

PROSPECTUS

1,720,000 Shares of Common Stock
6,925,208 Series A Warrants to Purchase up to 6,925,208 Shares of Common Stock
3,462,604 Series B Warrants to Purchase up to 3,462,604 Shares of Common Stock
5,205,208 Pre-Funded Warrants to Purchase up to 5,205,208 Shares of Common Stock
15,593,020 Shares of Common Stock Underlying the Series A Warrants, Series B Warrants and Pre-Funded Warrants
346,260 Placement Agent Warrants to Purchase up to 346,260 Shares of Common Stock
346,260 Shares of Common Stock Underlying the Placement Agent Warrants



Cingulate Inc.

We are offering 1,720,000 shares of common stock, par value \$0.0001 per share, together with Series A warrants to purchase up to 6,925,208 shares of common stock, which we refer to as the “Series A warrants,” and Series B warrants to purchase up to 3,462,604 shares of common stock, which we refer to as the “Series B warrants,” at a combined public offering price of \$0.5776 per share and accompanying warrants. The Series A warrants and the Series B warrants are hereinafter referred to as the “warrants.” Each share of our common stock is being sold together with one Series A warrant to purchase one share of common stock and one Series B warrant to purchase one-half of a share of common stock. The Series A warrants will have an exercise price of \$0.5776 per share and will be exercisable beginning on the effective date (the “Initial Exercise Date”) of stockholder approval of the issuance of the shares upon exercise of the warrants (“Warrant Stockholder Approval”). The Series A warrants will expire on the five year anniversary of the Initial Exercise Date. The Series B warrants will have an exercise price of \$0.5776 per share and will be exercisable beginning on the Initial Exercise Date. The Series B warrants will expire on the two year anniversary of the Initial Exercise Date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the Series A warrants and Series B warrants.

We are also offering pre-funded warrants to purchase up to 5,205,208 shares of common stock to those investors whose purchase of shares of our common stock in this offering would result in such investor, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the investor, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of the common stock that would otherwise result in the investor’s beneficial ownership exceeding 4.99% (or, at the election of the investor, 9.99%), pre-funded warrants each to purchase one share of our common stock at an exercise price of \$0.0001, which we refer to as the “pre-funded warrants.” Each pre-funded warrant will be exercisable upon issuance and will expire when exercised in full. Each pre-funded warrant is being sold together with one Series A warrant to purchase one share of common stock and one Series B warrant to purchase one-half of a share of common stock. The public offering price for each pre-funded warrant and the accompanying warrants is equal to the price per share of common stock and the accompanying warrants being sold to the public in this offering, minus \$0.0001. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the pre-funded warrants.

The shares of common stock and/or pre-funded warrants and the accompanying warrants can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance.

We have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent in connection with this offering. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agent is not purchasing or selling any of the securities we are offering and the placement agent is not required to arrange the purchase or sale of any specific number or dollar amount of securities. We have agreed to pay to the placement agent the placement agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. Since we will deliver the securities to be issued in this offering upon our receipt of investor funds, there is no arrangement for funds to be received in escrow, trust or similar arrangement. There is no minimum offering requirement as a condition of closing of this offering. Because there is no minimum offering amount required as a condition to closing this offering, we may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue our business goals described in this prospectus. In addition, because there is no escrow account and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill all of our contemplated objectives due to a lack of interest in this offering. Further, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. See the section entitled “Risk Factors” for more information. We will bear all costs associated with the offering. See “Plan of Distribution” on page 17 of this prospectus for more information regarding these arrangements.

Our common stock is listed on the Nasdaq Capital Market under the symbol “CING.” The closing price of our common stock on Nasdaq on September 8, 2023 was \$0.5776 per share. There is no established public trading market for the pre-funded warrants, Series A warrants or Series B warrants, and we do not expect such a market to develop. We do not intend to apply to list the pre-funded warrants, Series A warrants or Series B warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants, Series A warrants and Series B Warrants will be limited.

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 securities is highly speculative and involves a high degree of risk. See “Risk Factors” beginning on page 5 of this prospectus and in the documents incorporated by reference into this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

Per Share and	Per Pre-Funded	Total
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	Accompanying Warrants	Warrant and Accompanying Warrants	
Public offering price	\$ 0.5776	0.5775	\$ 3,999,479.62
Placement agent fees ⁽¹⁾	\$ 0.0404	0.0404	\$ 280,000.01
Proceeds to us, before expenses ⁽²⁾	\$ 0.5372	0.5371	\$ 3,719,479.61

- (1) We have agreed to pay the placement agent a cash fee equal to 7.0% of the gross proceeds raised in this offering. We have also agreed to reimburse the placement agent for certain of its offering related expenses, including reimbursement for non-accountable expenses in an amount up to \$50,000, legal fees and expenses in the amount of up to \$100,000, and for its clearing expenses in the amount of \$15,950. In addition, we have agreed to issue the placement agent or its designees warrants to purchase a number of shares of common stock equal to 5.0% of the shares of common stock sold in this offering (including the shares of common stock issuable upon the exercise of the pre-funded warrants), at an exercise price of \$0.722 per share, which represents 125% of the public offering price per share and accompanying warrant. For a description of compensation to be received by the placement agent, see “Plan of Distribution” for more information.
- (2) Because there is no minimum number of securities or amount of proceeds required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. For more information, see “Plan of Distribution.”

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.

Delivery of the securities offered hereby is expected to be made on or about September 13, 2023, subject to satisfaction of customary closing conditions.

H.C. Wainwright & Co.

The date of this prospectus is September 11, 2023.

