

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):
September 8, 2023

CINGULATE INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40874
(Commission
File Number)

86-3825535
(IRS Employer
Identification No.)

1901 W. 47th Place
Kansas City, KS 66205
(Address of principal executive offices) (Zip Code)

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

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

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

Item 1.01. Entry into a Definitive Agreement.

As previously disclosed on August 9, 2022, Cingulate Therapeutics LLC (“CTx”), a wholly-owned subsidiary of Cingulate Inc. (the “Company”), issued a Promissory Note (the “Original Note”) to Werth Family Investment Associates LLC (“WFIA”) with a principal amount of \$5,000,000 (the “Original Principal Amount”), and on May 9, 2023, CTx issued an Amended and Restated Promissory Note (the “A&R Note”) increasing the principal amount under the Original Note by \$3,000,000 to \$8,000,000. On September 8, 2023, the Company and CTx entered into a Note Conversion Agreement (the “Note Conversion Agreement”) with WFIA, pursuant to which WFIA agreed to convert the Original Principal Amount under the A&R Note plus all accrued interest thereon, or \$5,812,500, into pre-funded warrants (“Pre-Funded Warrants”) to purchase 6,838,235 shares (“Pre-Funded Warrant Shares”) of the Company’s common stock, par value \$0.0001 per share (the “Common Stock”), at a conversion price per Pre-Funded Warrant of \$0.85. The closing price of the Common Stock on Nasdaq on September 8, 2023 was \$0.05776 per share. The Pre-Funded Warrants have no expiration date and are exercisable immediately at an exercise price of \$0.0001 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), no more than 19.99% of the outstanding shares of Common Stock of the Company. After the conversion of the Original Principal Amount plus all accrued interest thereon and the issuance of the Pre-Funded Warrants, there was \$3,000,000 in principal and \$96,250 of accrued interest outstanding under the A&R Note.

Prior to the transactions described above, WFIA owned 2,798,320 shares of Common Stock and Peter J. Werth, a member of the Company’s Board of Directors (the “Board”) and the manager of WFIA, owned 21,849 shares of Common Stock, or an aggregate of 18% of the outstanding Common Stock of the Company.

The Audit Committee of the Board and the Board approved the Note Conversion Agreement pursuant to the Company’s Policy and Procedures for Related Person Transactions.

The Note Conversion Agreement contains customary representations, warranties, agreements and obligations of the parties.

The foregoing description of the Note Conversion Agreement and the Pre-Funded Warrants are not complete and are qualified in their entireties by reference to the full text of the the Note Conversion Agreement and the form of Pre-Funded Warrant, copies of which are filed herewith as Exhibit 10.1 and Exhibit 4.1, respectively, to this Current Report on Form 8-K and are incorporated by reference herein.

Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant

The information contained above in Item 1.01 related to the A&R Note and the Note Conversion Agreement is hereby incorporated by reference into this Item 2.03.

Item 3.02. Unregistered Sales of Equity Securities.

The information contained above in Item 1.01 related to the Note Conversion Agreement is hereby incorporated by reference into this Item 3.02. The Pre-Funded Warrants and Pre-Funded Warrant Shares have not been registered under the Securities Act of 1933, as amended (the “Securities Act”), and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder.

Item 7.01. Regulation FD Disclosure.

On September 8, 2023, the Company issued a press release announcing the Note Conversion Agreement. A copy of the press release is attached hereto as Exhibit 99.1.

On September 11, 2023, the Company issued a press release announcing detailed trial results from its Phase 3 adult efficacy and safety trial of CTx-1301 (dexamethylphenidate) for attention deficit/hyperactivity disorder (ADHD) that were presented on September 8, 2023 at the 36th Annual Psych Congress in Nashville, Tennessee. A copy of the press release is attached hereto as Exhibit 99.2.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibits 99.1 and 99.2, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be “filed” for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01. Other Events.

On September 11, 2023, the Company issued a press release announcing detailed trial results from its Phase 3 adult efficacy and safety trial of CTx-1301 (dexamethylphenidate) for ADHD that were presented on September 8, 2023 at the 36th Annual Psych Congress in Nashville, Tennessee. Top-line results for the Phase 3 adult trial were released on July 11, 2023 and included in the Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2023.

