,525,680
2021							357,539	357,539
Total	4,753,000	786,725	217,725	1,499,009	377,524	508,478	357,539	8,500,000

(8) Capital Stock

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 September 30, 2021 of which 11,115,780 shares of common stock were issued and outstanding. The Company has not issued any shares of preferred stock.

The 11,115,780 shares of common stock issued and outstanding at September 30, 2021 were issued in connection with the Reorganization Merger to convert Units of CTx outstanding immediately prior to the Reorganization Merger. and reflects the stock dividend and reverse stock split described below.

Stock Dividend

On September 30, 2021, the Company effected a stock dividend of 0.029 shares of common stock for each share of common stock outstanding (the "Stock Dividend"), or an aggregate of 448,045 shares of common stock. No fractional shares of common stock were issued in connection with the Stock Dividend, and all such fractional interests were rounded down to the nearest whole number.

Reverse Stock Split

On October 12, 2021, the Company effected the Reverse Stock Split, as further described in Note 14.

(9) Stock-Based Compensation

In September 2021, the Company's board of directors and stockholders adopted the 2021 Equity Incentive Plan (the "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.

The aggregate number of shares of common stock available for issuance in connection with options and other awards granted under the 2021 Plan is 1,690,286. The number of shares of common stock available for issuance under the 2021 Plan will automatically increase on January 1st of each year commencing with January 1, 2022 and on each January 1 thereafter until the expiration date, 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, 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.

As of September 30, 2021, no awards had been granted under the 2021 Plan.

(10) 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 September 30, 2021, 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 September 30, for federal or state income taxes. As the merger transaction described in Note 1 did not occur until September 29, 2021, the amounts relative thereto are immaterial for the recognition of an income tax benefit or expense.

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 totalling $133,568 at September 30, 2021, which was recorded as a component of income tax expense on the accompanying consolidated of operations.

The Company files income tax returns in the U.S. federal and various state jurisdictions. The Companies are not subject to U.S. federal and state income tax examinations by tax authorities for years before 2018.

The Company follows the provisions of FASB ASC 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 September 30, 2021.

	September 30, 2021
Deferred income tax assets:	
Current	
Accrued payroll and other miscellaneous	$ 362,476
Non-current	
Patents	84,213
Net operating losses	1,982
Gross deferred income tax assets	448,671
Less: valuation allowance	(133,568)
Net deferred income tax asset	315,103
Deferred income tax liabilities:	
Non-current	
Property and equipment	(315,103)
Gross deferred income tax liabilities	(315,103)
Net deferred tax asset (liability)	$ -

(11) Leases

The Company leases office space for its New Jersey based employees from a related party, as further described in Note 13. The base rent for this lease was $3,000 per month in 2020 and 2019 and it was entered into in January 2018, for a three-year lease agreement which ended as of December 31, 2020. On January 1, 2021, this lease was renewed for an additional three years with a base rent of $3,000 per month.

(12) License Agreement

CTx has a licensing agreement with a company related to the patents and licensed know-how for use in the development of its products. CTx 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 upon receipt of first marketing approval of each product in the field, payable on a per product basis.

The Company has not recorded any expense relating to the above milestones as it has not deemed them probable of occurring as of September 30, 2021.

(13) Related Party Transactions

A Member and general counsel of the Company is a partner with a law firm providing office facilities space that is leased by the Company. Rental expense incurred by the Company to the law firm was $27,000 for both the nine months ended September 30, 2021 and 2020, which approximates fair value. As of September 30, 2021 and December 31, 2020, the Company owed $0 and $27,000, respectively on this lease.

The Company has three loans outstanding with related parties, all three of which were Members of CTx and one was also on the Board of Managers of CTx. (See Note 5)

(14) Subsequent Events

Management evaluated events that occurred subsequent to September 30, 2021 through November 8, 2021, which is the date the interim financial statements were available to be issued.

On October 12, 2021, Cingulate effected a reverse stock split (the “Reverse Stock Split”) of its issued and outstanding shares of common stock at a ratio of 0.699-for-1. No fractional shares of common stock were issued in connection with the Reverse Stock Split, and all such fractional interests were rounded down to the nearest whole number. All share data, per share data and related information for all periods presented in the accompanying consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split.

3,571,428 Shares of Common Stock

CINGULATE®

PROSPECTUS

Aegis Capital Corp. **Laidlaw & Company (UK) Ltd.**

, 2021

Through and including , 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee and the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee.

	Amount
Securities and Exchange Commission registration fee	$ 2,809.97
FINRA filing fee	8,475.00
Nasdaq Capital Market listing fees	145,000.00
Accountants' fees and expenses	800,000.00
Legal fees and expenses	1,500,000.00
Transfer Agent's fees and expenses	25,000.00
Printing and engraving expenses	50,000.00
Underwriter Legal Fees and Expenses	150,000.00
Miscellaneous	300,000
Total expenses	$ 2,981,284.97

Item 14. Indemnification of Directors and Officers.

As permitted by Section 102 of the Delaware General Corporation Law, we have adopted provisions in our amended and restated certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our amended and restated certificate of incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our bylaws provide that:

- we may indemnify our directors, officers, and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;

- we may advance expenses to our directors, officers and employees in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and

- the rights provided in our bylaws are not exclusive.

Our amended and restated certificate of incorporation, filed as Exhibit 3.1 hereto, and our amended and restated bylaws, filed as Exhibit 3.2 hereto, provide for the indemnification provisions described above and elsewhere herein. We have entered into and intend to continue to enter into separate indemnification agreements with our directors and elective officers which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. In addition, we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment in some circumstances. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

The form of Underwriting Agreement, attached as Exhibit 1.1 hereto, under some circumstances provides for indemnification by the underwriters of us and our officers who sign this Registration Statement and directors for specified liabilities, including matters arising under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

On July 19, 2021, the Company issued one share of its common stock, par value $0.0001 per share, to Cingulate Therapeutics, LLC for $0.0001. Such issuance was exempt from registration under 4(a)(2) of the Securities Act of 1933, as amended, and Regulation D promulgated thereunder.

On September 29, 2021 the Company issued 11,115,780 shares of its common stock, par value $0.0001 per share, to the former holders of units of Cingulate Therapeutics LLC in connection with the Reorganization Merger. Such issuances were exempt from registration under 4(a)(2) of the Securities Act of 1933, as amended, and Regulation D promulgated thereunder.

Item 16. Exhibits and Financial Statement Schedules.

Exhibit No.	Description of Document
1.1*	Form of Underwriting Agreement.
2.1†**	Agreement and Plan of Merger, dated August 30, 2021, among Cingulate, Inc., Cingulate Therapeutics LLC, and Cingulate Pharma LLC
3.1**	Form of Amended and Restated Certificate of Incorporation of Cingulate Inc., to be effective upon completion of this offering.
3.2**	Form of Amended and Restated Bylaws of Cingulate Inc. to be effective upon completion of this offering
4.1**	Specimen Certificate representing shares of common stock of Cingulate Inc.
4.2*	Form of Underwriter Warrant.
5.1*	Opinion of Lowenstein Sandler LLP
10.1+**	Cingulate Inc. 2021 Omnibus Incentive Plan
10.2#**	Patent and Know-How License Agreement, dated August 8, 2018, between BDD Pharma Limited, Cingulate Therapeutics LLC and Drug Delivery International Limited
10.3#**	Master Services Agreement, dated August 20, 2018, by and between Pharmaceutical Manufacturing Research Services, Inc. and Cingulate Therapeutics LLC

10.4+**	Employment Agreement, dated September 23, 2021, between Cingulate Therapeutics LLC and Shane J. Schaffer
10.5+**	Employment Agreement, dated September 23, 2021, between Cingulate Therapeutics LLC and Matthew N. Brams
10.6+**	Employment Agreement, dated September 23, 2021, between Cingulate Therapeutics LLC and Laurie A. Myers
10.7+**	Employment Agreement, dated September 23, 2021, between Cingulate Therapeutics LLC and Craig S. Gilgallon
10.8+**	Employment Agreement, dated September 23, 2021, between Cingulate Therapeutics LLC and Louis G. Van Horn
10.9+**	Employment Agreement, dated September 23, 2021, between Cingulate Therapeutics LLC and Raul R. Silva
10.10**	Form of Indemnification Agreement to be entered into by Cingulate Inc. with its Officers and Directors
10.11**	Promissory Note, dated February 26, 2020, between Matthew Brams and Cingulate Therapeutics, LLC
10.12**	Promissory Note, dated September 30, 2020, between Matthew Brams and Cingulate Therapeutics, LLC
10.13**	Amendment to Notes, dated April 28, 2021, between Matthew Brams and Cingulate Therapeutics, LLC
10.14**	Promissory Note, dated July 25, 2020, between Raul Silva and Cingulate Therapeutics, LLC
10.15**	Amendment to Note, dated April 19, 2021, between Raul Silva and Cingulate Therapeutics, LLC
10.16**	Promissory Note, dated February 1, 2020, between Dresch Inc. and Cingulate Therapeutics, LLC
10.17**	Amendment to Note, dated May 20, 2021, between Dresch Inc. and Cingulate Therapeutics, LLC
10.18+**	Form of Nonqualified Stock Option Award under 2021 Plan
10.19+**	Form of Incentive Stock Option Award under 2021 Plan
10.20+**	Form of Restricted Stock Unit Award under 2021 Plan
10.21+**	Form of Restricted Stock Award under 2021 Plan
21.1**	List of subsidiaries of Cingulate Inc.
23.1*	Consent of KPMG LLP
23.2*	Consent of Lowenstein Sandler LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on the signature page of this Registration Statement)

† 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.

** Previously Filed.

+ Indicates a management contract or compensatory plan or agreement.

Certain portions of this exhibit have been omitted because the omitted information is (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Item 17. Undertakings.

(a) The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to

Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Kansas City, Kansas, on the day of November 10, 2021.

CINGULATE INC.

By: */s/ Shane J. Schaffer*
Name: Shane J. Schaffer
Title: Chief Executive Officer

POWER OF ATTORNEY

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated:

Signature	Title	Date
/s/ Shane J. Schaffer Shane J. Schaffer	Chief Executive Officer, Chairman (Principal Executive Officer)	November 10, 2021
/s/ Louis G. Van Horn Louis G. Van Horn	Chief Financial Officer (Principal Financial Officer)	November 10, 2021
* Jennifer L. Callahan	Corporate Controller (Principal Accounting Officer)	November 10, 2021
* Jeff Hargroves	Director	November 10, 2021
* Peter J. Werth	Director	November 10, 2021
* Jeff Conroy	Director	November 10, 2021
* Patrick Gallagher	Director	November 10, 2021
* Gregg Givens	Director	November 10, 2021
* Curt Medeiros	Director	November 10, 2021

*By: */s/ Shane J. Schaffer*
Shane J. Schaffer, Attorney-in-Fact

Exhibit 1.1

CINGULATE INC.

[____] Shares

Common Stock

UNDERWRITING AGREEMENT

________, 2021

Aegis Capital Corp.,
As Representative of the Underwriters
810 7th Avenue
New York, New York 10019

Ladies and Gentlemen:

Cingulate Inc., a Delaware corporation (the "Company"), proposes, subject to the terms and conditions contained herein, to sell to you and the other underwriters (the "Underwriters") named on Schedule I to this Underwriting Agreement (the "Agreement"), for whom you are acting as Representative (the "Representative"), an aggregate of [________] shares (the "Firm Shares" of the Company's common stock, $0.0001 par value per share (the "Common Stock"). The respective amounts of the Firm Shares to be purchased by each of the several Underwriters are set forth opposite their names on Schedule I hereto. In addition, the Company proposes to grant to the Underwriters an option to purchase up to an additional [___________] shares (the "Option Shares") of Common Stock from the Company for the purpose of covering over-allotments in connection with the sale of the Firm Shares. The Firm Shares and the Option Shares are collectively called the "Shares."

The Company has prepared and filed in conformity with the requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the published rules and regulations thereunder (the "Rules") adopted by the Securities and Exchange Commission (the "Commission"), a Registration Statement (as hereinafter defined) on Form S-1 (No. 333-259408), including a preliminary prospectus, and such amendments thereof as may have been required to the date of this Agreement. Copies of such Registration Statement (including all amendments thereof) and of the related Preliminary Prospectus (as hereinafter defined) have heretofore been delivered by the Company to you. The term "Preliminary Prospectus" means any preliminary prospectus included at any time as a part of the Registration Statement or filed with the Commission by the Company pursuant to Rule 424(a) of the Rules. The term "Registration Statement" as used in this Agreement means the initial registration statement (including all exhibits and financial schedules), as amended at the time and on the date it becomes effective (the "Effective Date"), including the information (if any) contained in the form of final prospectus filed with the Commission pursuant to Rule 424(b) of the Rules and deemed to be part thereof at the time of effectiveness pursuant to Rule 430A of the Rules. If the Company has filed an abbreviated registration statement to register additional Shares pursuant to Rule 462(b) under the Rules (the "462(b) Registration Statement"), then any reference herein to the Registration Statement shall also be deemed to include such 462(b) Registration Statement. The term "Prospectus" as used in this Agreement means the prospectus in the form included in the Registration Statement at the time of effectiveness or, if Rule 430A of the Rules is relied on, the term Prospectus shall also include the final prospectus filed with the Commission pursuant to and within the time limits described in Rule 424(b) of the Rules.

The Company understands that the Underwriters propose to make a public offering of the Shares, as set forth in and pursuant to the Statutory Prospectus (as hereinafter defined) and the Prospectus, as soon after the Effective Date and the date of this Agreement as the Representative deems advisable. The Company hereby confirms that the Underwriters and dealers have been authorized to distribute or cause to be distributed each Preliminary Prospectus, and each Issuer Free Writing Prospectus (as hereinafter defined) and are authorized to distribute the Prospectus (as from time to time amended or supplemented if the Company furnishes amendments or supplements thereto to the Underwriters).

1. Sale, Purchase, Delivery and Payment for the Shares. On the basis of the representations, warranties and agreements contained in, and subject to the terms and conditions of, this Agreement:

(a) The Company agrees to issue and sell to each of the Underwriters, and each of the Underwriters agrees, severally and not jointly, to purchase from the Company, at a purchase price of $[_____] per share (the "Initial Price"), the number of Firm Shares set forth opposite the name of such Underwriter under the column "Number of Firm Shares to be Purchased" on Schedule I to this Agreement, subject to adjustment in accordance with Section 8 hereof.

(b) The Company hereby grants to the several Underwriters an option to purchase, severally and not jointly, all or any part of the Option Shares at the Initial Price. The number of Option Shares to be purchased by each Underwriter shall be the same percentage (adjusted by the Representative to eliminate fractions) of the total number of Option Shares to be purchased by the Underwriters as such Underwriter is purchasing of the Firm Shares. Such option may be exercised only to cover over-allotments in the sales of the Firm Shares by the Underwriters and may be exercised in whole or in part at any time on or before 12:00 noon, New York City time, on the business day before the Firm Shares Closing Date (as defined below), and from time to time thereafter within thirty (30) days after the date of this Agreement, in each case upon written, facsimile or electronic notice, or verbal or telephonic notice confirmed by written, facsimile or electronic notice, by the Representative to the Company no later than 12:00 noon, New York City time, on the business day before the Firm Shares Closing Date or at least two (2) business days before the Option Shares Closing Date (as defined below), as the case may be, setting forth the number of Option Shares to be purchased and the time and date (if other than the Firm Shares Closing Date) of such purchase.