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ABOUT THIS PROSPECTUS

We incorporate by reference important information into this prospectus. You may obtain the information incorporated by reference without charge by following the instructions under “Where You Can Find More Information.” You should carefully read this prospectus as well as additional information described under “Incorporation of Certain Information By Reference,” before deciding to invest in our securities.

We have not, and the placement agent and its affiliates have not, authorized anyone to provide you with any information or to make any representation not contained or incorporated by reference in this prospectus or any related free writing prospectus. We do not, and the placement agent and its affiliates do not, take any responsibility for, and can provide no assurance as to the reliability of, any information that others may provide to you. This prospectus is not an offer to sell or an offer to buy securities in any jurisdiction where offers and sales are not permitted. The information in this prospectus is accurate only as of its date, regardless of the time of delivery of this prospectus or any sale of securities. You should also read and consider the information in the documents to which we have referred you under the caption “Where You Can Find More Information” in the prospectus.

Neither we nor the placement agent have done anything that would permit a public offering of the securities 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 the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside of the United States.

The information incorporated by reference or provided in this prospectus contains statistical data and estimates, including those relating to market size and competitive position of the markets in which we participate, that we obtained from our own internal estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable. While we believe our internal company research is reliable and the definitions of our market and industry are appropriate, neither this research nor these definitions have been verified by any independent source.

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 securities, you should carefully read this entire prospectus and the documents incorporated by reference herein, including the “Risk Factors” section in this prospectus and under similar captions in the documents incorporated by reference into this prospectus. 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 securities could decline, and you could lose part or all of your investment. Unless we state otherwise or the context otherwise requires, the terms “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 (as defined below), including our initial public 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 our initial public offering, to CTx and its consolidated subsidiaries.

Overview

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

We are targeting the ADHD stimulant-based treatment market, with an estimated US market size of \$18 billion as of September 2022. 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 80 million stimulant prescriptions were written during the 12-months ended September 2022. By contrast, non-stimulant medications are typically employed only in the second-line or adjunctive therapy setting and account for 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 59% of ADHD stimulant prescriptions by volume and nearly 83% 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 is a significant, unmet need within the current treatment paradigm for true once-daily ADHD stimulant medications with lasting duration and superior side effect profiles to better serve the needs of patients throughout their entire active-day.

Our two proprietary, first-line stimulant medications: CTx-1301 (dexamethylphenidate) 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 (ages 18+). Both CTx-1301 and CTx-1302 are designed to address the key shortcomings of currently approved stimulant therapies by: providing an immediate onset of action (within 30 minutes); offering ‘entire active-day’ duration; eliminating the need for a ‘booster/recovery’ dose of short-acting stimulant medications; minimizing or eliminating the rebound/crash symptoms associated with early medication ‘wear-off;’ and providing favorable tolerability with a controlled descent of drug blood levels. Furthermore, by eliminating the ‘booster’ dose 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.

Recent Developments

Phase 3 CTx-1301-022 study

Our Phase 3 CTx-1301-022 study ([NCT05631626](#)), which assessed efficacy and safety along with onset and duration of CTx-1301 in 21 adults (age range: 18-55 years) with ADHD in an adult laboratory classroom setting did not achieve statistical significance on the primary efficacy endpoint but demonstrated a trend towards significance despite its modest sample size in improving ADHD symptoms with a rapid onset of action and entire active-day duration. After a 5-week dose optimization period, subjects were either randomized to their optimized dose of CTx-1301 or placebo.

The overall Permanent Product Measure of Performance (PERMP) data showed a trend toward significance with a p-value of 0.089 despite the modest sample size. A meta-analysis conducted by Faraone and Glatt (*Clinical Psychiatry* 71:6 June 2010) using 11 published studies with long-acting stimulants in adults demonstrated the average effect size to be 0.73 (approximate range 0.5 to 0.9). In this trial subjects randomized to CTx-1301 demonstrated an effect size of 1.41 at 30 minutes and an effect size of 0.98 at 16 hours with an average effect size of 1.79 (range 0.88 to 2.60). Effect size represents the magnitude of a change in an outcome or the strength of a relationship, the practical significance. Effect size measures the magnitude of differences in outcomes between two groups in a study.

In addition, the secondary outcome using the Clinical Global Impression (CGI) Scale for severity of illness was associated with a decrease in the severity of illness in subjects randomized to CTx-1301 compared to placebo. This is noteworthy as the purpose of this study was to obtain estimates of effect size and it was not anticipated that significant treatment differences would be observed. CTx-1301 was well tolerated; 9% (n=1) of the subjects that were randomized to CTx-1301 experienced treatment emergent adverse events (TEAEs), while 30% (n=3) of subjects that were randomized to placebo experienced TEAEs. Patient reported outcomes on the overall satisfaction with CTx-1301 compared to subject's prior ADHD medication was favorable.

ATM and Equity Line Sales

During the period beginning July 1, 2023 and ending on the date of this prospectus, we sold 1,538,855 shares of common stock pursuant to an At The Market Offering Agreement with H.C. Wainwright & Co., LLC (the "ATM Agreement"), for net proceeds of \$1,595,429.

During the period beginning July 1, 2023 and ending on the date of this prospectus, we sold 240,000 shares of common stock pursuant to a purchase agreement with Lincoln Park Capital Fund, LLC (the "LP Purchase Agreement"), for net proceeds of \$196,167.

Private Placement with WFIA

On August 11, 2023, we entered into a Securities Purchase Agreement with Werth Family Investment Associates LLC ("WFIA") and issued, in a private placement priced at the market under Nasdaq rules, 1,823,155 shares of common stock at a purchase price per share of \$0.5485 (the "Private Placement"). Peter J. Werth, a member of our Board of Directors is the manager of WFIA.