Subjects who were randomized to their optimized dose of CTx-1301 showed improvements on the Permanent Product Measure of Performance (PERMP) scores (effect size 0.88 to 2.60; average of 1.79) compared to subjects randomized to placebo, with a trend towards statistical significance for PERMP ratings over the 16-hour period ($p=0.089$). The treatment effect size of CTx-1301 was 1.41 at 30 minutes and 0.98 at 16 hours, which corresponded to onset and duration of effect. For comparison, a meta-analysis using 11 published studies of long-acting stimulants in adults found the average effect size to be 0.73 (approximately ranging from 0.5 to 0.9) – see Faraone SV and Glatt SJ. *J Clin Psychiatry*. 2010;71(6):754-763.

A key secondary endpoint of the trial was a change in Clinical Global Impression Scale (CGI-S) scores from baseline (pre-dose) at Visit 2 to Visit 8. CGI-S scores showed significant improvements in severity of illness in patients taking CTx-1301 (-1.2) compared to placebo (0.0), ($p<0.001$). Additionally, CTx-1301 demonstrated a reduction in Adult ADHD Investigator Symptom Rating Scale (AISRS) scores (-16.3).

During the double-blind randomization period, only one treatment-emergent adverse event (mild) was reported among patients randomized to CTx-1301, while three treatment-emergent adverse events (one mild, two moderate) were reported among patients randomized to placebo. No patients reported experiencing insomnia during the randomized period.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
4.1	Form of Pre-Funded Warrant
10.1	Note Conversion Agreement, dated September 8, 2023, by and between the Company, Cingulate Therapeutics, LLC and Werth Family Investment Associates LLC
99.1	Press Release, dated September 8, 2023
99.2	Press Release, dated September 11, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

CINGULATE INC.

Dated: September 11, 2023

By: /s/ Shane J. Schaffer

Name: Shane J. Schaffer

Title: Chief Executive Officer

NEITHER THIS SECURITY NOR THE SECURITIES FOR WHICH THIS SECURITY IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES

PRE-FUNDED COMMON STOCK PURCHASE WARRANT

CINGULATE INC.

Warrant Shares: _____

Issue Date: September [●], 2023

Initial Exercise Date: September [●], 2023

THIS PRE-FUNDED COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, _____ or its assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date set forth above (the "Initial Exercise Date") and until this Warrant is exercised in full (the "Termination Date") but not thereafter, to subscribe for and purchase from Cingulate Inc., a Delaware corporation (the "Company"), up to _____ shares (as subject to adjustment hereunder, the "Warrant Shares") of Common Stock. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

Section 1. Definitions. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the bid price of the Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder.

“Commission” means the United States Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, par value \$0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

“Common Stock Equivalents” means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Subsidiaries” means the subsidiaries of the Company set forth on Exhibit 21.1 to the Registration Statement and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

“Trading Day” means a day on which the Common Stock is traded on a Trading Market.

“Trading Market” means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

“Transfer Agent” means Computershare Trust Company, N.A., the current transfer agent of the Company, with a mailing address of 480 Washington Blvd 26th Floor, Jersey City, NJ 07310, and any successor transfer agent of the Company.