(c) Payment of the purchase price for, and delivery of certificates for, the Firm Shares shall be made at the offices of Aegis Capital Corp., 810 7th Avenue New York, New York 10019, at 10:00 a.m., New York City time, on the second business day following the date of this Agreement or at such time on such other date, not later than ten (10) business days after the date of this Agreement, as shall be agreed upon by the Company and the Representative (such time and date of delivery and payment are called the "Firm Shares Closing Date"). In addition, in the event that any or all of the Option Shares are purchased by the Underwriters, payment of the purchase price, and delivery of the certificates, for such Option Shares shall be made at the above-mentioned offices, or at such other place as shall be agreed upon by the Representative and the Company, on each date of delivery as specified in the notice from the Representative to the Company (such time and date of delivery and payment are called the "Option Shares Closing Date"). The Firm Shares Closing Date and any Option Shares Closing Date are called, individually, a "Closing Date" and, together, the "Closing Dates."

(d) Payment for the Shares shall be made to the Company by wire transfer of immediately available funds or by certified or official bank check or checks payable in New York Clearing House (same day) funds drawn to the order of the Company, against delivery of the respective certificates to the Representative for the respective accounts of the Underwriters of certificates for the Shares to be purchased by them.

(e) The Shares shall be registered in such names and shall be in such denominations as the Representative shall request at least two (2) full business days before the Firm Shares Closing Date or, in the case of Option Shares, on the day of notice of exercise of the option as described in Section 1(b), and shall be delivered by or on behalf of the Company to the Representative through the facilities of the Depository Trust Company ("DTC") for the account of such Representative.

(f) As additional compensation for the Representative's services, the Company shall issue to the Representative or its designees on the Firm Shares Closing Date warrants (the "Representative's Warrant") to purchase that number of shares of Common Stock equal to 5% of the aggregate number of Firm Shares purchased by the Underwriters on the Firm Shares Closing Date. The Representative's Warrant will be exercisable at any time and from time to time, in whole or in part, during the period commencing six months from the commencement of sales of the public offering and ending four years and six months thereafter, at a price per share equal to 125% of the price to the public per share of the Shares. The Representative's Warrant and the shares of Common Stock issuable upon exercise thereof are sometimes hereinafter referred to collectively as the "Representative's Securities." The Representative understands and agrees that there are restrictions pursuant to FINRA Rule 5110 against transferring the Representative's Warrant and the underlying shares during the 180-day period after the commencement of sales of the public offering and by its acceptance thereof shall agree that it and its respective designees, if any, will not, sell, transfer, assign, pledge or hypothecate their respective Representative's Securities, or any portion thereof, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of such securities for a period of 180 days following the commencement of sales of the public offering to anyone other than (A) an Underwriter or a selected dealer in connection with the offering, or (B) a bona fide officer or partner of one of the Representative or of any such Underwriter or selected dealer; and only if any such transferee agrees to the foregoing lock-up restrictions. Delivery of the executed Representative's Warrant Agreement shall be made on the Closing Date and the Representative's Warrant shall be issued in the name or names and in such authorized denominations as the Representative may request.

2. Representations and Warranties of the Company. The Company represents and warrants to each Underwriter as of the date hereof, as of the Firm Shares Closing Date and as of each Option Shares Closing Date (if any), as follows:

(a) On the Effective Date, the Registration Statement complied, and on the date of the Prospectus, the date any post-effective amendment to the Registration Statement becomes effective, the date any supplement or amendment to the Prospectus is filed with the Commission, the Registration Statement and the Prospectus (and any amendment thereof or supplement thereto) will comply, in all material respects, with the requirements of the Securities Act and the Rules and the Securities and Exchange Act of 1934, as amended (the "Exchange Act") and the rules and regulations of the Commission thereunder. Neither the Registration Statement nor any amendments thereto as of the times they became effective, contained any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading; and on the Effective Date and the other dates referred to above neither the Registration Statement nor the Prospectus, nor any amendment or supplement of either of the foregoing, will contain any untrue statement of a material fact or will omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading. When any Preliminary Prospectus was first filed with the Commission (whether filed as part of the Registration Statement or any amendment thereto or pursuant to Rule 424(a) of the Rules) and when any amendment thereof or supplement thereto was first filed with the Commission, such Preliminary Prospectus as amended or supplemented complied in all material respects with the applicable provisions of the Securities Act and the Rules and did not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading. If applicable, each Preliminary Prospectus and the Prospectus delivered to the Underwriters for use in connection with this offering was identical to the electronically transmitted copies thereof filed with the Commission pursuant to the Commission's Electronic Data Gathering, Analysis and Retrieval system ("EDGAR"), except to the extent permitted by Regulation S-T. Notwithstanding the foregoing, none of the representations and warranties in this paragraph 2(a) shall apply to statements in, or omissions from, the Registration Statement, any Preliminary Prospectus or the Prospectus made in reliance upon, and in conformity with, information herein or otherwise furnished in writing by the Representative on behalf of the several Underwriters specifically for use in the Registration Statement, any Preliminary Prospectus or the Prospectus, as the case may be. With respect to the preceding sentence, the Company acknowledges that the only information furnished in writing by the Representative on behalf of the several Underwriters for use in the Registration Statement, any Preliminary Prospectus or the Prospectus is the statements contained in the fourth and thirteenth paragraphs under the caption "Underwriting" in the Prospectus (collectively, the "Underwriter Information").

(b) As of the Applicable Time (as hereinafter defined), none of (i) the price to the public and the number of Shares offered and sold, as indicated on the cover page of the Prospectus and the Statutory Prospectus (as hereinafter defined), together with the pricing information and other information set forth in Schedule V, all considered together (collectively, the "General Disclosure Package"), (ii) any individual Issuer Free Writing Prospectus when considered together with the General Disclosure Package, and (iii) any individual Written Testing-the Waters Communication (as defined herein), when considered together with the General Disclosure Package, included, includes or will include any untrue statement of a material fact or omitted, omits or will omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to statements in or omissions in the General Disclosure Package made in reliance upon and in conformity with the Underwriter Information.

Each Issuer Free Writing Prospectus (as hereinafter defined), including any electronic road show (including without limitation any "bona fide electronic road show" as defined in Rule 433(h)(5) under the Securities Act) (each, a "Road Show") (i) is identified in Schedule III hereto and (ii) complied when issued, and complies, in all material respects with the requirements of the Securities Act and the Rules and the Exchange Act and the rules and regulations of the Commission thereunder. The Company has made at least one version of the Road Show available without restriction by means of graphic communication to any person, including any potential investor in the Shares (and if there is more than one version of a Road Show for the offering that is a written communication, the version available without restriction was made available no later than the other versions).

As used in this Section and elsewhere in this Agreement:

"Applicable Time" means [ ]:00 [a.m.]/[p.m.] (Eastern time) on the date of this Agreement.

"Statutory Prospectus" as of any time means the Preliminary Prospectus relating to the Shares that is included in the Registration Statement immediately prior to the Applicable Time.

"Issuer Free Writing Prospectus" means each "free writing prospectus" (as defined in Rule 405 of the Rules) prepared by or on behalf of the Company or used or referred to by the Company in connection with the offering of the Shares, including, without limitation, each Road Show.

(c) The Registration Statement is effective under the Securities Act and no stop order preventing or suspending the effectiveness of the Registration Statement or suspending or preventing the use of any Preliminary Prospectus, the Prospectus or any "free writing prospectus", as defined in Rule 405 under the Rules, has been issued by the Commission and no proceedings for that purpose have been instituted, or to the knowledge of the Company, are threatened under the Securities Act. Any required filing of any Preliminary Prospectus and/or the Prospectus and any supplement thereto pursuant to Rule 424(b) of the Rules has been or will be made in the manner and within the time period required by such Rule 424(b). Any material required to be filed by the Company pursuant to Rule 433(d) or Rule 163(b)(2) of the Rules has been or will be made in the manner and within the time period required by such Rules.

(d) Each Issuer Free Writing Prospectus, if any, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Shares or until any earlier date that the Company notified or notifies the Representative as described in the next sentence, did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, the Statutory Prospectus or the Prospectus.

If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement, the Statutory Prospectus or the Prospectus or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances prevailing at the subsequent time, not misleading, the Company has promptly notified or will promptly notify the Representative and has promptly amended or will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(e) The financial statements of the Company (including all notes and schedules thereto) included in the Registration Statement, the Statutory Prospectus and Prospectus present fairly in all material respects the financial position of the Company and its consolidated subsidiaries at the dates indicated and the statement of operations, stockholders' equity and cash flows of the Company and its consolidated subsidiaries for the periods specified; and such financial statements and related schedules and notes thereto, and the unaudited financial information filed with the Commission as part of the Registration Statement, have been prepared in conformity with generally accepted accounting principles, consistently applied throughout the periods involved. The summary financial data included in the Statutory Prospectus and Prospectus present fairly in all material respects the information shown therein as of the respective dates and for the respective periods specified and have been presented on a basis consistent with the consolidated financial statements set forth in the Prospectus. The other financial information included in the Registration Statement, the Statutory Prospectus and the Prospectus has been derived from the accounting or other records of the Company and its consolidates subsidiaries and present fairly in all material respects the information shown thereby.

(f) KPMG LLP (the "Auditor"), whose reports are filed with the Commission as a part of the Registration Statement, are and, during the periods covered by their reports, were independent public accountants as required by the Securities Act and the Rules.

(g) The Company and each of its subsidiaries, including each entity (corporation, partnership, joint venture, association or other business organization) controlled directly or indirectly by the Company (each, a "subsidiary"), is duly organized, validly existing and in good standing under the laws of their respective jurisdictions of incorporation or organization and each such entity has all requisite power and authority to carry on its business as is currently being conducted as described in the Statutory Prospectus and the Prospectus, and to own, lease and operate its properties All of the issued shares of capital stock of, or other ownership interests in, each subsidiary have been duly and validly authorized and issued and are fully paid and non-assessable and are owned, directly or indirectly, by the Company, free and clear of any lien, charge, mortgage, pledge, security interest, claim, limitation on voting rights, equity, trust or other encumbrance, preferential arrangement, defect or restriction of any kind whatsoever. The Company and each of its subsidiaries is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the nature of the business conducted by it or location of the assets or properties owned, leased or licensed by it requires such qualification, except for such jurisdictions where the failure to so qualify individually or in the aggregate would not have a material adverse effect on the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company and its subsidiaries considered as a whole or in the context of the public offer and sale of Shares or underwriting of the Shares (a "Material Adverse Effect"); and to the Company's knowledge, no proceeding has been instituted or is threatened in any such jurisdiction revoking, limiting or curtailing, or seeking to revoke, limit or curtail, such power and authority or qualification or taken against it for its winding-up, liquidation or dissolution or for any similar or analogous proceeding in any jurisdiction, or for it to enter into any arrangement or composition for the benefit of creditors, or for the appointment of a receiver, administrative receiver, trustee or similar officer.

(h) At the time of filing the Registration Statement and on the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405 of the Rules, including (but not limited to) the Company or any other subsidiary in the preceding three (3) years not having been convicted of a felony or misdemeanor or having been made the subject of a judicial or administrative decree or order as described in Rule 405 of the Rules.

(i) The Company and each of its subsidiaries owns or possesses, have a valid license to or can acquire on reasonable terms legally enforceable rights to use all patents, provisional patent applications, patent rights, inventions, trademarks, trademark applications, trade names, service marks, copyrights, copyright applications, licenses, know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems, processes or procedures) and other similar rights and proprietary knowledge (in each case, whether registered or not and including applications for registration) (collectively, "Intangibles") necessary for the conduct of its business; except where failure to own or possess such rights individually or in the aggregate would not have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has received any notice of, or is not aware of, any infringement of or conflict with asserted rights of others with respect to any Intangibles and neither the Company nor any of its subsidiaries has knowledge of any infringement of or conflict with asserted rights of others or of any infringement of, or conflict with the Company and its subsidiaries' rights with respect to any Intangibles. The Company and each of its subsidiaries processes employed and the products and services dealt in by the Company or any of its subsidiaries do not, to its knowledge, infringe Intangibles of a third party and neither of the Company nor any of its subsidiaries has received any notice of infringement of or conflict with, and neither of the Company nor any of its subsidiaries has knowledge of any infringement of or conflict with, asserted rights of a third party with respect to any Intangibles, except for or in respect of any such infringements or conflicts that would not, individually or in the aggregate, have a Material Adverse Effect. The Company is not, except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, obligated to pay a royalty, grant a license or provide other consideration to any third party in connection with its Intangibles, and the public offer and sale of Shares will not trigger such payment, except for any such obligations that would not, individually or in the aggregate, have a Material Adverse Effect.

(j) The Company and each of its subsidiaries has good and marketable title in fee simple to all real property, and good and marketable title to all other property owned by it, that are material to the business of the Company and its subsidiaries, taken as whole, in each case free and clear of all liens, encumbrances, claims, security interests and defects, except such as do not materially affect the value of such property and do not materially interfere with the use made or proposed to be made of such property by the Company and its subsidiaries. All property held under lease by the Company and its subsidiaries is held by them under valid, existing and enforceable leases, free and clear of all liens, encumbrances, claims, security interests and defects, except such as are not material and do not materially interfere with the use made or proposed to be made of such property by the Company and its subsidiaries.

(k) Subsequent to the respective dates as of which information is given in the Registration Statement, the Statutory Prospectus and the Prospectus, (i) there has not been any event which could have a Material Adverse Effect; (ii) neither the Company nor any of its subsidiaries has sustained any loss or interference with its assets, businesses or properties (whether owned or leased) from fire, explosion, earthquake, flood or other calamity, whether or not covered by insurance, or from any labor dispute or any court or legislative or other governmental action, order or decree which would have a Material Adverse Effect; and (iii) since the date of the latest balance sheet included in the Registration Statement and the Prospectus, except as described in the Statutory Prospectus and the Prospectus, neither the Company nor its subsidiaries has (A) issued any securities or incurred any liability or obligation, direct or contingent, for borrowed money, except such liabilities or obligations incurred in the ordinary course of business, (B) entered into any transaction not in the ordinary course of business or (C) declared or paid any dividend or made any distribution on any shares of its stock or redeemed, purchased or otherwise acquired or agreed to redeem, purchase or otherwise acquire any shares of its capital stock.

(l) There is no document, contract or other agreement required to be described in the Registration Statement, the Statutory Prospectus or the Prospectus or to be filed as an exhibit to the Registration Statement which is not described or filed, in each case for the Registration Statement to comply in all material respects with the requirements of the Securities Act or Rules. Each description of a contract, document or other agreement in the Registration Statement, the Statutory Prospectus or the Prospectus accurately reflects in all material respects the terms of the underlying contract, document or other agreement. Each contract, document or other agreement described in the Registration Statement, the Statutory Prospectus or the Prospectus or listed in the exhibits to the Registration Statement is in full force and effect and is valid and enforceable by and against the Company or its subsidiary, as the case may be, in accordance with its terms, except as would not, individually or in the aggregate, be reasonably expected to result in a Material Adverse Effect. Neither the Company nor any of its subsidiaries, if a subsidiary is a party, nor to the Company's knowledge, any other party is in default in the observance or performance of any term or obligation to be performed by it under any such agreement, and no event has occurred which with notice or lapse of time or both, in either case, would constitute such a default, in any such case which default or event, individually or in the aggregate, would have a Material Adverse Effect. No default exists, and no event has occurred which with notice or lapse of time or both would constitute a default, in the due performance and observance of any term, covenant or condition, by the Company or its subsidiary, if a subsidiary is a party thereto, of any other agreement or instrument to which the Company or any of its subsidiaries is a party or by which Company or its properties or business or a subsidiary or its properties or business may be bound or affected which default or event, individually or in the aggregate, would have a Material Adverse Effect.