Our Organizational Structure

Cingulate Inc. is a Delaware corporation that was formed to serve as a holding company. In connection with our initial public offering, we effected certain organizational transactions. On September 29, 2021, 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.

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 securities.

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.

Implications of Being an Emerging Growth Company

As a company with less than \$1.235 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 \$1.235 billion in annual gross revenue, (2) December 31, 2026, (3) the date we are deemed to be a “large accelerated filer” as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, and (4) the date on which we have during the previous three-year period issued 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

The following summary contains basic information about this offering. The summary is not intended to be complete. You should read the full text and more specific details contained elsewhere in this prospectus and in the documents incorporated by reference.

Common Stock Offered	1,720,000 shares.
Pre-Funded Warrants Offered	We are also offering pre-funded warrants to purchase up to 5,205,208 shares of common stock to those investors whose purchase of shares of our common stock in this offering would result in such investor, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the investor, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of the common stock that would otherwise result in the investor's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%), pre-funded warrants each to purchase one share of our common stock at an exercise price of \$0.0001, which we refer to as pre-funded warrants. Each pre-funded warrant is being sold together with one Series A warrant to purchase one share of common stock and one Series B warrant to purchase one-half of a share of common stock. The combined public offering price for each pre-funded warrant and accompanying warrants is equal to the combined public offering price per share of common stock and accompanying warrants being sold in this offering, minus \$0.0001. For each pre-funded warrant we sell, the number of shares of common stock we sell will be decreased on a one-for-one basis. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the pre-funded warrants. See "Description of Securities We Are Offering" for additional information.
Warrants Offered	Each share of common stock or pre-funded warrant is being offered together with one Series A warrant to purchase one share of common stock and one Series B warrant to purchase one-half of a share of common stock. The Series A warrants will have an exercise price of \$0.5776 per share and will be exercisable beginning on the effective date of the Warrant Stockholder Approval. The Series A warrants will expire on the five year anniversary of the Initial Exercise Date. The Series B warrants will have an exercise price of \$0.5776 per share and will be exercisable beginning on the Initial Exercise Date. The Series B warrants will expire on the two year anniversary of the Initial Exercise Date. See "Description of Securities We Are Offering" for additional information.
Common Stock Outstanding prior to this Offering (1)	15,658,798 shares.
Common Stock Outstanding after this Offering (1)	22,584,006 shares, assuming all of the pre-funded warrants offered hereby are exercised and no exercise of the warrants offered hereby.
Use of Proceeds	We estimate that the net proceeds of this offering assuming no exercise of the warrants, after deducting placement agent fees and estimated offering expenses, will be approximately \$3.3 million, assuming no exercise of the warrants. We intend to use all of the net proceeds we receive from this offering for continued research and development and commercialization activities of CTx-1301, and for working capital, capital expenditures and general corporate purposes, including investing further in research and development efforts. See "Use of Proceeds."
Nasdaq Capital Markets Symbol	Our common stock is listed on the Nasdaq Capital Market under the symbol "CING." We do not intend to apply to list the pre-funded warrants, Series A warrants or Series B warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants, Series A warrants and Series B warrants will be limited.
Lock-up	All of our directors and executive officers have agreed subject to certain exceptions, not to sell, transfer or dispose of, directly or indirectly, any of our common stock or securities convertible into or exercisable or exchangeable for our common stock for a period of 90 days after the closing of this offering. See "Plan of Distribution" for more information.
Placement Agent Warrants	We have agreed to issue to the placement agent or its designees, warrants, or the placement agent warrants, to purchase up to 5.0% of the aggregate number of shares of common stock sold in this offering (including the shares of common stock issuable upon the exercise of the pre-funded Warrants) at an exercise price equal to 125% of the public offering price per share and accompanying warrants to be sold in this offering. The placement agent warrants will be exercisable upon issuance and will expire five years from the commencement of sales under this offering. See "Plan of Distribution" for additional information.
Risk Factors	Investment in our securities involves a high degree of risk and could result in a loss of your entire investment. See "Risk Factors" beginning on page 5, and the other information included and incorporated by reference in this prospectus for a discussion of the factors you should consider carefully before deciding to invest in our securities.

(1) The number of shares of our common stock to be outstanding immediately after this offering is based on 15,658,798 shares of our common stock outstanding as of September 11, 2023 and excludes, as of such date, the following:

- 1,424,995 shares of our common stock issuable upon exercise of outstanding stock options issued under our 2021 Equity Incentive Plan (the

“2021 Plan”), with a weighted average exercise price of \$3.03 per share;

- 1,361,315 shares of our common stock that are available for future issuance under the 2021 Plan;
- 4,999,998 shares of common stock issuable upon the exercise of warrants with a weighted average exercise price of \$6.06 per share; and
- 6,838,235 shares of common stock issuable upon the exercise of pre-funded warrants with a weighted average exercise price of \$0.0001 per share.

Unless expressly indicated or the context requires otherwise, all information in this prospectus assumes (i) we issue no pre-funded warrants and (ii) no exercise of the warrants offered hereby.

RISK FACTORS

An investment in our securities involves a high degree of risk. Before deciding whether to purchase our securities, including the shares of common stock offered by this prospectus, you should carefully consider the risks and uncertainties described under “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, any subsequent Quarterly Report on Form 10-Q and our other filings with the SEC, all of which are incorporated by reference herein. If any of these risks actually occur, our business, financial condition and results of operations could be materially and adversely affected and we may not be able to achieve our goals, the value of our securities could decline and you could lose some or all of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. If any of these risks occur, our business, results of operations or financial condition and prospects could be harmed. In that event, the market price of our common stock and the value of the warrants could decline, and you could lose all or part of your investment.