“VWAP” means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported on The Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the Holder.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form attached hereto as Annex A (the "Notice of Exercise"). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank, in either case in immediately available funds, unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. The Company shall have no obligation to inquire with respect to or otherwise confirm the authenticity of the signature(s) contained on any Notice of Exercise nor the authority of the person so executing such Notice of Exercise. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The aggregate exercise price of this Warrant, except for a nominal exercise price of \$0.0001 per Warrant Share, was pre-funded to the Company on or prior to the Initial Exercise Date and, consequently, no additional consideration (other than the nominal exercise price of \$0.0001 per Warrant Share) shall be required to be paid by the Holder to any Person to effect any exercise of this Warrant. The Holder shall not be entitled to the return or refund of all, or any portion, of such pre-paid aggregate exercise price under any circumstance or for any reason whatsoever. The remaining unpaid exercise price per share of Common Stock under this Warrant shall be \$0.0001, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. This Warrant may also be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of “regular trading hours” (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the Common Stock on the principal Trading Market as reported by Bloomberg L.P. (“Bloomberg”) as of the time of the Holder’s execution of the applicable Notice of Exercise if such Notice of Exercise is executed during “regular trading hours” on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of “regular trading hours” on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of “regular trading hours” on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the characteristics of the Warrant being exercised, and the holding period of the Warrant Shares being issued may be tacked on to the holding period of this Warrant. The Company agrees not to take any position contrary to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company's transfer agent is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) the Warrant Shares are eligible for resale by the Holder without volume or manner-of-sale limitations pursuant to Rule 144 (assuming cashless exercise of the Warrant), and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (ii) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (iii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that the Company shall have received payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each \$1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Stock on the date of the applicable Notice of Exercise), \$10 per Trading Day (increasing to \$20 per Trading Day on the third Trading Day after the Warrant Share Delivery Date) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of the delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares remaining available under this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including reasonable and customary brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Stock having a total purchase price of \$11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of \$10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder \$1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the assignment form attached hereto as Annex B (the "Assignment Form") duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Beneficial Ownership Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith and the calculations required under this Section 2(e). To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one (1) Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 19.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 19.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this Section 2(e) shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this Section 2(e) (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this Section 2(e) shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of the Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or reclassification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time while this Warrant is outstanding the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation); provided, that such Purchase Right shall terminate on, and shall not be held in abeyance for any period subsequent to the Termination Date.

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a “Distribution”), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that to the extent that the Holder’s right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation); provided, that such Purchase Right shall terminate on, and shall not be held in abeyance for any period subsequent to the Termination Date.

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company (and all of its Subsidiaries, taken as a whole), directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person (other than for the purpose of changing the Company’s name and/or the jurisdiction of incorporation of the Company or a holding company for the Company), (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of the outstanding equity securities of the Company having voting power are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of outstanding securities representing more than 50% of the aggregate voting power of the issued and outstanding equity securities of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires securities representing more than 50% of the aggregate voting power, including the power to vote on the election of directors of the Company, of the issued and outstanding equity securities of the Company (each a “Fundamental Transaction”), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the “Alternate Consideration”) receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. The Company shall require any successor entity in a Fundamental Transaction in which the Company is not the survivor (the “Successor Entity”) to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant and the other Transaction Documents referring to the “Company” shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (and all of its Subsidiaries, taken as a whole) is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by email to the Holder at its last email or other address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. Subject to compliance with any applicable securities laws and the conditions set forth in Section 4(d) hereof, this Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers a duly executed Assignment Form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary

d) Representation by the Holder. The Holder, by the acceptance hereof, represents and warrants that it is acquiring this Warrant and, upon any exercise hereof, will acquire the Warrant Shares issuable upon such exercise, for its own account and not with a view to or for distributing or reselling such Warrant Shares or any part thereof in violation of the Securities Act or any applicable state securities law, except pursuant to sales registered or exempted under the Securities Act.

Section 5. Miscellaneous.

a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a “cashless exercise” pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then such action may be taken or such right may be exercised on the next succeeding Trading Day.

d) Authorized Shares.

The Company covenants that during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. The Company and, by accepting this Warrant, the Holder each agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Warrant (whether brought against the Company or the Holder or their respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. The Company and, by accepting this Warrant, the Holder each hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. The Company and, by accepting this Warrant, the Holder each hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Warrant and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If the Company or the Holder shall commence an action, suit or proceeding to enforce any provisions of this Warrant, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for their reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holder hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by email or sent by a nationally recognized overnight courier service, addressed to the Company, at 1901 W. 47th Place, Kansas City, KS 66205, Attention: Louis G. Van Horn, CFO, email address: lvanhorn@cingulate.com, or such other email address or address as the Company may specify for such purposes by notice to the Holder. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by email, or sent by a nationally recognized overnight courier service addressed to the Holder at the email address or address of the Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via email at the email address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via email at the email address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided by the Company hereunder constitutes, or contains, material, non-public information regarding the Company or any subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by such Holder.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company on the one hand, and the Holder of this Warrant on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

o) Electronic Signatures. Electronically scanned and transmitted signatures, including by email attachment, shall be deemed originals for all purposes of this Warrant.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

CINGULATE INC.