(m) The statistical and market related data included in the Registration Statement, the Statutory Prospectus or the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate.

(n) Neither the Company nor any subsidiary (i) is in violation of its certificate or articles of incorporation, bylaws, certificate of formation, limited liability company agreement, partnership agreement or other organizational documents, (ii) is in default under, and no event has occurred which, with notice or lapse of time, or both, would constitute a default under, or result in the creation or imposition of any lien, charge, mortgage, pledge, security interest, claim, limitation on voting rights, equity, trust or other encumbrance, preferential arrangement, defect or restriction of any kind whatsoever, upon, any property or assets of the Company or any subsidiary pursuant to, any bond, debenture, note, indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which it is a party or by which it is bound or to which any of its properties or assets is subject, or (iii) is in violation of any statute, law, rule, regulation, ordinance, directive, judgment, decree or order of any judicial, regulatory or other legal or governmental agency or body, foreign or domestic, except (in the case of clauses (ii) and (iii) above) for violations or defaults that could not (individually or in the aggregate) reasonably be excepted to have a Material Adverse Effect.

(o) The Company has full right, power and authority to execute and deliver this Agreement and the Representative's Warrant Agreement, and to perform its obligations hereunder and thereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of this Agreement and the Representative's Warrant Agreement, and the consummation by it of the transactions contemplated hereby and thereby has been duly and validly taken.

(p) This Agreement and the Representative's Warrant Agreement have been duly authorized, executed and delivered by the Company and each, assuming the due authorization, execution and delivery by the other parties hereto, constitutes a valid and legally binding agreement of the Company, enforceable in accordance with its terms, except as (i) the enforcement hereof may be limited by bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles (whether considered in a proceeding at law or in equity) relating to enforceability and (ii) rights to indemnification and contribution hereunder may be limited by applicable law and public policy considerations.

(q) Neither the execution, delivery and performance of this Agreement by the Company nor the consummation of any of the transactions contemplated hereby (including, without limitation, the issuance and sale by the Company of the Shares) will give rise to a right to terminate or accelerate the due date of any payment due under, or conflict with or result in the breach of any term or provision of, or constitute a default (or an event which with notice or lapse of time or both would constitute a default) under, or require any consent or waiver under, or result in the execution or imposition of any lien, charge or encumbrance upon any properties or assets of the Company or its subsidiaries pursuant to the terms of, any indenture, mortgage, deed of trust or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which either the Company or its subsidiaries or any of their properties or businesses is bound, or any franchise, license, permit, judgment, decree, order, statute, rule or regulation applicable to the Company or any of its subsidiaries or violate any provision of the charter or bylaws or other organizational documents of the Company or any of its subsidiaries, except (A) for such consents or waivers which have already been obtained and are in full force and effect and (B) in the case of clause (i) above, for any such conflict, breach , violation, default, termination, lien, charge or encumbrance that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(r) The Company has authorized and outstanding capital stock as set forth under the caption "Capitalization" in the Statutory Prospectus and the Prospectus. All of the issued and outstanding shares of capital stock of the Company have been duly and validly issued and are fully paid and nonassessable and have been issued in compliance with all federal, state and local. There are no statutory preemptive or other similar rights to subscribe for or to purchase or acquire any shares of capital stock of the Company or any of its subsidiaries, or any such rights pursuant to its charter, certificate of incorporation or bylaws or any other applicable organizational documents or any agreement or instrument to or by which the Company or any of its subsidiaries is a party or bound. The Shares and the Representative's Securities have been duly authorized for issuance and sale pursuant to this Agreement and when issued and sold pursuant to this Agreement, will be duly and validly issued, fully paid and nonassessable; the holders thereof are not and will not be subject to personal liability by reason of being such holders; none of them will be issued in violation of any preemptive or other similar right; and all corporate action required to be taken for the authorization, issuance and sale of the Shares and the Representative's Securities has been duly and validly taken. When paid for and issued in accordance with the Representative's Warrant Agreement, the underlying shares will be validly issued, fully paid and non-assessable; the holders thereof are not and will not be subject to personal liability by reason of being such holders; the underlying shares are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. Except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, there is no outstanding option, warrant or other right calling for the issuance of, and there is no commitment, plan or arrangement to issue, any share of capital stock of the Company or any of its subsidiaries or any security convertible into, or exercisable or exchangeable for, such shares. The exercise price of each option to acquire Common Stock (each, a "Company Stock Option") is no less than the fair market value of a share of Common Stock as determined on the date of grant of such Company Stock Option. All grants of Company Stock Options were validly issued and properly approved by the Board of Directors of the Company (and, if required, by a committee of the Board of Directors of the Company and/or the shareholders of the Company) in material compliance with all applicable laws and the terms of the plans under which such Company Stock Options were issued and were recorded on the Company Financial Statements, in accordance with generally accepted accounting principles, and no such grants involved any "back dating", "forward dating," "spring loading" or similar practices with respect to the effective date of grant. The Shares conform in all material respects to all statements in relation thereto contained in the Registration Statement and the Statutory Prospectus and the Prospectus.

(s) No holder of any security of the Company has any right, which has not been waived, to have any security owned by such holder included in the Registration Statement or to demand registration of any security owned by such holder for a period of one hundred and eighty (180) days after the Firm Shares Closing Date. Each director and executive officer of the Company, each employee of the Company and each stockholder of the Company listed on Schedule II hereto has delivered to the Representative his enforceable written lock-up agreement in the form attached to this Agreement as Exhibit A hereto ("Lock-Up Agreement").

(t) There are no legal or governmental proceedings pending to which the Company or any of its subsidiaries is a party or of which any property of the Company or any of its subsidiaries is the subject which, if determined adversely to the Company or any of its subsidiaries could individually or in the aggregate have a Material Adverse Effect; and, to the knowledge of the Company, no such proceedings are threatened or contemplated by governmental authorities or threatened by others.

(u) All necessary corporate action has been duly and validly taken by the Company to authorize the execution, delivery and performance of this Agreement and the issuance and sale of the Shares by the Company.

(v) Neither the Company nor any of its subsidiaries is involved in any labor dispute nor, to the knowledge of the Company, is any such dispute threatened, which dispute would have a Material Adverse Effect. The Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers or contractors which would have a Material Adverse Effect. The Company is not aware of any threatened or pending litigation between the Company or its subsidiaries and any of its executive officers which, if adversely determined, could have a Material Adverse Effect and has no reason to believe that such executive officers will not remain in the employment of the Company.

(w) No transaction has occurred between or among the Company and any of its officers or directors, shareholders or any affiliate or affiliates of any such officer or director or shareholder that is required to be described in and is not described in the Registration Statement, the Statutory Prospectus and the Prospectus.

(x) The Company has not taken, nor will it take, directly or indirectly, any action designed to, or which might reasonably be expected to cause or result in, or which has constituted or which might reasonably be expected to constitute, the stabilization or manipulation of the price of the Common Stock or any security of the Company to facilitate the sale or resale of any of the Shares.

(y) The Company and each of its subsidiaries has duly paid all national, regional and local taxes of any kind (including but not limited to, income taxes, capital gain taxes, withholding taxes, sales and transfer taxes, energy and real estate taxes, labor market and social contribution taxes, customs duties, VAT, registration fees and similar levies, duties, charges, stamps and imposts of whatever nature as well as any penalty, fine, surcharge or interest relating thereto) which have become due and payable with regard to the period up to and including the of this Agreement (other than tax deficiencies which the Company or any of its subsidiaries is contesting in good faith and for which the Company or any of its subsidiaries have provided adequate provisions if required by generally accepted accounting principles), except for such failures that would not, individually or in the aggregate, have a Material Adverse Effect. The Company and each of its subsidiaries has filed all federal, state, local and foreign tax returns which are required to be filed through the date hereof, which returns are true and correct in all material respects or has received timely extensions thereof, and has paid all taxes shown on such returns and all assessments received by it to the extent that the same are material and have become due. There are no tax audits or investigations pending, which if adversely determined would have a Material Adverse Effect; nor are there any material proposed additional tax assessments against the Company or any of its subsidiaries.

(z) The Shares have been duly authorized for quotation on the National Association of Securities Dealers Automated Quotation ("Nasdaq") Capital Market System, subject to official Notice of Issuance. A registration statement has been filed on Form 8-A pursuant to Section 12 of the Exchange Act, which registration statement complies in all material respects with the Exchange Act.

(aa) The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or the quotation of the Common Stock on the Nasdaq Capital Market, nor has the Company received any notification that the Commission or the Nasdaq Capital Market is contemplating terminating such registration or quotation.

(bb) The books, records and accounts of the Company and its subsidiaries accurately and fairly reflect the transactions in, and dispositions of, the assets of, and the results of operations of, the Company and its subsidiaries. The Company and each of its subsidiaries maintains a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(cc) The Company has established and maintains disclosure controls and procedures (as such term is defined in Rule 13a-15 under the Exchange Act), which: (i) are designed to ensure that material information relating to the Company is made known to the Company's principal executive officer and its principal financial officer by others within the Company; (ii) provide for the periodic evaluation of the effectiveness of such disclosure controls and procedures at the end of the periods in which the periodic reports are required to be prepared; and (iii) are effective in all material respects to perform the functions for which they were established.

(dd) Based on the evaluation of its disclosure controls and procedures, the Company is not aware of (i) any material weakness or significant deficiency in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize and report financial data or any material weaknesses in internal controls; or (ii) any fraud, whether or not material, that involves management or other employees who have a role in the Company's internal controls.

(ee) Except as described in the Statutory Prospectus and the Prospectus and as preapproved in accordance with the requirements set forth in Section 10A of the Exchange Act, the Auditor has not been engaged by the Company to perform any "prohibited activities" (as defined in Section 10A of the Exchange Act).

(ff) Except as described in the Statutory Prospectus and the Prospectus, there are no material off-balance sheet arrangements (as defined in Item 303 of Regulation S-K) that have or are reasonably likely to have a material current or future effect on the Company's financial condition, revenues or expenses, changes in financial condition, results of operations, liquidity, capital expenditures or capital resources.

(gg) The Company's Board of Directors has validly appointed an audit committee whose composition satisfies the requirements of Rule 5605 of the Nasdaq Stock Market and the Board of Directors and/or the audit committee has adopted a charter that satisfies the requirements of Rule 5605 of the Nasdaq Stock Market.

(hh) The Company is in compliance with all other applicable provisions of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), any related rules and regulations promulgated by the Commission and corporate governance requirements under applicable Nasdaq regulations upon the effectiveness of such provisions and has no reason to believe that it will not be able to comply with such provisions at the time of effectiveness.

(ii) The Company and its subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are customary in the businesses in which they are engaged or propose to engage after giving effect to the transactions described in the Statutory Prospectus and the Prospectus; all policies of insurance and fidelity or surety bonds insuring the Company or any of its subsidiaries or the Company's or its subsidiaries' respective businesses, assets, employees, officers and directors are in full force and effect; the Company and each of its subsidiaries are in compliance with the terms of such policies and instruments in all material respects; and neither the Company nor any subsidiary of the Company has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that is not materially greater than the current cost. Neither the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(jj) Each approval, consent, order, authorization, designation, declaration or filing of, by or with any regulatory, administrative or other governmental body necessary in connection with the execution and delivery by the Company of this Agreement and the consummation of the transactions herein contemplated required to be obtained or performed by the Company, except for (i) such additional steps as may be required by the Financial Industry Regulatory Authority ("FINRA"); (ii) as may be necessary to qualify the Shares for public offering by the Underwriters under the state securities or Blue Sky laws; and (iii) the approval by the Nasdaq Capital Market for the listing of the Shares.

(kk) There are no affiliations with FINRA among the Company's officers, directors or, to the best of the knowledge of the Company, any five percent or greater stockholder of the Company, except as set forth in the Registration Statement or otherwise disclosed in writing to the Representative.

(ll) (i) Each of the Company and each of its subsidiaries is in compliance in all material respects with all rules, laws and regulation relating to the use, treatment, storage and disposal of toxic substances and protection of health or the environment (each such law, an "Environmental Law") which are applicable to its business; (ii) neither the Company nor its subsidiaries has received any notice from any governmental authority or third party of an asserted claim under Environmental Laws; (iii) each of the Company and each of its subsidiaries has received all permits, licenses or other approvals required of it under applicable Environmental Laws to conduct its business and is in compliance with all terms and conditions of any such permit, license or approval; (iv) to the Company's knowledge, no facts currently exist that will require the Company or any of its subsidiaries to make future material capital expenditures to comply with applicable Environmental Laws; and (v) no property which is or has been owned, leased or occupied by the Company or its subsidiaries has been designated as a Superfund site pursuant to the Comprehensive Environmental Response, Compensation of Liability Act of 1980, as amended (42 U.S.C. Section 9601, et. seq.) ("CERCLA 1980") or otherwise designated as a contaminated site under other Environmental Laws. Neither the Company nor any of its subsidiaries has been named as a "potentially responsible party" under CERCLA 1980.

(mm) The Company is not and, after giving effect to the offering and sale of the Shares and the application of proceeds thereof as described in the Statutory Prospectus and the Prospectus, will not be an "investment company" within the meaning of the Investment Company Act of 1940, as amended (the "Investment Company Act").

(nn) The Company or any other person associated with or acting on behalf of the Company including, without limitation, any director, officer or employee or, to the knowledge of the Company, any agent, of the Company or its subsidiaries, has not, directly or indirectly, while acting on behalf of the Company or its subsidiaries (i) used any corporate funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity; (ii) made any direct or indirect unlawful payment or unlawful benefit to foreign or domestic government officials or employees or to foreign or domestic political parties or campaigns from corporate funds; (iii) violated or is in violation of, or engaged in any activity or conduct which would constitute an offense under, any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any provision of any applicable non-U.S. anti-bribery or anti-corruption law or regulation ("Anti-Corruption Laws"); or (iv) made any other unlawful payment. Neither the Company nor its subsidiaries will directly or indirectly use the proceeds of the public offer and sale of Shares or lend, contribute or otherwise make available such proceeds to any subsidiary, affiliate, joint venture partner or any other person or entity for the purpose of financing or facilitating any activity in violation of applicable Anti-Corruption Laws.

(oo) The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending, or to the best knowledge of the Company, threatened.

(pp) Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or any of its subsidiaries, is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and the Company will not directly or indirectly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(qq) Except as described in the Statutory Prospectus and the Prospectus, the Company has not sold or issued any shares of capital stock during the six-month period preceding the date of the Prospectus, including any sales pursuant to Rule 144A under, or Regulations D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, qualified stock options plans or other employee compensation plans or pursuant to outstanding options, rights or warrants.