Risks Related to Our Financial Position and Need for Capital

Following this offering, we will need to raise additional capital to complete the development and commercialization efforts for CTx-1301, CTx-1302 and/or 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.

Following this offering, we will need to raise additional capital 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 holder of our \$8.0 million amended and restated promissory note not demanding payment prior to maturity;
- 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 may enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions.

If we are unable to raise additional capital when required or on acceptable terms, 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 securityholders losing some or all of their investment in us. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

In addition, if we are unable to secure sufficient capital to fund our operations, we may have to enter into strategic collaborations that could require us to share commercial rights to 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 securityholders.

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. Our financial situation creates doubt whether we will continue as a going concern.

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, CTx-1302 and/or CTx-2103, development expenses will continue to increase for any future assets. As CTx-1301 advances to Phase 3 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 \$80.0 million as of June 30, 2023. 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.

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 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.

This offering is being made on a best efforts basis and we may sell fewer than all of the securities offered hereby and may receive significantly less in net proceeds from this offering. We believe that the net proceeds from this offering, together with our cash on hand, will satisfy our capital needs until early November under our current business plan. Following this offering, we will need to raise additional capital to fund our operations and continue to support our planned development and commercialization activities.

Risks Related to This Offering and Ownership of 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 commercialization activities for CTx-1301, 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 securities, 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 securities to decline.

If you purchase securities in this offering, you will suffer immediate dilution of your investment.

You will incur immediate and substantial dilution as a result of this offering. The public offering price per share of common stock and accompanying warrants and the public offering price per pre-funded warrant and accompanying warrants will be substantially higher than the as adjusted net tangible book value per share of our common stock after giving effect to this offering. Therefore, if you purchase securities in this offering, you will pay a price per share of common stock you acquire that substantially exceeds our pro forma net tangible book value per share after this offering. Based on the offering price of \$0.5776 per share of common stock and accompanying warrants and our pro forma net tangible book deficit as of June 30, 2023, you will experience immediate dilution of \$0.58 per share, representing the difference between our as adjusted net tangible book value per share after giving effect to this offering and the public offering price.

There is no public market for the pre-funded warrants or warrants offered by us.

There is no established public trading market for the pre-funded warrants or warrants, and we do not expect such a market to develop. In addition, we do not intend to apply to list the pre-funded warrants or warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants and warrants will be limited.

Holders of pre-funded warrants and warrants purchased in this offering will have no rights as common stockholders until such holders exercise their pre-funded warrants or warrants and acquire our common stock.

Until holders of the pre-funded warrants and warrants acquire shares of our common stock upon exercise thereof, such holders will have no rights with respect to the shares of our common stock underlying the pre-funded warrants and warrants. Upon exercise of the pre-funded warrants and warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The warrants are speculative in nature.

The warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Moreover, following this offering, the market value of the warrants, if any, will be uncertain and there can be no assurance that the market value of the warrants will equal or exceed their imputed offering price. The warrants will not be listed or quoted for trading on any market or exchange. There can be no assurance that the market price of our common stock will ever equal or exceed the exercise price of the warrants, and consequently, the warrants may expire valueless.

The warrants are not exercisable until stockholder approval.

The Series A warrants will have an exercise price of \$0.5776 per share and will be exercisable beginning on the effective date of the Warrant Stockholder Approval. The Series A warrants will expire on the five year anniversary of the Initial Exercise Date. The Series B warrants will have an exercise price of \$0.5776 per share and will be exercisable beginning on the Initial Exercise Date. The Series B warrants will expire on the two year anniversary of the Initial Exercise Date. While we intend to promptly seek Warrant Stockholder Approval, there is no guarantee that the Warrant Stockholder Approval will ever be obtained. If we are unable to obtain the Warrant Stockholder Approval, the warrants may have no value.

Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including: (i) timely delivery of shares; (ii) agreement to not enter into variable rate financings for one year from closing, subject to certain exceptions; (iii) agreement to not enter into any financings for 60 days from closing; and (iv) indemnification for breach of contract.

This is a best efforts offering, with no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans, including our near-term business plans.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to support our continued operations, including our near-term continued operations. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds, which may not be available or available on terms acceptable to us.

Because there is no minimum required for the offering to close, investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus.

We have not specified a minimum offering amount nor have or will we establish an escrow account in connection with this offering. Because there is no escrow account and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Further, because there is no escrow account in operation and no minimum investment amount, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. Investor funds will not be returned under any circumstances whether during or after the offering.

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

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

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

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

In addition, in the future, we may issue additional shares of common stock, warrants or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. We may also issue additional shares of common stock to satisfy our outstanding promissory note in favor of Werth Family Investment Associates LLC, an entity controlled by Peter Werth, a member of our Board of Directors. Any such issuances could result in substantial dilution to our existing stockholders and could cause the price of our common stock or warrants to decline.

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

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

If we fail to regain compliance with the continued listing requirements of Nasdaq, our common stock and/or warrants may be delisted and the price of our common stock and/or warrants and our ability to access the capital markets could be negatively impacted.

Our common stock and warrants are currently listed for trading on Nasdaq. On May 16, 2023, we received a notice from Nasdaq stating that we no longer comply with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5550(b)(1) for continued listing. We submitted a plan of compliance to Nasdaq on June 30, 2023. On July 28, 2023, Nasdaq notified us that that it granted an extension until November 13, 2023 to regain compliance with the minimum stockholders' equity requirement, conditioned upon achievement of certain milestones included in the plan of compliance previously submitted to Nasdaq, including a plan to raise additional capital. If we fail to evidence compliance upon filing our periodic report for the quarter ending September 30, 2023 by November 13, 2023, we may be subject to delisting. If Nasdaq determines to delist our securities, we will have the right to appeal to a Nasdaq hearings panel. There can be no assurance that we will be able to regain compliance with the applicable Nasdaq listing requirements.