By: _____

Name: Shane J. Schaffer

Title: Chief Executive Officer

NOTICE OF EXERCISE

TO: **CINGULATE INC.**

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

in lawful money of the United States; or

if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Warrant Shares shall be delivered to the following DWAC Account Number:

(4) Accredited Investor. The undersigned is an “accredited investor” as defined in Regulation D promulgated under the Securities Act of 1933, as amended.

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to exercise the Warrant to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____, _____

Holder's Signature: _____

Holder's Address: _____

NOTE CONVERSION AGREEMENT

This **NOTE CONVERSION AGREEMENT** (this “**Agreement**”) is made and entered into as of September 8, 2023 (the “**Effective Date**”), by and among Cingulate Therapeutics LLC, a Delaware limited liability company (the “**Company**”), Cingulate Inc., a Delaware corporation (the “**Parent**”) and Werth Family Investment Associates LLC, a Connecticut limited liability company (the “**Holder**”).

RECITALS

WHEREAS, on August 9, 2022, the Company issued a Promissory Note (the “**Original Note**”) to the Holder with a principal amount of \$5,000,000 (the “**Original Principal Amount**”);

WHEREAS, on May 9, 2023, the Company issued an Amended and Restated Promissory Note (the “**A&R Note**”) increasing the principal amount under the Original Note by \$3,000,000 to \$8,000,000; and

WHEREAS, the Company and the Holder desire to convert the Original Principal Amount plus all accrued interest thereon (the “**Converted Amount**”) into pre-funded warrants of the Parent (the “**Pre-Funded Warrants**”) to purchase shares of the Parent’s common stock (the “**Common Stock**”), par value \$0.0001 per share (the “**Pre-Funded Warrant Shares**” and together with the Pre-Funded Warrants, the “**Securities**”), at a conversion price per Pre-Funded Warrant of \$0.85 (the “**Conversion Price**”).

AGREEMENT

Now, THEREFORE, in consideration of the premises and the covenants and agreements set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. Conversion. On the Effective Date, the Converted Amount shall be converted into Pre-Funded Warrants at the Conversion Price, resulting in the issuance by Parent of Pre-Funded Warrants to purchase 6,838,235 shares of Common Stock, or the Converted Amount divided by the Conversion Price. Such Pre-Funded Warrants shall be on the form attached hereto as Exhibit A. The Company and the Holder agree that after the conversion of the Original Amount and the issuance of the Pre-Funded Warrants, there will be \$3,000,000 in principal and \$96,250 of accrued interest outstanding under the A&R Note.

2. Holder’s Representations and Warranties. The Holder represents and warrants to the Company and the Parent that:

(a) Understandings or Arrangements. The Holder is acquiring the Securities as principal for its own account and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Securities (this representation and warranty not limiting the Holder’s right to sell the Securities in compliance with applicable federal and state securities laws). The Holder understands that the Securities are “restricted securities” and have not been registered under the Securities Act of 1933, as amended (the “**Securities Act**”) or any applicable state securities law and is acquiring such Securities as principal for his, her or its own account and not with a view to or for distributing or reselling such Securities or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing any of such Securities in violation of the Securities Act or any applicable state securities law and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Securities in violation of the Securities Act or any applicable state securities law (this representation and warranty not limiting the Holder’s right to sell such Securities pursuant in compliance with applicable federal and state securities laws). The Holder is acquiring the Securities in the ordinary course of its business.

(b) Holder Status. At the time the Holder was offered the Securities, it was, and as of the date hereof it is, and on each date on which it exercises any Pre-Funded Warrants, it will be an “accredited investor” as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7), (a)(8), (a)(9), (a)(12), or (a)(13) under the Securities Act.

3. Miscellaneous.

(a) Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns.