(rr) The Company has fulfilled its obligations, if any, under the minimum funding standards of Section 302 of the U.S. Employee Retirement Income Security Act of 1974 ("ERISA") and the regulations and published interpretations thereunder with respect to each "plan" as defined in Section 3(3) of ERISA and such regulations and published interpretations in which its employees are eligible to participate and each such plan is in compliance in all material respects with the presently applicable provisions of ERISA and such regulations and published interpretations. No "Reportable Event" (as defined in 12 ERISA) has occurred with respect to any "Pension Plan" (as defined in ERISA) for which the Company could have any material liability.

(ss) None of the Company, its directors or its officers has distributed nor will distribute prior to the later of (i) the Firm Shares Closing Date, or the Option Shares Closing Date, and (ii) completion of the distribution of the Shares, any offering material in connection with the offering and sale of the Shares other than any Preliminary Prospectus, the Prospectus, the Registration Statement and other materials, if any, permitted by the Securities Act and consistent with the terms of this Agreement.

(tt) Since the date of the preliminary prospectus included in the Registration Statement filed with the Commission on [_________] (or, if earlier, the first date on which the Company engaged directly or through any Person authorized to act on its behalf in any Testing-the-Waters Communication (as defined herein)) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "Emerging Growth Company"). "Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.

(uu) The Company (a) has not alone engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representative with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act, and (b) has not authorized anyone other than the Representative to engage in Testing-the-Waters Communications. The Company reconfirms that the Representative has been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications (as defined herein) other than those listed on Schedule IV hereto. "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.

(vv) The Company and each of its subsidiaries has all requisite corporate power and authority, and all necessary authorizations, approvals, consents, orders, licenses, certificates and permits of and from all governmental or regulatory bodies or any other person or entity (collectively, the “Permits”), to own, lease and license its assets and properties and conduct its business, all of which are valid and in full force and effect, except where the lack of such Permits, individually or in the aggregate, would not have a Material Adverse Effect. The Company and each of its subsidiaries has fulfilled and performed in all material respects all of its obligations with respect to such Permits and no event has occurred that allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other material impairment of the rights of the Company thereunder. Except as may be required under the Securities Act and state and foreign Blue Sky laws, no other Permits are required to enter into, deliver and perform this Agreement and to issue and sell the Shares.

3. Conditions of the Underwriters’ Obligations. The obligations of the Underwriters under this Agreement are several and not joint. The respective obligations of the Underwriters to purchase the Shares are subject to each of the following terms and conditions:

(a) Notification that the Registration Statement has become effective shall have been received by the Representative and the Prospectus shall have been timely filed with the Commission in accordance with Section 4(a) of this Agreement and any material required to be filed by the Company pursuant to Rule 433(d) of the Rules shall have been timely filed with the Commission in accordance with such rule.

(b) No order preventing or suspending the use of any Preliminary Prospectus, the Prospectus or any “free writing prospectus” (as defined in Rule 405 of the Rules), shall have been or shall be in effect and no order suspending the effectiveness of the Registration Statement shall be in effect and no proceedings for such purpose shall be pending before or threatened by the Commission, and any requests for additional information on the part of the Commission (to be included in the Registration Statement or the Prospectus or otherwise) shall have been complied with to the satisfaction of the Commission and the Representative. If the Company has elected to rely upon Rule 430A, Rule 430A information previously omitted from the effective Registration Statement pursuant to Rule 430A shall have been transmitted to the Commission for filing pursuant to Rule 424(b) within the prescribed time period and the Company shall have provided evidence satisfactory to the Underwriters of such timely filing, or a post-effective amendment providing such information shall have been promptly filed and declared effective in accordance with the requirements of Rule 430A.

(c) The representations and warranties of the Company contained in this Agreement and in the certificates delivered pursuant to Section 3(d) shall be true and correct when made and on and as of each Closing Date as if made on such date. The Company shall have performed, in all material respects, all covenants and agreements and satisfied all the conditions contained in this Agreement required to be performed or satisfied by it at or before such Closing Date.

(d) The Representative shall have received on each Closing Date a certificate, addressed to the Representative and dated such Closing Date, of the chief executive or chief operating officer and the chief financial officer or chief accounting officer of the Company to the effect that: (i) the representations, warranties and agreements of the Company in this Agreement were true and correct when made and are true and correct as of such Closing Date; (ii) the Company has performed all covenants and agreements and satisfied all conditions contained herein; and (iii) they have carefully examined the Registration Statement, the Prospectus, the General Disclosure Package, and any individual Issuer Free Writing Prospectus and, in their opinion (A) as of the Effective Date the Registration Statement and Prospectus did not include, and as of the Applicable Time, neither (i) the General Disclosure Package, nor (ii) any individual Issuer Free Writing Prospectus, when considered together with the General Disclosure Package, included any untrue statement of a material fact and did not omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, and (B) since the Effective Date, no event has occurred which should have been set forth in a supplement or otherwise required an amendment to the Registration Statement, the Statutory Prospectus or the Prospectus; (iv) no stop order suspending the effectiveness of the Registration Statement has been issued and, to their knowledge, no proceedings for that purpose have been instituted or are pending under the Securities Act and (v) there has not occurred any Material Adverse Effect.

(e) The Representative shall have received: (i) simultaneously with the execution of this Agreement, a signed letter from the Auditor addressed to the Representative and dated the date of this Agreement, in form and substance reasonably satisfactory to the Representative, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement and the General Disclosure Package, and (ii) on each Closing Date, a signed letter from the Auditor addressed to the Representative and dated the date of such Closing Date(s), in form and substance reasonably satisfactory to the Representative containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement and the Prospectus.

(f) The Representative shall have received on each Closing Date from Lowenstein Sandler LLP, counsel for the Company, an opinion and negative assurance statement, addressed to the Representative and dated such Closing Date, in form and substance reasonably satisfactory to the Representative.

(g) The Representative shall have received on each Closing Date from Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., intellectual property counsel for the Company, an opinion and negative assurance statement, addressed to the Representative and dated such Closing Date, in form and substance reasonably satisfactory to the Representative.

(h) The Representative shall have received on the Closing Date from Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., counsel for the Representative, a negative assurance statement, addressed to the Representative and dated as of such Closing Date, with respect to such matters as the Representative may reasonably require, and the Company shall have furnished or provided access to such counsel of such documents as they request for enabling them to pass upon such matters.

(i) All proceedings taken in connection with the sale of the Firm Shares and the Option Shares as herein contemplated shall be reasonably satisfactory in form and substance to the Representative and its counsel.

(j) The Representative shall have received copies of the Lock-up Agreements executed by each entity or person listed on Schedule II hereto. In the event that Aegis Capital Corp., in its sole discretion, agrees to release or waive any restriction set forth in a Lock-Up Agreement for an officer or director of the Company, and provides the Company with notice of the impending release or waiver at least three (3) Business Days before the effective date of such release or waiver (which release or waiver shall be substantially in the Form found at Exhibit A-1 attached hereto), the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit A-2 attached hereto through a major news service at least two (2) Business Days before the effective date of the release or waiver.

(k) The Shares shall have been approved for quotation on the Nasdaq Capital Market, subject only to official notice of issuance., and the Company has taken no action designed to, or likely to have the effect of, delisting the Shares, nor has the Company received any notification that the Nasdaq Capital Market is contemplating terminating such listing.

(l) The Representative shall be reasonably satisfied that since the respective dates as of which information is given in the Registration Statement, the Statutory Prospectus, the General Disclosure Package and the Prospectus, (i) there shall not have been any material change in the capital stock of the Company or any material change in the indebtedness (other than in the ordinary course of business) of the Company, (ii) except as set forth or contemplated by the Registration Statement, the Statutory Prospectus, the General Disclosure Package or the Prospectus, no material oral or written agreement or other transaction shall have been entered into by the Company that is not in the ordinary course of business or that could reasonably be expected to result in a material reduction in the future earnings of the Company, (iii) no loss or damage (whether or not insured) to the property of the Company shall have been sustained that had or could reasonably be expected to have a Material Adverse Effect, (iv) no legal or governmental action, suit or proceeding affecting the Company or any of its properties that is material to the Company or that affects or could reasonably be expected to affect the transactions contemplated by this Agreement shall have been instituted or threatened and (v) there shall not have been any material change in the assets, properties, condition (financial or otherwise), or in the results of operations, business affairs or business prospects of the Company or its subsidiaries considered as a whole that makes it impractical or inadvisable in the Representative's judgment to proceed with the purchase or offering of the Shares as contemplated hereby.

(m) FINRA shall have confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and agreements in connection with the offering of the Shares.

(n) The Company shall have furnished or caused to be furnished to the Representative such further certificates or documents as the Representative shall have reasonably requested.

(o) A Representative's Warrant Agreement, substantially in the form of Exhibit B hereto, executed by an officer of the Company, delivered to the Representative on the Firm Shares Closing Date.

4. Covenants and other Agreements of the Company and the Underwriters.

(a) The Company covenants and agrees as follows:

(i) The Company will use its best efforts to cause the Registration Statement, if not effective at the time of execution of this Agreement, and any amendments thereto, to become effective as promptly as possible. The Company shall prepare the Prospectus in a form approved by the Representative and file such Prospectus pursuant to Rule 424(b) under the Securities Act not later than the Commission's close of business on the second business day following the execution and delivery of this Agreement, or, if applicable, such earlier time as may be required by the Rules. The Company will file with the Commission all Issuer Free Writing Prospectuses in the time and manner required under Rules 433(d) or 163(b)(2), as the case may be.

(ii) The Company shall promptly advise the Representative in writing (A) when any post-effective amendment to the Registration Statement shall have become effective or any supplement to the Prospectus shall have been filed, (B) of any request by the Commission for any amendment of the Registration Statement or the Prospectus or for any additional information, (C) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any order preventing or suspending the use of any preliminary prospectus or any "free writing prospectus", as defined in Rule 405 of the Rules, or the institution or threatening of any proceeding for that purpose and (D) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose. The Company shall not file any amendment of the Registration Statement or supplement to the Prospectus or any Issuer Free Writing Prospectus unless the Company has furnished the Representative a copy for its review and obtained the Representative's consent (not to be reasonably withheld) prior to filing and shall not file any such proposed amendment or supplement to which the Representative reasonably objects. The Company shall use its reasonable best efforts to prevent the issuance of any such stop order and, if issued, to obtain as soon as possible the withdrawal thereof.

(iii) If, at any time when a prospectus relating to the Shares (or, in lieu thereof, the notice referred to in Rule 173(a) of the Rules) is required to be delivered under the Securities Act, any event occurs as a result of which the Prospectus as then amended or supplemented would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made not misleading, or if it shall be necessary to amend or supplement the Prospectus to comply with the Securities Act or the Rules, the Company promptly shall prepare and file with the Commission, subject to the second sentence of paragraph (ii) of this Section 4(a), an amendment or supplement which shall correct such statement or omission or an amendment which shall effect such compliance.

(iv) If at any time following issuance of an Issuer Free Writing Prospectus there occurs an event or development as a result of which such Issuer Free Writing Prospectus would conflict with the information contained in the Registration Statement or would include an untrue statement of a material fact or would omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances prevailing at the subsequent time, not misleading, the Company will promptly notify the Representative and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(v) The Company shall make generally available to its security holders and to the Representative as soon as practicable, but not later than forty-five (45) days after the end of the 12-month period beginning at the end of the fiscal quarter of the Company during which the Effective Date occurs (or ninety (90) days if such 12-month period coincides with the Company's fiscal year), an earning statement (which need not be audited) of the Company, covering such 12-month period, which shall satisfy the provisions of Section 11(a) of the Securities Act or Rule 158 of the Rules.

(vi) The Company shall furnish to the Representative and counsel for the Underwriters, without charge, signed copies of the Registration Statement (including all exhibits thereto and amendments thereof) and to each other Underwriter a copy of the Registration Statement (without exhibits thereto) and all amendments thereof and, so long as delivery of a prospectus by an Underwriter or dealer may be required by the Securities Act or the Rules, as many copies of any Preliminary Prospectus, any Issuer Free Writing Prospectus and the Prospectus and any amendments thereof and supplements thereto as the Representative may reasonably request. If applicable, the copies of the Registration Statement, preliminary prospectus, any Issuer Free Writing Prospectus and Prospectus and each amendment and supplement thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(vii) The Company shall cooperate with the Representative and its counsel in endeavoring to qualify the Shares for offer and sale in connection with the offering under the laws of such jurisdictions as the Representative may designate and shall maintain such qualifications in effect so long as required for the distribution of the Shares.

(viii) The Company, during the period when the Prospectus (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules) is required to be delivered under the Securities Act and the Rules or the Exchange Act, will file all reports and other documents required to be filed with the Commission pursuant to Section 13, 14 or 15 of the Exchange Act within the time periods required by the Exchange Act and the regulations promulgated thereunder.

(ix) Without the prior written consent of Aegis Capital Corp., for a period of three hundred sixty five (365) days after the Firm Shares Closing Date, the Company shall not offer, issue, sell or register with the Commission (other than on Form S-8 or on any successor form), or otherwise dispose of, directly or indirectly, any equity securities of the Company (or any securities convertible into, exercisable for or exchangeable for equity securities of the Company), or enter into any agreement or announce the intention to do any of the foregoing, except for the issuance of (i) the Shares pursuant to the Registration Statement, (ii) shares of Common Stock, restricted stock, restricted stock units or options to employees, officers, directors or consultants of the Company pursuant to any stock or option plan duly adopted for such purpose by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose, (iii) the issuance of the Representative's Securities and (iv) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith during the prohibitive period set forth in this Section 4(a)(ix). In the event that during this period, (A) any shares are issued pursuant to the Company's existing equity incentive plan or bonus plan that are exercisable during such 365-day period or (B) any registration is effected on Form S-8 or on any successor form relating to shares that are exercisable during such 365-day period, the Company shall obtain the written agreement of such grantee or purchaser or holder of such registered securities that, for a period of three hundred sixty five (365) days after the Firm Shares Closing Date, such person will not, without the prior written consent of Aegis Capital Corp., offer for sale, sell, distribute, grant any option for the sale of, or otherwise dispose of, directly or indirectly, or exercise any registration rights with respect to, any securities owned by such person. Notwithstanding the foregoing, the Company represents and warrants that each such grantee or purchaser or holder of such registered securities shall be subject to similar lockup restrictions as set forth on Exhibit A attached hereto and the Company shall enforce such rights and impose stop-transfer restrictions on any such sale or other transfer or disposition of such shares until the end of the applicable period.

(x) On or before completion of this offering, the Company shall make all filings required under applicable securities laws and by the Nasdaq Capital Market (including any required registration under the Exchange Act).

(xi) Prior to the Closing Date, the Company will issue no press release or other communications directly or indirectly and hold no press conference with respect to the Company, the condition, financial or otherwise, or the earnings, business affairs or business prospects of any of them, or the offering of the Shares without the prior written consent of the Representative unless in the judgment of the Company and its counsel, and after notification to the Representative, such press release or communication is required by law.

(xii) The Company will apply the net proceeds from the offering of the Shares in the manner set forth under “Use of Proceeds” in the Prospectus.

(xiii) The Company will promptly notify the Representative if the Company ceases to be an Emerging Growth Company at any time prior to the later of (a) completion of the distribution of the Shares within the meaning of the Securities Act and (b) completion of the 365-day restricted period referred to in Section 4(a)(ix) hereof.