In addition, on July 28, 2023, we received notice from Nasdaq indicating that we are not in compliance with the requirement to maintain a minimum bid price of \$1.00 per share for continued listing on Nasdaq. We were provided a compliance period of 180 calendar days from the date of the notice, or until January 24, 2024, to regain compliance with the minimum closing bid requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). We may be eligible for an additional 180 calendar day compliance period. There can be no assurance that we will regain compliance with the minimum closing bid requirement during the 180-day compliance period, secure a second period of 180 days to regain compliance or maintain compliance with the other Nasdaq listing requirements.

We will continue to monitor the closing bid price of our common stock and may, if appropriate, consider available options, including implementation of a reverse stock split of our common stock, to regain compliance with the minimum closing bid requirement. If we seek to implement a reverse stock split in order to remain listed on Nasdaq, the announcement or implementation of such a reverse stock split could negatively affect the price of our common stock and/or warrants.

We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum stockholders' equity of \$2.5 million and a minimum closing bid price of \$1.00 per share or risk delisting, which could have a material adverse effect on our business. If our common stock and warrants are delisted from Nasdaq, it could materially reduce the liquidity of our common stock and warrants and result in a corresponding material reduction in the price of our common stock and warrants as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. If our common stock and warrants are delisted, it could be more difficult to buy or sell our common stock and warrants or to obtain accurate quotations, and the price of our common stock and warrants could suffer a material decline. Delisting could also impair our ability to raise capital on acceptable terms, if at all.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This prospectus and any documents we incorporate by reference contain 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 ability to maintain compliance with the continued listing requirements of the Nasdaq Capital Market;
- our lack of operating history and need for additional capital;
- our plans to develop and commercialize our product candidates;
- the timing of our planned clinical trials for CTx-1301, CTx-1302, and CTx-2103;
- the timing of our New Drug Application (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 cash;
- our competitive position and projections relating to our competitors or our industry;
- our ability to identify, recruit, and retain key personnel;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”);
- our plans to identify additional product candidates with significant commercial potential that are consistent with our commercial objectives; and
- our estimates regarding future revenue and expenses.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. You should refer to the “Risk Factors” section of this prospectus and the documents we incorporate by reference 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 and the documents we incorporate by reference 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 incorporate by 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.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$3.3 million after deducting placement agent fees and estimated offering expenses payable by us and assuming no sale of any pre-funded warrants and no exercise of the warrants. However, because this is a best efforts offering with no minimum number of securities or amount of proceeds as a condition to closing, the actual offering amount, the placement agent's fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus, and we may not sell all or any of the securities we are offering. As a result, we may receive significantly less in net proceeds.

We intend to use all of the net proceeds we receive from this offering for continued research and development and commercialization activities of CTx-1301, and for working capital, capital expenditures and general corporate purposes, including investing further in research and development efforts.

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 and the documents incorporated by reference herein. 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.

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.

DILUTION

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

As of June 30, 2023, we had a net tangible book deficit of approximately \$(6.1 million), or approximately \$(0.51) per share of common stock. Our net tangible book deficit per share represents our total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding as of June 30, 2023.

After giving effect to the sale of shares pursuant to the ATM Agreement, the LP Purchase Agreement and the Private Placement, our pro forma tangible net book deficit as of June 30, 2023 would have been approximately \$(3.3 million), or approximately \$(0.21) per share of common stock, an increase of approximately \$0.30 per share of common stock.

After giving effect to the sale of 1,720,000 shares of common stock and accompanying warrants at an offering price of \$0.5776 per share and accompanying warrants and pre-funded warrants to purchase up to 5,205,208 shares of common stock and accompanying warrants an offering price of \$0.5775 per pre-funded warrant and accompanying warrants in this offering, and after deducting placement agent fees and estimated offering expenses payable by us, and assuming all of the pre-funded warrants offered in this offering are exercised, no exercise of the warrants being offered in this offering, that no value is attributed to such warrants and that such warrants are classified as and accounted for as equity, our pro forma as adjusted net tangible book value as of June 30, 2023 would have been approximately \$35,000, or approximately \$0.00 per share of common stock. This amount represents an immediate increase in pro forma as adjusted net tangible book value of \$0.21 per share to our existing stockholders and an immediate dilution of \$0.58 per share to investors participating in this offering. We determine dilution per share to investors participating in this offering by subtracting the pro forma as adjusted net tangible book value per share after giving effect to this offering from the public offering price per share and accompanying warrants paid by investors participating in this offering. The following table illustrates this dilution:

Public offering price per share and accompanying warrants	\$	0.5776
Historical net tangible book deficit per share of common stock as of June 30, 2023	\$	(0.51)
Increase in net tangible book deficit attributable to the sale of shares pursuant to the ATM Agreement, the LP Purchase Agreement and the Private Placement	\$	<u>0.30</u>
Pro forma net tangible book deficit after giving effect to the sale of shares pursuant to the ATM Agreement, the LP Purchase Agreement and the Private Placement	\$	(0.21)
Increase in pro forma net tangible book deficit per share attributable to this offering	\$	<u>0.21</u>
Pro forma adjusted net tangible book value per share after this offering	\$	<u>0.00</u>
Dilution per share to new investors purchasing shares in this offering	\$	<u><u>0.58</u></u>

The table and discussion above are based on 12,056,788 shares of our common stock outstanding as June 30, 2023 (15,658,798 shares of common stock on a pro forma basis after giving effect to the sale of shares pursuant to the ATM Agreement, the LP Purchase Agreement and the Private Placement), and excludes, as of such date, the following:

- 1,349,679 shares of our common stock issuable upon exercise of outstanding stock options issued under the 2021 Plan with a weighted average exercise price of \$3.16 per share;
- 1,436,631 shares of our common stock that are available for future issuance under the 2021 Plan; and
- 4,999,998 shares of common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of \$6.06 per share

The information discussed above is illustrative only and will adjust based on the actual public offering price and other terms of this offering determined at pricing.