(b) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Agreement shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of this Agreement), and hereby irrevocably waives, and agrees not to assert in any Proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such Proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law.

(c) Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by electronic mail, or otherwise by electronic transmission (including any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) evidencing an intent to sign this Agreement, such electronic mail or other electronic transmission shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such signature page were an original. Execution and delivery of this Agreement by electronic mail or other electronic transmission is legal, valid and binding for all purposes.

(d) Severability. In the event that any provision of this Agreement, or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and shall be interpreted so as reasonably to effect the intent of the parties hereto. The parties hereto further agree to use their commercially reasonable efforts to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such void or unenforceable provision.

(e) Entire Agreement. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

(f) Amendment; Waiver. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and the Holder. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right.

(g) Rules of Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise this Agreement and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Agreement or any amendments thereto.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

In WITNESS WHEREOF, the Company, the Parent and the Holder have executed this NOTE CONVERSION AGREEMENT as of the date first set forth above.

COMPANY:

CINGULATE THERAPEUTICS LLC

By: /s/ Shane J. Schaffer

Name: Shane J. Schaffer

Title: Chief Executive Officer

PARENT:

CINGULATE INC.

By: /s/ Shane J. Schaffer

Name: Shane J. Schaffer

Title: Chief Executive Officer

HOLDER:

WERTH FAMILY INVESTMENT ASSOCIATES LLC

By: /s/ Peter J. Werth

Name: Peter J. Werth

Title: Manager

[SIGNATURE PAGE TO NOTE CONVERSION AGREEMENT]

EXHIBIT A

Form of Pre-Funded Warrant

Werth Family Investment Associates Converts \$5.8 Million of Debt into Cingulate Equity at a Premium

Conversion Follows \$1.0 Million Capital Investment in August 2023

KANSAS CITY, Kan., September 8, 2023 (GLOBE NEWSWIRE) — Cingulate Inc. (NASDAQ: CING) (Cingulate), a biopharmaceutical company utilizing its proprietary Precision Timed Release™ (PTR™) drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products, announced today that Werth Family Investment Associates, LLC (“WFIA”), the manager of which is Peter J. Werth, a member of the Cingulate board of directors, has converted \$5.8 million of debt and accrued interest into Cingulate equity, at a conversion price of \$0.85 per share. The closing price of Cingulate’s common stock on Nasdaq on September 8, 2023 was \$0.5776 per share. The debt conversion follows WFIA’s purchase of \$1.0 million of Cingulate common stock in a private placement transaction in August 2023.

Cingulate, Cingulate Therapeutics LLC (CTx) and WFIA entered into a Note Conversion Agreement on September 8, 2023, pursuant to which WFIA agreed to convert \$5.0 million of principal under its outstanding notes, plus all accrued interest thereon, or \$5.8 million total, into pre-funded warrants (“Pre-Funded Warrants”) to purchase 6,838,235 shares of Cingulate’s common stock. The Pre-Funded Warrants have no expiration date and are exercisable immediately at an exercise price of \$0.0001 per share, subject to a beneficial ownership blocker of 19.99%. Following the conversion, \$3.0 million in principal plus \$0.1 million in accrued interest remained outstanding under the WFIA note which matures in August 2025.

The offer and sale of the securities described above are being offered in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the “Act”), and Regulation D promulgated thereunder and, along with the shares of common stock underlying the warrants, have not been registered under the Act, or applicable state securities laws. Accordingly, the securities issued in the private placement and the shares of common stock underlying the warrants may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Act and such applicable state securities laws.

This press release does not constitute an offer to sell or the solicitation of an offer to buy any of the securities described herein, nor shall there be any sale of these securities in any state or other jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

About Attention Deficit/Hyperactivity Disorder (ADHD)

ADHD is a chronic neurobiological and developmental disorder that affects millions of children and often continues into adulthood. The condition is marked by an ongoing pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development. In the U.S., approximately 6.4 million children and adolescents (11 percent) aged under the age of 18 have been diagnosed with ADHD. Among this group, approximately 80 percent receive treatment, with 65-90 percent demonstrating clinical ADHD symptoms that persist into adulthood. Adult ADHD prevalence is estimated at approximately 11 million patients (4.4 percent), almost double the size of the child and adolescent segment combined, however, only an estimated 20 percent receive treatment.