(xiv) If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representative and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

(b) The Company agrees to pay, or reimburse if paid by the Representative, whether or not the transactions contemplated hereby are consummated or this Agreement is terminated, all costs and expenses incident to the public offering of the Shares and the performance of the obligations of the Company under this Agreement including those relating to: (i) all filing fees and expenses relating to the registration of the Shares with the Commission; (ii) all FINRA filing fees; (iii) all fees and expenses relating to the listing of the Company’s equity or equity-linked securities on Nasdaq; (iv) all fees, expenses and disbursements relating to the registration or qualification of the Shares under the “blue sky” securities laws of such states and other jurisdictions as the Representative may reasonably designate unless such filings are not required in connection with the Company’s proposed Nasdaq listing; (v) all fees, expenses and disbursements relating to the registration, qualification or exemption of the Shares under the securities laws of such foreign jurisdictions as the Representative may reasonably designate; (vi) the costs of all mailing and printing of the offering documents; (vii) transfer and/or stamp taxes, if any, payable upon the transfer of Shares from the Company to the Representative; and (viii) the fees and expenses of the Company’s accountants; and (iv) $150,000 for the Representative’s fees and expenses related to the offering including “road show”, diligence, and reasonable legal fees and disbursements for the Representative’s counsel. Such amounts are inclusive of the $25,000 advance paid by the Company to the Representative prior to the date of this Agreement.

(c) On each Closing Date, the Company shall pay to the Representative, by deduction from the proceeds of the sale of the Shares at that closing, a non-accountable expense allowance equal to one percent (1.0%) of the gross proceeds from the sale of the Shares on that Closing Date.

(d) The Company acknowledges and agrees that each of the Underwriters has acted and is acting solely in the capacity of a principal in an arm's length transaction between the Company, on the one hand, and the Underwriters, on the other hand, with respect to the offering of Shares contemplated hereby (including in connection with determining the terms of the offering) and not as a financial advisor, agent or fiduciary to the Company or any other person, and that the Underwriters may have interests that differ from those of the Company. Additionally, the Company acknowledges and agrees that the Underwriters have not and will not advise the Company or any other person as to any legal, tax, investment, accounting or regulatory matters in any jurisdiction. The Company has consulted with its own advisors concerning such matters and shall be responsible for making its own independent investigation and appraisal of the transactions contemplated hereby, and the Underwriters shall have no responsibility or liability to the Company or any other person with respect thereto, whether arising prior to or after the date hereof. Any review by the Underwriters of the Company, the transactions contemplated hereby or other matters relating to such transactions have been and will be performed solely for the benefit of the Underwriters and shall not be on behalf of the Company. The Company agrees that it will not claim that the Underwriters, or any of them, has rendered advisory services of any nature or respect, or owes a fiduciary duty to the company or any other person in connection with any such transaction or the process leading thereto.

(e) The Company represents and agrees that, unless it obtains the prior consent of the Representative, and each Underwriter represents and agrees that, unless it obtains the prior consent of the Company and the Representative, it has not made and will not make any offer relating to the Shares that would constitute an "issuer free writing prospectus," as defined in Rule 433, or that would otherwise constitute a "free writing prospectus," as defined in Rule 405, required to be filed with the Commission. The Company has complied and will comply with the requirements of Rule 433 under the Securities Act applicable to any Issuer Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping. The Company represents that it has satisfied and agrees that it will satisfy the conditions set forth in Rule 433 of the Rules to avoid a requirement to file with the Commission any Road Show.

5. Indemnification.

(a) The Company agrees to indemnify and hold harmless each Underwriter, its officers and employees and each person, if any, who controls any Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all losses, claims, damages and liabilities, joint or several (including any reasonable investigation, legal and other expenses incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted), to which they, or any of them, may become subject under the Securities Act, the Exchange Act or other federal or state law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities arise, directly or indirectly, in connection with, out of or are based upon i) any untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, the Registration Statement, the Statutory Prospectus, the Prospectus, any Issuer Free Writing Prospectus or any “issuer-information” filed or required to be filed pursuant to Rule 433(d) of the Rules, any amendment thereof or supplement thereto, any Written Testing-the-Waters Communication, or in any Blue Sky application or other information or other documents executed by the Company filed in any state or other jurisdiction to qualify any or all of the Shares and Representative’s Securities under the securities laws thereof (any such application, document or information being hereinafter referred to as a “Blue Sky Application”), ii) any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or iii) any actual or alleged breach by the Company of any of its obligations, or of any of its representations, warranties and undertakings, set out in this Agreement; provided, however, that such indemnity shall not inure to the benefit of any Underwriter (or any person controlling such Underwriter) on account of any losses, claims, damages or liabilities arising from the sale of the Shares to any person by such Underwriter if such untrue statement or omission or alleged untrue statement or omission was made in such preliminary prospectus, the Registration Statement, the Prospectus, the Statutory Prospectus, any Issuer Free Writing Prospectus or such amendment or supplement thereto, any Written Testing-the-Waters Communication, or in any Blue Sky Application in reliance upon and in conformity with the Underwriter Information, or if any such losses, claims, damages or liabilities have arisen from (i) the fraud, gross negligence, willful misconduct or bad faith of, or material breach of the Agreement by the person entitled to indemnification to the extent finally judicially determined by a court of competent jurisdiction or by a regulatory authority (as appropriate) or (ii) a breach of the duties owed by an person to indemnification under relevant regulatory rules to the extent finally judicially determined by a court of competent jurisdiction or by a regulatory authority (as appropriate). This indemnity agreement will be in addition to any liability which the Company may otherwise have.

(b) Each Underwriter, severally and not jointly, agrees to indemnify and hold harmless the Company, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, each director of the Company, and each officer of the Company who signs the Registration Statement, against any losses, claims, damages or liabilities to which such party may become subject, under the Securities Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, the Registration Statement or the Prospectus, or any amendment or supplement thereto, or arise, directly or indirectly, in connection with, out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in any Preliminary Prospectus, the Registration Statement, the Statutory Prospectus or the Prospectus or any such amendment or supplement in reliance upon and in conformity with the Underwriter Information; provided, however, that the obligation of each Underwriter to indemnify the Company (including any controlling person, director or officer thereof) shall be limited to the amount of the underwriting discount and commissions applicable to the Shares to be purchased by such Underwriter hereunder, and that that such indemnity shall not inure to the benefit of the Company (or any person controlling such Company) on account of any losses, claims, damages or liabilities arising from (i) the fraud, gross negligence, willful misconduct or bad faith of, or material breach of the Agreement by the person entitled to indemnification to the extent finally judicially determined by a court of competent jurisdiction or by a regulatory authority (as appropriate) or (ii) a breach of the duties owed by an person to indemnification under relevant regulatory rules to the extent finally judicially determined by a court of competent jurisdiction or by a regulatory authority (as appropriate)..

(c) Any party that proposes to assert the right to be indemnified under this Section will, promptly after receipt of notice of commencement of any action, suit or proceeding against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section, notify each such indemnifying party of the commencement of such action, suit or proceeding, enclosing a copy of all papers served. No indemnification provided for in Section 5(a) or 5(b) shall be available to any party who shall fail to give notice as provided in this Section 5(c) if the party to whom notice was not given was unaware of the proceeding to which such notice would have related and was prejudiced by the failure to give such notice but the omission so to notify such indemnifying party of any such action, suit or proceeding shall not relieve it from any liability that it may have to any indemnified party for contribution or otherwise than under this Section. In case any such action, suit or proceeding shall be brought against any indemnified party and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in, and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof and the approval by the indemnified party of such counsel, the indemnifying party shall not be liable to such indemnified party for any legal or other expenses, except as provided below and except for the reasonable costs of investigation subsequently incurred by such indemnified party in connection with the defense thereof. The indemnified party shall have the right to employ its counsel in any such action, but the fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the employment of counsel by such indemnified party has been authorized in writing by the indemnifying parties, (ii) the indemnified party shall have been advised by counsel that there may be one or more legal defenses available to it which are different from or in addition to those available to the indemnifying party (in which case the indemnifying parties shall not have the right to direct the defense of such action on behalf of the indemnified party) or (iii) the indemnifying parties shall not have employed counsel to assume the defense of such action within a reasonable time after notice of the commencement thereof, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying parties. An indemnifying party shall not be liable for any settlement of any action, suit, and proceeding or claim effected without its written consent, which consent shall not be unreasonably withheld or delayed.

6. Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in Section 5(a) or 5(b) is due in accordance with its terms but for any reason is unavailable to or insufficient to hold harmless an indemnified party in respect to any losses, liabilities, claims, damages or expenses referred to therein, then each indemnifying party shall contribute to the aggregate losses, liabilities, claims, damages and expenses (including any investigation, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claims asserted, but after deducting any contribution received by any person entitled hereunder to contribution from any person who may be liable for contribution) incurred by such indemnified party, as incurred, in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other hand from the offering of the Shares pursuant to this Agreement or, if such allocation is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to above but also the relative fault of the Company on the one hand and the Underwriters on the other hand in connection with the statements or omissions which resulted in such losses, liabilities, claims, damages or expenses, as well as any other relevant equitable considerations. The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 6 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above. The aggregate amount of losses, liabilities, claims, damages and expenses incurred by an indemnified party and referred to above shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission. Notwithstanding the provisions of this Section 6, no Underwriter (except as may be provided in the Agreement Among Underwriters) shall be required to contribute any amount in excess of the underwriting discounts and commissions applicable to the Shares purchased by such Underwriter. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 6, each person, if any, who controls an Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act shall have the same rights to contribution as such Underwriter, and each director of the Company, including any person who, with his or her consent, is named in the Registration Statement as about to become a director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Section 15 of the Securities Act or Section 20 of the Exchange Act, shall have the same rights to contribution as the Company. Any party entitled to contribution will, promptly after receipt of notice of commencement of any action, suit or proceeding against such party in respect of which a claim for contribution may be made against another party or parties under this Section 6, notify such party or parties from whom contribution may be sought, but the omission so to notify such party or parties from whom contribution may be sought shall not relieve the party or parties from whom contribution may be sought from any other obligation it or they may have hereunder or otherwise than under this Section 6. No party shall be liable for contribution with respect to any action, suit, proceeding or claim settled without its written consent. The Underwriters' obligations to contribute pursuant to this Section 6 are several in proportion to their respective underwriting commitments and not joint.

7. Termination.

(a) This Agreement may be terminated with respect to the Shares to be purchased on a Closing Date by the Representative by notifying the Company at any time at or before a Closing Date in the absolute discretion of the Representative if: (i) there has occurred any material adverse change in the securities markets or any event, act or occurrence that has materially disrupted, or in the opinion of the Representative, will in the future materially disrupt, the securities markets or there shall be such a material adverse change in general financial, political or economic conditions or the effect of international conditions on the financial markets in the United States is such as to make it, in the judgment of the Representative, inadvisable or impracticable to market the Shares or enforce contracts for the sale of the Shares; (ii) there has occurred any outbreak or material escalation of hostilities or acts of terrorism or other calamity or crisis the effect of which on the financial markets of the United States is such as to make it, in the judgment of the Representative, inadvisable or impracticable to market the Shares or enforce contracts for the sale of the Shares; (iii) trading in the Shares or any securities of the Company has been suspended or materially limited by the Commission or trading generally on the New York Stock Exchange, Inc., or the Nasdaq Stock Market has been suspended or materially limited, or minimum or maximum ranges for prices for securities shall have been fixed, or maximum ranges for prices for securities have been required, by any of said exchanges or by such system or by order of the Commission, FINRA, or any other governmental or regulatory authority; (iv) a banking moratorium has been declared by any state or federal authority; or (v) in the judgment of the Representative, there has been, since the time of execution of this Agreement or since the respective dates as of which information is given in the Prospectus, any material adverse change in the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company and its subsidiaries considered as a whole, whether or not arising in the ordinary course of business.

(b) If this Agreement is terminated pursuant to any of its provisions, the Company shall not be under any liability to any Underwriter, and no Underwriter shall be under any liability to the Company, except that (y) if this Agreement is terminated by the Representative or the Underwriters because of any failure, refusal or inability on the part of the Company to comply with the terms or to fulfill any of the conditions of this Agreement, the Company will reimburse the Underwriters for all reasonable out-of-pocket expenses (including the reasonable fees and disbursements of their counsel) incurred by them in connection with the proposed purchase and sale of the Shares or in contemplation of performing their obligations hereunder and (z) no Underwriter who shall have failed or refused to purchase the Shares agreed to be purchased by it under this Agreement, without some reason sufficient hereunder to justify cancellation or termination of its obligations under this Agreement, shall be relieved of liability to the Company or to the other Underwriters for damages occasioned by its failure or refusal.

8. Substitution of Underwriters. If any Underwriter shall default in its obligation to purchase on any Closing Date the Shares agreed to be purchased hereunder on such Closing Date, the Representative shall have the right, within thirty-six (36) hours thereafter, to make arrangements for one or more of the non-defaulting Underwriters, or any other underwriters, to purchase such Shares on the terms contained herein. If, however, the Representative shall not have completed such arrangements within such 36-hour period, then the Company shall be entitled to a further period of thirty-six (36) hours within which to procure another party or other parties satisfactory to the Underwriters to purchase such Shares on such terms. If, after giving effect to any arrangements for the purchase of the Shares of a defaulting Underwriter or Underwriters by the Representative and the Company as provided above, the aggregate number of Shares which remains unpurchased on such Closing Date does not exceed one-eleventh (1/11) of the aggregate number of all the Shares that all the Underwriters are obligated to purchase on such date, then the Company shall have the right to require each non-defaulting Underwriter to purchase the number of Shares which such Underwriter agreed to purchase hereunder at such date and, in addition, to require each non-defaulting Underwriter to purchase its pro rata share (based on the number of Shares which such Underwriter agreed to purchase hereunder) of the Shares of such defaulting Underwriter or Underwriters for which such arrangements have not been made; but nothing herein shall relieve a defaulting Underwriter from liability for its default. In any such case, either the Representative or the Company shall have the right to postpone the applicable Closing Date for a period of not more than seven (7) days in order to effect any necessary changes and arrangements (including any necessary amendments or supplements to the Registration Statement or Prospectus or any other documents), and the Company agrees to file promptly any amendments to the Registration Statement or the Prospectus which in the opinion of the Company and the Underwriters and their counsel may thereby be made necessary.

If, after giving effect to any arrangements for the purchase of the Shares of a defaulting Underwriter or Underwriters by the Representative and the Company as provided above, the aggregate number of such Shares which remains unpurchased exceeds 10% of the aggregate number of all the Shares to be purchased at such date, then this Agreement, or, with respect to a Closing Date which occurs after the First Closing Date, the obligations of the Underwriters to purchase and of the Company to sell the Option Shares to be purchased and sold on such date, shall terminate, without liability on the part of any non-defaulting Underwriter to the Company, and without liability on the part of the Company, except as provided in Sections 4(b), 5, 6 and 7. The provisions of this Section 8 shall not in any way affect the liability of any defaulting Underwriter to the Company or the non-defaulting Underwriters arising out of such default. The term "Underwriter" as used in this Agreement shall include any person substituted under this Section 8 with like effect as if such person had originally been a party to this Agreement with respect to such Shares.