DESCRIPTION OF CAPITAL STOCK

The following description summarizes the most important terms of our securities. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation and restated bylaws, copies of which are filed as exhibits to the registration statement of which this prospectus forms a part, which are incorporated by reference herein.

Authorized Capitalization

We 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.

As of August 11, 2023, there were 15,658,798 shares of common stock outstanding, and no shares of preferred stock outstanding.

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.

Preferred Stock

Our board of directors has 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. No shares of preferred stock are outstanding, and we have no present plan to issue any shares of preferred stock.

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 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, we 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 transfer agent of our common stock is Computershare Trust Company, N.A.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering 1,720,000 shares of our common stock at a combined public offering price of \$0.5776 per share and accompanying warrants. We are also offering pre-funded warrants to purchase up to 5,205,208 shares of common stock to those purchasers whose purchase of shares of our common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock following the consummation of this offering in lieu of the shares of common stocks that would result in such excess ownership. Each share of our common stock or pre-funded warrant is being sold together with one Series A warrant to purchase one share of common stock and one Series B warrant to purchase one-half of a share of common stock. The shares of our common stock and/or pre-funded warrants and related warrants will be issued separately. We are also registering the shares of our common stock issuable from time to time upon exercise of the pre-funded warrants and warrants offered hereby.

Common Stock

The material terms and provisions of our common stock are described under the caption “Description of Capital Stock” in this prospectus.

Warrants

The following summary of certain terms and provisions of the Series A warrants and Series B warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of warrants, the forms of which are filed as exhibits to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the forms of warrant for a complete description of the terms and conditions of the warrants.

Duration and Exercise Price

The Series A warrants will have an exercise price of \$0.5776 per share and will be exercisable beginning on the effective date of the Warrant Stockholder Approval. The Series A warrants will expire on the five year anniversary of the Initial Exercise Date. The Series B warrants will have an exercise price of \$0.5776 per share and will be exercisable beginning on the Initial Exercise Date. The Series B warrants will expire on the two year anniversary of the Initial Exercise Date. The exercise price and number of shares of common stock issuable upon exercise of the warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The warrants will be issued separately from the common stock and pre-funded warrants and may be transferred separately immediately thereafter. The warrants will be issued in certificated form only.

Exercisability

The warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of such holder’s warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days’ prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder’s warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise

If, at the time a holder exercises its warrants, a registration statement registering the issuance or resale of the shares of common stock underlying the warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrant.

Fundamental Transactions

In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our shares of common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the voting power represented by our outstanding shares of capital stock, any person or group becoming the beneficial owner of more than 50% of the voting power represented by our outstanding shares of capital stock, any merger with or into another entity or a tender offer or exchange offer approved by more than 50% of the voting power represented by our outstanding shares of capital, then upon any subsequent exercise of a warrant, the holder will have the right to receive as alternative consideration, for each share of our common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of our common stock for which the warrant is exercisable immediately prior to such event. Notwithstanding the foregoing, in the event of a fundamental transaction, the holders of the warrants have the right to require us or a successor entity to redeem the warrants for cash in the amount of the Black-Scholes Value (as defined in each warrant) of the unexercised portion of the warrants concurrently with or within 30 days following the consummation of a fundamental transaction.

However, in the event of a fundamental transaction which is not in our control, including a fundamental transaction not approved by our board of directors, the holders of the warrants will only be entitled to receive from us or our successor entity, as of the date of consummation of such fundamental transaction the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the warrant that is being offered and paid to the holders of our common stock in connection with the fundamental transaction, whether that consideration is in the form of cash, stock or any combination of cash and stock, or whether the holders of our common stock are given the choice to receive alternative forms of consideration in connection with the fundamental transaction.

Transferability

Subject to applicable laws, a warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the next whole share or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Trading Market

There is no established trading market for the warrants, and we do not expect such a market to develop. We do not intend to apply to list the warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the warrants will be extremely limited.

Right as a Stockholder

Except as otherwise provided in the warrants or by virtue of the holder's ownership of shares of our common stock, such holder of warrants does not have the rights or privileges of a holder of our common stock, including any voting rights, until such holder exercises such holder's warrants. The warrants will provide that the holders of the warrants have the right to participate in distributions or dividends paid on our shares of common stock.

Waivers and Amendments

The warrants may be modified or amended or the provisions of such warrants waived with our consent and the consent of the holders of at least a majority of the outstanding warrants.

Pre-funded Warrants

The following summary of certain terms and provisions of the pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration and Exercise Price

Each pre-funded warrant offered hereby will have an initial exercise price per share of common stock equal to \$0.0001. The pre-funded warrants will be immediately exercisable and will expire when exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of share dividends, share splits, reorganizations or similar events affecting our shares of common stock and the exercise price.

Exercisability

The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding shares of common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding shares after exercising the holder's pre-funded warrants up to 9.99% of the number of our shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded warrants in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding shares of common stock.

Cashless Exercise

In lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the pre-funded warrants. Rather, at the Company's election, the number of shares of common stock to be issued will be rounded up to the next whole share or the Company will pay a cash adjustment in an amount equal to such fraction multiplied by the exercise price.