9. <u>Miscellaneous</u>. The respective agreements, representations, warranties, indemnities and other statements of the Company and the several Underwriters, as set forth in this Agreement or made by or on behalf of them pursuant to this Agreement, shall remain in full force and effect, regardless of any investigation (or any statement as to the results thereof) made by or on behalf of any Underwriter or the Company or any of their respective officers, directors or controlling persons referred to in Sections 5 and 6 hereof, and shall survive delivery of and payment for the Shares. In addition, the provisions of Sections 4(b), 5, 6 and 7 shall survive the termination or cancellation of this Agreement.

This Agreement has been and is made for the benefit of the Underwriters, the Company, and their respective successors and assigns, and, to the extent expressed herein, for the benefit of persons controlling any of the Underwriters, or the Company, and directors and officers of the Company, and their respective successors and assigns, and no other person shall acquire or have any right under or by virtue of this Agreement. The term "successors and assigns" shall not include any purchaser of Shares from any Underwriter merely because of such purchase.

All notices and communications hereunder shall be in writing and mailed or delivered or by telephone or facsimile if subsequently confirmed in writing, (a) if to the Representative, c/o Aegis Capital Corp., 810 7th Avenue, New York, NY 10019 Attention: [ ], with a copy to Sichenzia Ross Ference LLP, 1185 Avenue of the Americas, 31st Floor, New York, New York 10036 Attention: Gregory Sichenzia, and (b) if to the Company, to its agent for service as such agent's address appears on the cover page of the Registration Statement, with a copy to Lowenstein Sandler LLP, 1251 Avenue of the Americas, New York, New York 10020, Attention: Steven M. Skolnick, Esq.

This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state.

[Remainder of Page Intentionally Left Blank. Signature Page Follows.]

This Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

Please confirm that the foregoing correctly sets forth the agreement among us.

Very truly yours,

CINGULATE INC.

By: ________________________
Name:
Title:

Confirmed:

AEGIS CAPITAL CORP.

By: ________________________
Name:
Title:

Acting severally on behalf of itself
and as representative of the several
Underwriters named in Schedule I annexed
hereto.

[Signature Page to Underwriting Agreement]

SCHEDULE I

Name	Number of Firm Shares to Be Purchased
Aegis Capital Corp.	
Laidlaw & Company (UK) Ltd.	
Total	

SCHEDULE II

Lock-up Signatories

1. Shane J. Schaffer
2. Louis G. Van Horn
3. Laurie A. Myers
4. Craig S. Gilgallon
5. Raul R. Silva
6. Matthew Brams
7. Jeff Hargroves
8. Peter J. Werth
9. Jeff Conroy
10. Patrick Gallagher
11. Gregg Givens
12. Curt Medeiros
13. Werth Family Investment Associates LLC
14. Fountainhead Shrugged, LLC
15. Kari Fogleman
16. Jenny Callahan
17. Jeff Bennett
18. Naama Courtemanche
19. Steve Abele
20. Spencer Chestnut
21. Holly Mitzel
22. Michael Cattaneo
23. Kelly Koehn
24. Thomas Dalton
25. Ryan Schultz

SCHEDULE III

Issuer Free Writing Prospectuses

SCHEDULE IV

Testing-the-Waters Communications

SCHEDULE V

Final Terms

Number of Firm Shares	
Number of Option Shares	
Number of Representative's Warrants	
Public Offering Price per Firm Share	$
Exercise Price of Representative's Warrant	$
Public Offering Price per Option Share	$
Underwriting Discount per Firm Share	$
Underwriting Discount per Option Share	$
Non-accountable expense allowance per Firm Share	$
Non-accountable expense allowance per Option Share	$
Trade Date	[ ], 2021
Settlement Date	[ ], 2021

Exhibit A

FORM OF LOCK-UP AGREEMENT

__________, 2021

Aegis Capital Corp.,
As Representative of the Underwriters
810 7th Avenue
New York, New York 10019

Re: Initial Public Offering of Cingulate Inc.

Ladies and Gentlemen:

The undersigned understands that you, as Representative of the several Underwriters, propose to enter into an Underwriting Agreement (the "Underwriting Agreement") with the Cingulate Inc., a Delaware corporation (the "Company"), providing for the Company's initial public offering (the "Offering") by the several Underwriters named in Schedule I to the Underwriting Agreement (the "Underwriters") of common stock of the Company, par value $0.0001 per share (the "Securities") pursuant to a registration statement on Form S-1 filed with the Securities and Exchange Commission (the "SEC"). Capitalized terms used but not defined herein shall have the meaning assigned to it in the Underwriting Agreement.

In consideration of the Underwriters' agreement to enter into the Underwriting Agreement and to proceed with the Offering of the Securities, and for other good and valuable consideration, receipt of which is hereby acknowledged, the undersigned hereby agrees that, without the prior written consent of the Representative (the "Requisite Consent"), the undersigned will not, during the period ending 180 days after the Firm Shares Closing Date (the "Lock-Up Period"), directly or indirectly (1) offer, pledge, assign, encumber, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, any equity securities of the Company, Interests and Securities, or any securities convertible into or exercisable or exchangeable for equity securities of the Company ("Related Securities") owned either of record or beneficially (as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act")) by the undersigned on the date hereof or hereafter acquired or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Securities or Related Securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Securities or such other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing. In addition, the undersigned agrees that, without the prior written consent of the Representative, the undersigned will not, during the Lock-Up Period, make any demand for, or exercise any right with respect to, the registration of any Securities or any Related Securities. The foregoing shall not apply to (a) transactions relating to securities acquired in the Offering or in open market transactions after the completion of the Offering, provided that no filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made during the Lock-Up Period in connection with subsequent sales of such securities acquired in the Offering or in such open market transactions; (b) transfers of Securities or any Related Securities (i) as a bona fide gift or for bona fide estate planning purposes, (ii) upon death or by will, testamentary document or intestate succession, (iii) to an immediate family member of the undersigned or to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned (for purposes of this agreement, "immediate family" shall mean any relationship by blood, current or former marriage or adoption, not more remote than first cousin), (iv) not involving a change in beneficial ownership, or (v) if the undersigned is a trust, to any beneficiary of the undersigned or the estate of any such beneficiary; (c) distributions of Securities or any Related Securities to stockholders, direct or indirect affiliates (within the meaning set forth in Rule 405 under the Securities Act of 1933, as amended (the "Securities Act")), current or former partners (general or limited), members or managers of the undersigned, as applicable, or to the estates of any such stockholders, affiliates, partners, members or managers; (d) the transfer to the Company of Securities upon a vesting event of the Company's securities or upon the exercise of options or warrants to purchase the Company's securities, in each case on a "cashless" or "net exercise" basis or to cover tax withholding obligations of the undersigned in connection with such vesting or exercise, provided that any related filing under Section 16(a) of the Exchange Act reporting a disposition of Securities made in connection with such vesting or exercise shall contain a description of the transaction and indicate that the disposition was made as part of such vesting or exercise or to cover tax withholding obligations in connection therewith; (e) transfers of Securities or any Related Securities by operation of law, such as pursuant to a qualified domestic order or in connection with a divorce decree; (f) sales under any existing Rule 10b5-1 plan or the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Securities or any Related Securities, provided that (i) such plan does not provide for the transfer of Securities or any Related Securities during the Lock-Up Period and (ii) no public announcement or filing under the Exchange Act regarding the establishment of such plan shall be required or shall be voluntarily made by or on behalf of the undersigned or the Company during the Lock-Up Period; or (g) the transfer of Securities pursuant to a bona fide third party tender offer, merger, consolidation or other similar transaction made to all holders of the shares of common stock of the Company involving a change of control (as defined below) of the Company after the closing of the Offering and approved by the Company's board of directors; *provided* that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the Securities owned by the undersigned shall remain subject to the restrictions contained in this lock-up agreement; *provided*, in the case of clauses (b)-(c), that such transfer shall not involve a disposition for value and the transferee agrees in writing with the Representative and the Company to be bound by the terms hereof. For purposes of clause (g) above, "change of control" shall mean the consummation of any bona fide third party tender offer, merger, amalgamation, consolidation or other similar transaction the result of which is that any "person" (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of a majority of total voting power of the voting stock of the Company.

If the undersigned is an officer or director of the Company, (i) the Representative on behalf of the Underwriters agrees that, at least three business days before the effective date of any Requisite Consent to release or waive the foregoing restrictions in connection with a transfer of shares of Securities or other Related Securities, the Representative on behalf of the Underwriters will notify the Company of the impending release or waiver, and (ii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver. Any Requisite Consent to release or waive the foregoing restrictions in connection with a transfer of , shares of Securities or other Related Securities, granted by the Representative on behalf of the Underwriters hereunder to any such officer or director, shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if (a) the release or waiver is effected solely to permit a transfer not for consideration and (b) the transferee has agreed in writing to be bound by the same terms described in this agreement to the extent and for the duration that such terms remain in effect at the time of the transfer.

The undersigned understands that the Company and the Underwriters are relying upon this agreement in proceeding toward consummation of the Offering. The undersigned further understands that this agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representatives, successors and assigns.

The undersigned acknowledges and agrees that the Underwriters have not provided any recommendation or investment advice nor have the Underwriters solicited any action from the undersigned with respect to the Offering of the Securities and the undersigned has consulted their own legal, accounting, financial, regulatory and tax advisors to the extent deemed appropriate. The undersigned further acknowledges and agrees that the Underwriters are not making a recommendation to you to participate in the Offering or sell any Securities at the price determined in the Offering, and nothing set forth in such disclosures or documentation is intended to suggest that any Underwriter is making such a recommendation.

In furtherance of the foregoing, the Company, and any duly appointed transfer agent for the registration or transfer of the securities described herein, are hereby authorized to decline to make any transfer of securities if such transfer would constitute a violation or breach of this agreement.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this agreement.

The undersigned understands that, if (a) the Underwriting Agreement does not become effective by January 3, 2022, (b) the Company informs the undersigned that the Board of Directors has determined not to proceed with the Offering or the registration statement filed with the SEC in connection with the Offering is withdrawn, or (c) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Securities, this agreement shall terminate and the undersigned shall be released from all obligations hereunder. For the avoidance of doubt, this Agreement shall remain in effect in the event that the Company converts from a limited liability company into a corporation after the date of this agreement, and any securities issued to the undersigned in connection with such conversion shall be deemed Securities or Related Securities for purposes of this Agreement.

The undersigned, whether or not participating in the Offering, understands that the Representative on behalf of the Underwriters is entering into the Underwriting Agreement and proceeding with the Offering in reliance upon this agreement.

[Signature page follows.]

This agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflict of laws principles thereof (other than New York General Obligations Law § 5-1401).

Very truly yours,

[STOCKHOLDER]

By: ______________________________
Name:
Title:

Exhibit A-1

[Form of Waiver of Lock-up]

[Aegis Letterhead]

[corporation]
Public Offering of Common Stock

[ ], 20[ ]

[Name and Address of
Officer or Director
Requesting Waiver]

Dear Mr./Ms. [Name]:

This letter is being delivered to you in connection with the offering by [Corporation] (the "Company") of [ ] shares of common stock, $0.0001 par value (the "Common Stock") of the Company, and the lock-up agreement dated [ ], 20[ ] (the "Lock-up Agreement"), executed by you in connection with such offering, and your request for a [waiver] [release] dated [ ], 20[ ], with respect to [ ] shares of Common Stock (the "Securities").

Aegis Capital Corp hereby agrees to [waive] [release] the transfer restrictions set forth in the Lock-up Letter, but only with respect to the Securities, effective [ ], 20[ ][date to be 3 business days from date of letter]; provided, however, that such [waiver] [release] is conditioned on the Company announcing the impending [waiver] [release] by press release through a major news service at least two (2) business days before effectiveness of such [waiver] [release]. This letter will serve as notice to the Company of the impending [waiver] [release].

Except as expressly [waived] [released] hereby, the Lock-up Letter shall remain in full force and effect.

Yours very truly,

AEGIS CAPITAL CORP.

By: ____________________
Name:
Title:

cc: [Company contact]

Exhibit A-2

[Form of Lock Up Waiver/Release Company Press Release]

[Company]
[Date]

("[Company]") announced today that Aegis Capital Corp., the [lead book-running] manager in the Company's recent public sale of [ ] shares of common stock, is [waiving] [releasing] a lock-up restriction with respect to [ ] shares of the Company's common stock held by [ ], an [officer/director] of the Company. The [waiver] [release] will take effect on [ ], 20[ ], and the related shares may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

EXHIBIT B

Form of Representative’s Warrant Agreement

Exhibit 4.2

THE REGISTERED HOLDER OF THIS PURCHASE WARRANT BY ITS ACCEPTANCE HEREOF, AGREES THAT IT WILL NOT SELL, TRANSFER OR ASSIGN THIS PURCHASE WARRANT EXCEPT AS HEREIN PROVIDED AND THE REGISTERED HOLDER OF THIS PURCHASE WARRANT AGREES THAT IT WILL NOT SELL, TRANSFER, ASSIGN, PLEDGE OR HYPOTHECATE THIS PURCHASE WARRANT FOR A PERIOD OF ONE HUNDRED EIGHTY DAYS FOLLOWING NOVEMBER [•], 2021 (SUCH DATE, THE COMMENCEMENT OF SALES OF THE OFFERING OR THE ***"EFFECTIVE DATE"***) TO ANYONE OTHER THAN (I) AEGIS CAPITAL CORP. OR A SELECTED DEALER IN CONNECTION WITH THE OFFERING FOR WHICH THIS PURCHASE WARRANT WAS ISSUED TO THE UNDERWRITER AS CONSIDERATION (THE ***"OFFERING"***), OR (II) A BONA FIDE OFFICER OR PARTNER OF AEGIS CAPITAL CORP.

THIS PURCHASE WARRANT IS NOT EXERCISABLE PRIOR TO MAY [•], 2022. VOID AFTER 5:00 P.M., EASTERN TIME, NOVEMBER [•], 2026.

COMMON STOCK PURCHASE WARRANT

For the Purchase of [•] Shares of Common Stock

of

CINGULATE INC.

1. Purchase Warrant. THIS CERTIFIES THAT, in consideration of funds duly paid by or on behalf of Aegis Capital Corp. (***"Aegis"*** or ***"Holder"***), as registered owner of this Purchase Warrant, to Cingulate Inc., a Delaware corporation (the ***"Company"***), Holder is entitled, at any time or from time to time beginning May [•], 2022 (the ***"Exercisable Date"***), and at or before 5:00 p.m., Eastern time, November [•], 2026 (the ***"Expiration Date"***), but not thereafter, to subscribe for, purchase and receive, in whole or in part, up to [•] shares of common stock of the Company, par value $0.0001 per share (the ***"Shares"***), subject to adjustment as provided in Section 6 hereof. If the Expiration Date is a day on which banking institutions are authorized by law to close, then this Purchase Warrant may be exercised on the next succeeding day which is not such a day in accordance with the terms herein. During the period ending on the Expiration Date, the Company agrees not to take any action that would terminate this Purchase Warrant. This Purchase Warrant is initially exercisable at $[•] per Share; provided, however, that upon the occurrence of any of the events specified in Section 6 hereof, the rights granted by this Purchase Warrant, including the exercise price per Share and the number of Shares to be received upon such exercise, shall be adjusted as therein specified. The term ***"Exercise Price"*** shall mean the initial exercise price or the adjusted exercise price, depending on the context.