Transferability

Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrants to us together with the appropriate instruments of transfer.

Trading Market

There is no established trading market for the warrants, and we do not expect such a market to develop. We do not intend to apply to list the pre-funded warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants will be extremely limited.

Right as a Shareholder

Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our shares of common stock, including any voting rights, until they exercise their pre-funded warrants. The pre-funded warrants will provide that the holders of the pre-funded warrants have the right to participate in distributions or dividends paid on our shares of common stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our shares of common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of the voting power represented by our outstanding shares of capital stock, any person or group becoming the beneficial owner of more than 50% of the voting power represented by our outstanding shares of capital stock, any merger with or into another entity or a tender offer or exchange offer approved by more than 50% of the voting power represented by our outstanding shares of capital, then upon any subsequent exercise of a pre-funded warrant, the holder will have the right to receive as alternative consideration, for each share of our common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of our common stock for which the pre-funded warrant is exercisable immediately prior to such event.

Placement Agent Warrants

We have also agreed to issue to the placement agent (or its designees) placement agent warrants to purchase up to 346,260 shares of common stock. The placement agent warrants will be exercisable immediately and will have substantially the same terms as the warrants described above, except that the placement agent warrants will have an exercise price of \$0.722 per share (representing 125% of the offering price per share and accompanying warrants) and a termination date that will be five years from the commencement of the sales pursuant to this offering. See "Plan of Distribution" below.

PLAN OF DISTRIBUTION

Pursuant to an engagement agreement, dated August 27, 2023, we have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent to solicit offers to purchase the securities offered pursuant to this prospectus on a reasonable best efforts basis. The engagement agreement does not give rise to any commitment by the placement agent to purchase any of our securities, and the placement agent will have no authority to bind us by virtue of the engagement agreement. The placement agent is not purchasing or selling any of the securities offered by us under this prospectus, nor is it required to arrange for the purchase or sale of any specific number or dollar amount of securities. This is a best efforts offering and there is no minimum offering amount required as a condition to the closing of this offering. The placement agent has agreed to use reasonable best efforts to arrange for the sale of the securities by us. Therefore, we may not sell all of the shares of common stock, pre-funded warrants and warrants being offered. The terms of this offering are subject to market conditions and negotiations between us, the placement agent and prospective investors. The placement agent does not guarantee that it will be able to raise new capital in any prospective offering. The placement agent may engage sub-agents or selected dealers to assist with the offering.

Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract is material to larger purchasers in this offering as a means to enforce the following covenants uniquely available to them under the securities purchase agreement: (i) a covenant to not enter into variable rate financings for a period of one year following the closing of the offering, subject to certain exceptions; and (ii) a covenant to not enter into any equity financings 60 for days from closing of the offering, subject to certain exceptions. The nature of the representations, warranties and covenants in the securities purchase agreements shall include:

- standard issuer representations and warranties on matters such as organization, qualification, authorization, no conflict, no governmental filings required, current in SEC filings, no litigation, labor or other compliance issues, environmental, intellectual property and title matters and compliance with various laws such as the Foreign Corrupt Practices Act; and
- covenants regarding matters such as registration of warrant shares, no integration with other offerings, no stockholder rights plans, no material nonpublic information, use of proceeds, indemnification of purchasers, reservation and listing of shares of common stock, and no subsequent equity sales for 60 days.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the securities being offered pursuant to this prospectus on or about September 13, 2023. There is no minimum number of securities or amount of proceeds that is a condition to closing of this offering.

Fees and Expenses

We have agreed to pay the placement agent a total cash fee equal to 7.0% of the aggregate gross proceeds raised in the offering. We will reimburse the placement agent a nonaccountable expense allowance of \$50,000, its legal fees and expenses in an amount up to \$100,000 and its clearing expense in an amount up to \$15,950 in connection with this offering. We estimate the total offering expenses of this offering that will be payable by us, excluding the placement agent fees and expenses, will be approximately \$212,000.

Placement Agent Warrants

In addition, we have agreed to issue to the placement agent or its designees warrants, or the placement agent warrants, to purchase up to 5% of the aggregate number of shares of common stock sold in this offering (including shares underlying any pre-funded warrants), at an exercise price equal to 125 % of the public offering price per share and accompanying warrants to be sold in this offering. The placement agent warrants will be exercisable upon issuance and will expire five years from the commencement of sales under this offering.

If at the time of exercise there is no effective registration statement registering, or the prospectus contained therein is not available for the resale of warrant shares by the holders of the placement agent warrants, then the placement agent warrants may be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the holders shall be entitled to receive a number of warrant shares as calculated in the placement agent warrants.

The placement agent warrants provide for customary anti-dilution provisions (for share dividends, splits and recapitalizations and the like) consistent with FINRA Rule 5110.

Tail

In the event that any investors that were contacted by the placement agent or were introduced to the Company by the placement agent during the term of our engagement agreement with the placement agent provide any capital to us in a public or private offering or capital-raising transaction within 12 months following the termination or expiration of our engagement agreement with the placement agent, we shall pay the placement agent the cash and warrant compensation provided above on the gross proceeds from such investors. The placement agent will only be entitled to such fee to the extent that the parties are directly introduced to us by the placement agent, in accordance with FINRA Rule 2010.

Right of First Refusal

Subject to consummation of the offering, we have granted a right of first refusal to the placement agent pursuant to which it has the right to act as the sole book-running manager, underwriter or placement agent, as applicable, if we decide to raise capital through a public offering (including an at-the-market facility) or private placement or any other capital-raising financing of equity, equity-linked or debt securities pursuant to which we engage an investment bank or broker/dealer at any time prior to the twelve (12) months following the consummation of this offering.

Lock-Up Agreements

Our officers and directors have agreed with the placement agent to be subject to a lock-up period of 90 days following the closing of this offering. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed to similar lock-up restrictions on the issuance and sale of our securities for 60 days following the closing of this offering, subject to certain exceptions. The placement agent may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

In addition, subject to certain exceptions, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of our common stock or upon a specified or contingent event in the future, or enter into any agreement to issue securities at a future determined price for a period of one year following the closing date of this offering.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including certain liabilities under the Securities Act, or to contribute to payments that the placement agent may be required to make in respect of those liabilities.

In addition, we will indemnify the purchasers of securities in this offering against liabilities arising out of or relating to (i) any breach of any of the representations, warranties, covenants or agreements made by us in the securities purchase agreement or related documents or (ii) any action instituted against a purchaser by a third party (other than a third party who is affiliated with such purchaser) with respect to the securities purchase agreement or related documents and the transactions contemplated thereby, subject to certain exceptions

Regulation M Compliance

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any fees received by it and any profit realized on the sale of our securities offered hereby by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent will be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Other Relationships

The placement agent and its affiliates have engaged, and may in the future engage, in investment banking transactions and other commercial dealings in the ordinary course of business with us or our affiliates. The placement agent has received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the placement agent and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The placement agent and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

The placement agent serves as the placement agent pursuant to our at-the-market offering. In connection with the ATM Agreement, the placement agent is entitled to a commission of 3.0% of the gross proceeds from each sale of shares of our common stock pursuant to such agreement. In connection with entering into the ATM Agreement, we reimbursed the placement agent \$50,000 for its expenses. In addition, we agreed to reimburse the placement agent up to \$2,500 per due diligence update session for expenses of its counsel and any incidental expenses.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the placement agent and the placement agent may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the placement agent and should not be relied upon by investors.

Transfer Agent

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Nasdaq listing

Our shares of common stock are listed on Nasdaq under the symbol "CING."

LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon for us by Lowenstein Sandler LLP, New York, New York. Ellenoff Grossman & Schole LLP, New York, New York, is counsel for the placement agent in connection with this offering.

EXPERTS

Our consolidated financial statements as of December 31, 2022 and 2021, and for each of the years in the two-year period ended December 31, 2022, have been incorporated by reference herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2022 and 2021 consolidated financial statements contains an explanatory paragraph that states that our 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.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The following documents filed with the SEC are incorporated by reference into this prospectus:

- our Annual Report on [Form 10-K](#) for the year ended December 31, 2022, filed on March 10, 2023;
- our Quarterly Reports on Form 10-Q for the quarters ended [March 31, 2023](#) and [June 30, 2023](#), filed on May 10, 2023 and August 14, 2023, respectively;
- our Current Reports on Form 8-K, filed on [January 3, 2023](#), [January 9, 2023](#), [March 13, 2023](#), [April 25, 2023](#), [May 3, 2023](#), [May 5, 2023](#), [May 10, 2023](#), [May 19, 2023](#), [June 8, 2023](#), [June 16, 2023](#), [June 29, 2023](#), [July 11, 2023](#), [August 1, 2023](#), [August 14, 2023](#) and [September 11, 2023](#) (other than any portions thereof deemed furnished and not filed);
- our Definitive Proxy Statement on [Schedule 14A](#), filed on May 5, 2023 (other than any portions thereof deemed furnished and not filed); and
- the description of our common stock contained in our Registration Statement on [Form 8-A](#), filed with the SEC on December 3, 2021, including any amendments thereto or reports filed for the purposes of updating this description, including [Exhibit 4.5](#) to our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 28, 2022.

We also incorporate by reference all documents we file pursuant to Section 13(a), 13(c), 14 or 15 of the Exchange Act (other than any portions of filings that are furnished rather than filed pursuant to Items 2.02 and 7.01 of a Current Report on Form 8-K) after the date of the initial registration statement of which this prospectus is a part and prior to effectiveness of such registration statement. All documents we file in the future pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the termination of the offering are also incorporated by reference and are an important part of this prospectus.

Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for the purposes of this registration statement to the extent that a statement contained herein or in any other subsequently filed document which also is or deemed to be incorporated by reference herein modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this registration statement.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. You should rely only on the information contained in this prospectus or incorporated by reference into this prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any jurisdiction where the offer is not permitted. You should assume that the information contained in this prospectus, or any document incorporated by reference in this prospectus, is accurate only as of the date of those respective documents, regardless of the time of delivery of this prospectus or any sale of our securities.

We are subject to the informational requirements of the Exchange Act and in accordance therewith we file annual, quarterly, and other reports, proxy statements and other information with the Commission under the Exchange Act. Such reports, proxy statements and other information, including the Registration Statement, and exhibits and schedules thereto, are available to the public through the Commission's website at www.sec.gov.

We make available free of charge on or through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with or otherwise furnish it to the Commission. The registration statement and the documents referred to under "*Incorporation of Certain Information by Reference*" are also available on our website cingulate.com.

We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

1,720,000 Shares of Common Stock
6,925,208 Series A Warrants to Purchase up to 6,925,208 Shares of Common Stock
3,462,604 Series B Warrants to Purchase up to 3,462,604 Shares of Common Stock
5,205,208 Pre-Funded Warrants to Purchase up to 5,205,208 Shares of Common Stock
15,593,020 Shares of Common Stock Underlying the Series A Warrants, Series B Warrants and Pre-Funded Warrants
346,260 Placement Agent Warrants to Purchase up to 346,260 Shares of Common Stock
346,260 Shares of Common Stock Underlying the Placement Agent Warrants



H.C. Wainwright & Co

PROSPECTUS

September 11, 2023