2. Exercise.

2.1 Exercise Form. In order to exercise this Purchase Warrant, the exercise form attached hereto must be duly executed and completed and delivered to the Company, together with this Purchase Warrant and payment of the Exercise Price for the Shares being purchased payable in cash by wire transfer of immediately available funds to an account designated by the Company or by certified check or official bank check. If the subscription rights represented hereby shall not be exercised at or before 5:00 p.m., Eastern time, on the Expiration Date, this Purchase Warrant shall become and be void without further force or effect, and all rights represented hereby shall cease and expire. Each exercise hereof shall be irrevocable.

2.2 Cashless Exercise. In lieu of exercising this Purchase Warrant by payment of cash or check payable to the order of the Company pursuant to Section 2.1 above, Holder may elect to receive the number of Shares equal to the value of this Purchase Warrant (or the portion thereof being exercised), by surrender of this Purchase Warrant to the Company, together with the exercise form attached hereto, in which event the Company will issue to Holder Shares in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where,

X = The number of Shares to be issued to Holder;
Y = The number of Shares for which the Purchase Warrant is being exercised;
A = The fair market value of one Share; and
B = The Exercise Price.

For purposes of this Section 2.2, the fair market value of a Share is defined as follows:

(i) if the Company's common stock is traded on a national securities exchange, the OTCQB or OTCQX, the value shall be deemed to be the closing price on such exchange, the OTCQB or OTCQX, as the case may be, on the Business Day immediately preceding the date that the exercise form is delivered pursuant to Section 8.4 in connection with the exercise of the Purchase Warrant; or

(ii) if the Company's common stock is not then traded on a securities exchange, the OTCQB or OTCQX and if prices for the Company's common stock are then reported on the "Pink Sheets" published by OTC Markets Group, Inc., the value shall be deemed to be the closing bid prior to the exercise form being submitted in connection with the exercise of the Purchase Warrant so reported; provided, however, if there is no active public market, the value shall be the fair market value thereof, as determined in good faith by the Company's Board of Directors.

2.3 Legend. Each certificate for the securities purchased under this Purchase Warrant shall bear a legend as follows unless such securities have been registered under the Securities Act of 1933, as amended (the ***"Act"***):

The securities represented by this certificate have not been registered under the Securities Act of 1933, as amended (the "Act"), or applicable state law. Neither the securities nor any interest therein may be offered for sale, sold or otherwise transferred except pursuant to an effective registration statement under the Act, or pursuant to an exemption from registration under the Act and applicable state law which, in the opinion of counsel to the Company, is available.

2.4 Resale of Shares. Holder and the Company acknowledge that as of the date hereof the Staff of the Division of Corporation Finance of the SEC has published Compliance & Disclosure Interpretation 528.04 in the Securities Act Rules section thereof, stating that the holder of securities issued in connection with a public offering may not rely upon Rule 144 promulgated under the Act to establish an exemption from registration requirements under Section 4(a)(1) under the Act, but may nonetheless apply Rule 144 constructively for the resale of such shares in the following manner: (a) provided that six months has elapsed since the last sale under the registration statement, an underwriter or finder may resell the securities in accordance with the provisions of Rule 144(c), (e), and (f), except for the notice requirement; (b) a purchaser of the shares from an underwriter receives restricted securities unless the sale is made with an appropriate, current prospectus, or unless the sale is made pursuant to the conditions contained in (a) above; (c) a purchaser of the shares from an underwriter who receives restricted securities may include the underwriter's holding period, provided that the underwriter or finder is not an affiliate of the issuer; and (d) if an underwriter transfers the shares to its employees, the employees may tack the firm's holding period for purposes of Rule 144(d), but they must aggregate sales of the distributed shares with those of other employees, as well as those of the underwriter or finder, for a six-month period from the date of the transfer to the employees. Holder and the Company also acknowledge that the Staff of the Division of Corporation Finance of the SEC has advised in various no-action letters that the holding period associated with securities issued without registration to a service provider commences upon the completion of the services, which the Company agrees and acknowledges shall be the final closing of the Offering, and that Rule 144(d)(3)(ii) provides that securities acquired from the issuer solely in exchange for other securities of the same issuer shall be deemed to have been acquired at the same time as the securities surrendered for conversion (which the Company agrees is the date of the initial issuance of this Purchase Warrant). In the event that following a reasonably-timed written request by Holder to transfer the Shares in accordance with Compliance & Disclosure Interpretation 528.04 counsel for the Company in good faith concludes that Compliance & Disclosure Interpretation 528.04 no longer may be relied upon as a result of changes in applicable laws, regulations, or interpretations of the SEC Division of Corporation Finance, or as a result of judicial interpretations not known by the Company or its counsel on the date hereof (either, a ***"Registration Trigger Event"***), then the Company shall promptly, and in any event within five (5) business days following the request, provide written notice to Holder of such determination. As a condition to giving such notice, the parties shall negotiate in good faith a single demand registration right pursuant to an agreement in customary form reasonably acceptable to the parties; provided that notwithstanding anything to the contrary, the obligations of the Company pursuant to this Section 2 shall terminate on the fifth anniversary of the Effective Date. In the absence of such conclusion by counsel for the Company, the Company shall, upon such a request of Holder given no earlier than six months after the final closing of the Offering, instruct its transfer agent to permit the transfer of such shares in accordance with Compliance & Disclosure Interpretation 528.04, provided that Holder has provided such documentation as shall be reasonably be requested by the Company to establish compliance with the conditions of Compliance & Disclosure Interpretation 528.04. Notwithstanding anything to the contrary, pursuant to FINRA Rule 5110(g)(8)(A), the Holder shall not be entitled to more than one demand registration right hereunder and the duration of the registration rights hereunder shall not exceed five years from the Effective Date.

3. Transfer.

3.1 General Restrictions. The registered Holder of this Purchase Warrant agrees by his, her or its acceptance hereof, that such Holder will not: (a) sell, transfer, assign, pledge or hypothecate this Purchase Warrant for a period of one hundred eighty (180) days following the Effective Date to anyone other than: (i) Aegis or an underwriter, placement agent, or a selected dealer participating in the Offering, or (ii) a bona fide officer or partner of Aegis or of any such underwriter, placement agent or selected dealer, in each case in accordance with FINRA Conduct Rule 5110(g)(1), or (b) for a period of one hundred eighty (180) days following the Effective Date cause this Purchase Warrant or the securities issuable hereunder to be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of this Purchase Warrant or the securities hereunder, except as provided for in FINRA Rule 5110(g)(2). After 180 days after the Effective Date, transfers to others may be made subject to compliance with or exemptions from applicable securities laws. In order to make any permitted assignment, the Holder must deliver to the Company the assignment form attached hereto duly executed and completed, together with the Purchase Warrant and payment of all transfer taxes, if any, payable in connection therewith. The Company shall within five (5) Business Days transfer this Purchase Warrant on the books of the Company and shall execute and deliver a new Purchase Warrant or Purchase Warrants of like tenor to the appropriate assignee(s) expressly evidencing the right to purchase the aggregate number of Shares purchasable hereunder or such portion of such number as shall be contemplated by any such assignment.

3.2 Restrictions Imposed by the Act. The securities evidenced by this Purchase Warrant shall not be transferred unless and until: (i) if required by applicable law, the Company has received the opinion of counsel for the Company or an opinion of counsel for the registered Holder acceptable to the Company and its counsel that the securities may be transferred pursuant to an exemption from registration under the Act and applicable state securities laws, or (ii) a registration statement or a post-effective amendment to the Registration Statement relating to the offer and sale of such securities has been filed by the Company and declared effective by the U.S. Securities and Exchange Commission (the ***"Commission"***) and compliance with applicable state securities law has been established.

4. Piggyback Registration Rights.

4.1 Grant of Right. Whenever the Company proposes to register any shares of its common stock under the Act (other than (i) a registration effected solely to implement an employee benefit plan or a transaction to which Rule 145 of the Act is applicable, or (ii) a registration statement on Form S-3 related to a universal shelf offering for the benefit of the Company, Form S-4, S-8 or any successor form thereto or another form not available for registering the Shares issuable upon exercise of this Purchase Warrant for sale to the public, whether for its own account or for the account of one or more stockholders of the Company (a ***"Piggyback Registration"***), the Company shall give prompt written notice (in any event no later than ten (10) Business Days prior to the filing of such registration statement) to the Holder of the Company's intention to effect such a registration and, subject to the remaining provisions of this Section 4.1, shall include in such registration such number of Shares underlying this Purchase Warrant (the ***"Registrable Securities"***) that the Holders have (within ten (10) Business Days of the respective Holder's receipt of such notice) requested in writing (including such number) to be included within such registration. If a Piggyback Registration is an underwritten offering and the managing underwriter advises the Company that it has determined in good faith that marketing factors require a limit on the number of shares of common stock to be included in such registration, including all Shares issuable upon exercise of this Purchase Warrant (if the Holder has elected to include such shares in such Piggyback Registration) and all other shares of common stock proposed to be included in such underwritten offering, the Company shall include in such registration (i) first, the number of shares of common stock that the Company proposes to sell and (ii) second, the number of shares of common stock, if any, requested to be included therein by selling stockholders (including the Holder) allocated pro rata among all such persons on the basis of the number of shares of common stock then owned by each such person. If any Piggyback Registration is initiated as a primary underwritten offering on behalf of the Company, the Company shall select the investment banking firm or firms to act as the managing underwriter or underwriters in connection with such offering. Notwithstanding anything to the contrary, the obligations of the Company pursuant to this Section 4.1 shall terminate on the earlier of (i) the seventh anniversary of the Effective Date and (ii) the date that Rule 144 would allow the Holder to sell its Registrable Securities during any ninety (90) day period, and shall not be applicable so long as the Company's Registration Statement on Form S-1 (No. 333-259408) covering the Registrable Securities remains effective at such time.

4.2 Indemnification. The Company shall indemnify the Holder(s) of the Registrable Securities to be sold pursuant to any registration statement hereunder and each person, if any, who controls such Holders within the meaning of Section 15 of the Act or Section 20(a) of the Securities Exchange Act of 1934, as amended (***"Exchange Act"***), against all loss, claim, damage, expense or liability (including all reasonable attorneys' fees and other out-of-pocket expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which any of them may become subject under the Act, the Exchange Act or otherwise, arising from such registration statement but only to the same extent and with the same effect as the provisions pursuant to which the Company has agreed to indemnify Aegis contained in the Underwriting Agreement between Aegis and the Company, dated as of November [•], 2021. The Holder(s) of the Registrable Securities to be sold pursuant to such registration statement, and their successors and assigns, shall severally, and not jointly, indemnify the Company, against all loss, claim, damage, expense or liability (including all reasonable attorneys' fees and other expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which they may become subject under the Act, the Exchange Act or otherwise, arising from information furnished by or on behalf of such Holders, or their successors or assigns, in writing, for specific inclusion in such registration statement to the same extent and with the same effect as the provisions contained in the Underwriting Agreement pursuant to which Aegis has agreed to indemnify the Company.

4.3 Exercise of Purchase Warrants. Nothing contained in this Purchase Warrant shall be construed as requiring the Holder(s) to exercise their Purchase Warrants prior to or after the initial filing of any registration statement or the effectiveness thereof.

4.4 Documents Delivered to Holders. The Company shall deliver promptly to each Holder participating in the offering requesting the correspondence and memoranda described below, copies of all correspondence between the Commission and the Company, its counsel or auditors and all memoranda relating to discussions with the Commission or its staff with respect to the registration statement and permit each Holder and underwriter to do such investigation, upon reasonable advance notice, with respect to information contained in or omitted from the registration statement as it deems reasonably necessary to comply with applicable securities laws or rules of FINRA. Such investigation shall include access to books, records and properties and opportunities to discuss the business of the Company with its officers and independent auditors, all to such reasonable extent and at such reasonable times, during normal business hours, as any such Holder shall reasonably request.

4.5 Underwriting Agreement. The Holders shall be parties to any underwriting agreement relating to a Piggyback Registration. Such Holders shall not be required to make any representations or warranties to or agreements with the Company or the underwriters except as they may relate to such Holders, their Shares and the amount and nature of their ownership thereof and their intended methods of distribution.

4.6 Documents to be Delivered by Holder(s). Each of the Holder(s) participating in any of the foregoing offerings shall furnish to the Company a completed and executed questionnaire provided by the Company requesting information customarily sought of selling security holders.

4.7 Damages. Should the Company fail to comply with such provisions, the Holder(s) shall, in addition to any other legal or other relief available to the Holder(s), be entitled to obtain specific performance or other equitable (including injunctive) relief against the threatened breach of such provisions or the continuation of any such breach, without the necessity of proving actual damages and without the necessity of posting bond or other security.

5. New Purchase Warrants to be Issued.

5.1 Partial Exercise or Transfer. Subject to the restrictions in Section 3 hereof, this Purchase Warrant may be exercised or assigned in whole or in part. In the event of the exercise or assignment hereof in part only, upon surrender of this Purchase Warrant for cancellation, together with the duly executed exercise or assignment form and funds sufficient to pay any Exercise Price and/or transfer tax if exercised pursuant to Section 2.1 hereto, the Company shall cause to be delivered to the Holder without charge a new Purchase Warrant of like tenor to this Purchase Warrant in the name of the Holder evidencing the right of the Holder to purchase the number of Shares purchasable hereunder as to which this Purchase Warrant has not been exercised or assigned.

5.2 Lost Certificate. Upon receipt by the Company of evidence satisfactory to it of the loss, theft, destruction or mutilation of this Purchase Warrant and of reasonably satisfactory indemnification or the posting of a bond, determined in the sole discretion of the Company, the Company shall execute and deliver a new Purchase Warrant of like tenor and date. Any such new Purchase Warrant executed and delivered as a result of such loss, theft, mutilation or destruction shall constitute a substitute contractual obligation on the part of the Company.

6. Adjustments.

6.1 Adjustments to Exercise Price and Number of Securities. The Exercise Price and the number of Shares underlying the Purchase Warrant shall be subject to adjustment from time to time as hereinafter set forth:

6.1.1 Share Dividends; Split Ups. If, after the date hereof, and subject to the provisions of Section 6.3 below, the number of outstanding Shares is increased by a stock dividend payable in Shares or by a split up of Shares or other similar event, then, on the effective day thereof, the number of Shares purchasable hereunder shall be increased in proportion to such increase in outstanding Shares, and the Exercise Price shall be proportionately decreased.

6.1.2 Aggregation of Shares. If, after the date hereof, and subject to the provisions of Section 6.3 below, the number of outstanding Shares is decreased by a consolidation, combination or reclassification of Shares or other similar event, then, on the effective date thereof, the number of Shares purchasable hereunder shall be decreased in proportion to such decrease in outstanding Shares, and the Exercise Price shall be proportionately increased.

6.1.3 Replacement of Securities upon Reorganization, etc. In case of any reclassification or reorganization of the outstanding Shares other than a change covered by Section 6.1.1 or 6.1.2 hereof or that solely affects the par value of such Shares, or in the case of any share reconstruction or amalgamation or consolidation or merger of the Company with or into another corporation (other than a consolidation or share reconstruction or amalgamation or merger in which the Company is the continuing corporation and that does not result in any reclassification or reorganization of the outstanding Shares), or in the case of any sale or conveyance to another corporation or entity of the property of the Company as an entirety or substantially as an entirety in connection with which the Company is dissolved, the Holder of this Purchase Warrant shall have the right thereafter (until the expiration of the right of exercise of this Purchase Warrant) to receive upon the exercise hereof, for the same aggregate Exercise Price payable hereunder immediately prior to such event, the kind and amount of shares of stock or other securities or property (including cash) receivable upon such reclassification, reorganization, share reconstruction or amalgamation, or consolidation, or upon a dissolution following any such sale or transfer, by a Holder of the number of Shares of the Company obtainable upon exercise of this Purchase Warrant immediately prior to such event; and if any reclassification also results in a change in Shares covered by Section 6.1.1 or 6.1.2, then such adjustment shall be made pursuant to Sections 6.1.1, 6.1.2 and this Section 6.1.3. The provisions of this Section 6.1.3 shall similarly apply to successive reclassifications, reorganizations, share reconstructions or amalgamations, or consolidations, sales or other transfers.

6.1.4 Changes in Form of Purchase Warrant. This form of Purchase Warrant need not be changed because of any change pursuant to this Section 6.1, and Purchase Warrants issued after such change may state the same Exercise Price and the same number of Shares as are stated in the Purchase Warrants initially issued pursuant to this Agreement. The acceptance by any Holder of the issuance of new Purchase Warrants reflecting a required or permissive change shall not be deemed to waive any rights to an adjustment occurring after the Exercisable Date or the computation thereof.

6.2 Substitute Purchase Warrant. In case of any consolidation of the Company with, or share reconstruction or amalgamation or merger of the Company with or into, another corporation (other than a consolidation or share reconstruction or amalgamation or merger which does not result in any reclassification or change of the outstanding Shares), the corporation formed by such consolidation or share reconstruction or amalgamation shall execute and deliver to the Holder a supplemental Purchase Warrant providing that the holder of each Purchase Warrant then outstanding or to be outstanding shall have the right thereafter (until the stated expiration of such Purchase Warrant) to receive, upon exercise of such Purchase Warrant, the kind and amount of shares of stock and other securities and property receivable upon such consolidation or share reconstruction or amalgamation, by a holder of the number of Shares of the Company for which such Purchase Warrant might have been exercised immediately prior to such consolidation, share reconstruction or amalgamation or merger, sale or transfer. Such supplemental Purchase Warrant shall provide for adjustments which shall be identical to the adjustments provided for in this Section 6. The above provision of this Section shall similarly apply to successive consolidations or share reconstructions or amalgamations or mergers.

6.3 Elimination of Fractional Interests. The Company shall not be required to issue certificates representing fractions of Shares upon the exercise of the Purchase Warrant, nor shall it be required to issue scrip or pay cash in lieu of any fractional interests, it being the intent of the parties that all fractional interests shall be eliminated by rounding any fraction up or down, as the case may be, to the nearest whole number of Shares or other securities, properties or rights.

7. Reservation. The Company shall at all times reserve and keep available out of its authorized Shares, solely for the purpose of issuance upon exercise of the Purchase Warrants, such number of Shares as shall be issuable upon the exercise thereof. The Company covenants and agrees that, upon exercise of the Purchase Warrants and payment of the Exercise Price therefor, in accordance with the terms hereby, all Shares issuable upon such exercise shall be duly and validly issued, fully paid and non-assessable and not subject to preemptive rights of any shareholder.

8. Certain Notice Requirements.

8.1 Holder's Right to Receive Notice. Nothing herein shall be construed as conferring upon the Holders the right to vote or consent or to receive notice as a shareholder for the election of directors or any other matter, or as having any rights whatsoever as a shareholder of the Company. If, however, at any time prior to the expiration of the Purchase Warrants and their exercise, any of the events described in Section 8.2 shall occur, then, in one or more of said events, the Company shall deliver to each Holder a copy of each notice relating to such events given to the other shareholders of the Company at the same time and in the same manner that such notice is given to the shareholders.

8.2 Events Requiring Notice. The Company shall be required to give the notice described in this Section 8 upon one or more of the following events: (i) if the Company shall take a record of the holders of its Shares for the purpose of entitling them to receive a dividend or distribution payable otherwise than in cash, or a cash dividend or distribution payable otherwise than out of retained earnings, as indicated by the accounting treatment of such dividend or distribution on the books of the Company, or (ii) the Company shall offer to all the holders of its Shares any additional shares of capital stock of the Company or securities convertible into or exchangeable for shares of capital stock of the Company, or any option, right or warrant to subscribe therefor.

8.3 Notice of Change in Exercise Price. The Company shall, promptly after an event requiring a change in the Exercise Price pursuant to Section 6 hereof, send notice to the Holders of such event and change (***"Price Notice"***). The Price Notice shall describe the event causing the change and the method of calculating same.

8.4 Transmittal of Notices. All notices, requests, consents and other communications under this Purchase Warrant shall be in writing and shall be deemed to have been duly made when hand delivered, or mailed by express mail or private courier service: (i) if to the registered Holder of the Purchase Warrant, to the address of such Holder as shown on the books of the Company, or (ii) if to the Company, to following address or to such other address as the Company may designate by notice to the Holders:

If to the Holder:

Aegis Capital Corp.,
810 Seventh Avenue, 18th Floor,
New York, NY 10019
Attention: Global Equity Markets

with a copy (which shall not constitute notice) to:

Sichenzia Ference Ross LLP
1185 Avenue of the Americas
31st Floor
New York, NY 10036
Attention: Gregory Sichenzia

If to the Company:

Cingulate Inc.
1901 W. 47th Place
Kansas City, KS 66205
Attention: Shane J. Schaffer

with a copy (which shall not constitute notice) to:

Lowenstein Sandler LLP
1251 Avenue of the Americas
New York, New York 10020
Attention: Steven M. Skolnick, Esq

9. Miscellaneous.

9.1 Amendments. The Company and Aegis may from time to time supplement or amend this Purchase Warrant without the approval of any of the Holders in order to cure any ambiguity, to correct or supplement any provision contained herein that may be defective or inconsistent with any other provisions herein, or to make any other provisions in regard to matters or questions arising hereunder that the Company and Aegis may deem necessary or desirable and that the Company and Aegis deem shall not adversely affect the interest of the Holders. All other modifications or amendments shall require the written consent of and be signed by (i) the Company and (ii) the Holder(s) of Purchase Warrants then-exercisable for at least a majority of the Shares then-exercisable pursuant to all then-outstanding Purchase Warrants.

9.2 Headings. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Purchase Warrant.

9.3. Entire Agreement. This Purchase Warrant (together with the other agreements and documents being delivered pursuant to or in connection with this Purchase Warrant) constitutes the entire agreement of the parties hereto with respect to the subject matter hereof, and supersedes all prior agreements and understandings of the parties, oral and written, with respect to the subject matter hereof.

9.4 Binding Effect. This Purchase Warrant shall inure solely to the benefit of and shall be binding upon, the Holder and the Company and their permitted assignees, respective successors, legal representative and assigns, and no other person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Purchase Warrant or any provisions herein contained.

9.5 Governing Law; Submission to Jurisdiction; Trial by Jury. This Purchase Warrant shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflict of laws principles thereof. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Purchase Warrant shall be brought and enforced in the courts located in the City of New York, County of New York, and State of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. Any process or summons to be served upon the Company may be served by transmitting a copy thereof by registered or certified mail, return receipt requested, postage prepaid, addressed to it at the address set forth in Section 8 hereof. Such mailing shall be deemed personal service and shall be legal and binding upon the Company in any action, proceeding or claim. The Company and the Holder agree that the prevailing party(ies) in any such action shall be entitled to recover from the other party(ies) all of its reasonable attorneys' fees and expenses relating to such action or proceeding and/or incurred in connection with the preparation therefor. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and the Holder hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

9.6 Waiver, etc. The failure of the Company or the Holder to at any time enforce any of the provisions of this Purchase Warrant shall not be deemed or construed to be a waiver of any such provision, nor to in any way affect the validity of this Purchase Warrant or any provision hereof or the right of the Company or any Holder to thereafter enforce each and every provision of this Purchase Warrant. No waiver of any breach, non-compliance or non-fulfillment of any of the provisions of this Purchase Warrant shall be effective unless set forth in a written instrument executed by the party or parties against whom or which enforcement of such waiver is sought; and no waiver of any such breach, non-compliance or non-fulfillment shall be construed or deemed to be a waiver of any other or subsequent breach, non-compliance or non-fulfillment.

9.7 Exchange Agreement. As a condition of the Holder's receipt and acceptance of this Purchase Warrant, Holder agrees that, at any time prior to the complete exercise of this Purchase Warrant by Holder, if the Company and Aegis enter into an agreement (***"Exchange Agreement"***) pursuant to which they agree that all outstanding Purchase Warrants will be exchanged for securities or cash or a combination of both, then Holder shall agree to such exchange and become a party to the Exchange Agreement.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Company has caused this Purchase Warrant to be signed by its duly authorized officer as of the date first written above.

CINGULATE INC.

By: ________________________
Name: Shane J. Schaffer
Title: Chief Executive Officer

[*Form to be used to exercise Purchase Warrant*]

Date: __________, 20___

The undersigned hereby elects irrevocably to exercise the Purchase Warrant for ______ shares of common stock, par value $0.0001 per share (the ***"Shares"***), of Cingulate Inc., a Delaware corporation (the ***"Company"***), and hereby makes payment of $____ (at the rate of $____ per Share) in payment of the Exercise Price pursuant thereto. Please issue the Shares as to which this Purchase Warrant is exercised in accordance with the instructions given below and, if applicable, a new Purchase Warrant representing the number of Shares for which this Purchase Warrant has not been exercised.

or

The undersigned hereby elects irrevocably to convert its right to purchase ___ Shares of the Company under the Purchase Warrant for ______ Shares, as determined in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where,

X = The number of Shares to be issued to Holder;
Y = The number of Shares for which the Purchase Warrant is being exercised;
A = The fair market value of one Share which is equal to $_____; and
B = The Exercise Price which is equal to $______ per share

The undersigned agrees and acknowledges that the calculation set forth above is subject to confirmation by the Company and any disagreement with respect to the calculation shall be resolved by the Company in its sole discretion.

Please issue the Shares as to which this Purchase Warrant is exercised in accordance with the instructions given below and, if applicable, a new Purchase Warrant representing the number of Shares for which this Purchase Warrant has not been converted.

Signature ___________________________________

Signature Guaranteed _________________________

INSTRUCTIONS FOR REGISTRATION OF SECURITIES

Name: ____
(Print in Block Letters)

Address: ____
____

NOTICE: The signature to this form must correspond with the name as written upon the face of the Purchase Warrant without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank, other than a savings bank, or by a trust company or by a firm having membership on a registered national securities exchange.

[*Form to be used to assign Purchase Warrant*]

ASSIGNMENT

(To be executed by the registered Holder to effect a transfer of the within Purchase Warrant):

FOR VALUE RECEIVED, ___________________ does hereby sell, assign and transfer unto the right to purchase shares of Common Stock, par value $0.0001 per share, of Cingulate Inc., a Delaware corporation (the ***"Company"***), evidenced by the Purchase Warrant and does hereby authorize the Company to transfer such right on the books of the Company.

Dated: __________, 20__

Signature ____________________________________

Signature Guaranteed __________________________

NOTICE: The signature to this form must correspond with the name as written upon the face of the within Purchase Warrant without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank, other than a savings bank, or by a trust company or by a firm having membership on a registered national securities exchange.

Exhibit 5.1

Lowenstein Sandler

November 10, 2021

Cingulate Inc.
1901 W. 47th Place
Kansas City, KS 66205

Ladies and Gentlemen:

We have acted as counsel for Cingulate Inc., a Delaware corporation (the "Company"), in connection with the preparation and filing of a Registration Statement on Form S-1 (File No. 333-259408) (the "Registration Statement"), including a related prospectus filed with the Registration Statement (the "Prospectus"), with the Securities and Exchange Commission (the "Commission") pursuant to the Securities Act of 1933, as amended (the "Securities Act") covering an underwritten public offering of (i) 4,107,142 shares (the "Shares") of common stock par value $0.0001 per share (the "Common Stock"), including 535,714 Shares that may be sold by the Company pursuant to the exercise of an over-allotment option granted to the underwriters and (ii) warrants (the "Underwriter Warrants") to purchase up to 178,571 shares of Common Stock as contemplated pursuant to the Registration Statement (the "Underwriter Warrant Shares"). The Shares and the Underwriter Warrants are to be sold by the Company pursuant to an underwriting agreement (the "Underwriting Agreement") to be entered into between the Company and the underwriter(s) named therein. This opinion is being rendered in connection with the filing of the Registration Statement with the Commission.

In connection with this opinion, we have examined originals or copies (certified or otherwise identified to our satisfaction) of (i) the Company's Certificate of Incorporation and Bylaws, as currently in effect, (ii) the form of the Amended and Restated Certificate of Incorporation, filed as Exhibit 3.1 to the Registration Statement and the form of Amended and Restated Bylaws, filed as Exhibit 3.2 to the Registration Statement, each of which will be in effect upon closing of the offering contemplated by the Registration Statement, (iii) the Registration Statement and related Prospectus, (iv) the form of Underwriting Agreement, (v) the form of Underwriter Warrant and (vi) such corporate records, agreements, documents and other instruments, and such certificates or comparable documents of public officials or of officers and representatives of the Company, as we have deemed relevant and necessary as a basis for the opinion hereinafter set forth.

In such examination, we have assumed the genuineness of all signatures, the legal capacity of all natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as certified, conformed or photostatic copies, and the authenticity of the originals of such latter documents. As to certain questions of fact material to this opinion, we have relied upon certificates or comparable documents of officers and representatives of the Company and have not sought to independently verify such facts.

Based on the foregoing, and subject to the assumptions, limitations and qualifications stated herein, we are of the opinion that (i) the Shares, when issued and sold as contemplated in the Registration Statement and the related Prospectus, and upon payment and delivery in accordance with the Underwriting Agreement, will be validly issued, fully paid and non-assessable, (ii) the Underwriter Warrants have been duly and validly authorized and when issued and sold in accordance with the terms and conditions of the Underwriting Agreement, will be valid and binding obligations of the Company and (iii) the Underwriter Warrant Shares, when issued, sold and paid for in accordance with the terms of the Underwriter Warrants, will be validly issued, fully paid and non-assessable.

The opinion expressed herein is limited to the General Corporation Law of the State of Delaware (including reported judicial decisions interpreting the General Corporation Law of the State of Delaware) and, with respect to the enforceability of Underwriter Warrants, the laws of the State of New York, and we express no opinion as to the effect on the matters covered by this letter of the laws of any other jurisdiction.

We hereby consent to the filing of this letter as an exhibit to the Registration Statement and to the reference to our firm under the caption "Legal Matters" in the Prospectus which is a part of the Registration Statement. In giving such consents, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the Rules and Regulations of the Commission promulgated thereunder.

Very truly yours,

/s/ Lowenstein Sandler LLP

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Cingulate Inc.

We consent to the use of our report dated May 21, 2021, with respect to the consolidated financial statements of Cingulate Therapeutics LLC and subsidiaries, included herein and to the reference to our firm under the heading “Experts” in the prospectus.

/s/ KPMG LLP

Kansas City, Missouri
November 10, 2021