About CTx-1301

Cingulate’s lead candidate, CTx-1301, utilizes Cingulate’s proprietary PTR drug delivery platform to create a breakthrough, multi-core formulation of the active pharmaceutical ingredient dexamethylphenidate, a compound approved by the FDA for the treatment of ADHD. Dexamethylphenidate is part of the stimulant class of medicines and increases norepinephrine and dopamine activity in the brain to affect attention and behavior. While stimulants are the gold-standard of ADHD treatment due to their efficacy and safety, the long-standing challenge remains, providing patients entire active-day duration of action. CTx-1301 is designed to precisely deliver three releases of medication at the predefined time, ratio, and style of release to optimize patient care in one tablet. The result is a rapid onset and entire active-day efficacy, with the third dose being released around the time when other extended-release stimulant products begin to wear off.

About Precision Timed Release™ (PTR™) Platform Technology

Cingulate is developing ADHD and anxiety disorder product candidates capable of achieving true once-daily dosing using Cingulate's innovative PTR drug delivery platform technology. It incorporates a proprietary Erosion Barrier Layer (EBL) providing control of drug release at precise, pre-defined times with no release of drug prior to the intended release. The EBL technology is enrobed around a drug-containing core to give a tablet-in-tablet dose form. It is designed to erode at a controlled rate until eventually the drug is released from the core tablet. The EBL formulation, Oralogik™, is licensed from BDD Pharma.

Cingulate intends to utilize its PTR technology to expand and augment its clinical-stage pipeline by identifying and developing additional product candidates in other therapeutic areas in addition to Anxiety and ADHD where one or more active pharmaceutical ingredients need to be delivered several times a day at specific, predefined time intervals and released in a manner that would offer significant improvement over existing therapies. To see Cingulate's PTR Platform click [here](#).

About Cingulate Inc.

Cingulate Inc. (NASDAQ: CING), is a biopharmaceutical company utilizing its proprietary PTR drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products, designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. With an initial focus on the treatment of ADHD, Cingulate is identifying and evaluating additional therapeutic areas where PTR technology may be employed to develop future product candidates, including to treat anxiety disorders. Cingulate is headquartered in Kansas City. For more information visit Cingulate.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include all statements, other than statements of historical fact, regarding our current views and assumptions with respect to future events regarding our business, including statements with respect to our plans, assumptions, expectations, beliefs and objectives with respect to product development, clinical studies, clinical and regulatory timelines, market opportunity, competitive position, business strategies, potential growth opportunities and other statements that are predictive in nature. These statements are generally identified by the use of such words as "may," "could," "should," "would," "believe," "anticipate," "forecast," "estimate," "expect," "intend," "plan," "continue," "outlook," "will," "potential" and similar statements of a future or forward-looking nature. Readers are cautioned that any forward-looking information provided by us or on our behalf is not a guarantee of future performance. Actual results may differ materially from those contained in these forward-looking statements as a result of various factors disclosed in our filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of our Annual Report on Form 10-K filed with the SEC on March 10, 2023. All forward-looking statements speak only as of the date on which they are made, and we undertake no duty to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

Investor Relations:

Matt Kreps
Darrow Associates
mkreps@darrowir.com
(214) 597-8200

Thomas Dalton
Vice President, Investor & Public Relations, Cingulate
tdalton@cingulate.com
(913) 942-2301

Media Relations

Melyssa Weible
Elixir Health Public Relations
mweible@elixirhealthpr.com
(201) 723-5805



Cingulate Announces Detailed Trial Results from Phase 3 Adult Efficacy and Safety Trial of CTx-1301 (dexamethylphenidate) for ADHD

CTx-1301 Demonstrated Clinically Meaningful Improvements in Permanent Product Measure of Performance (PERMP) and Clinical Global Impression Scale (CGI-S) Scores, with Investigators Observing Trend Toward Significance

Treatment Effect Size of 1.41 and 0.98 Observed at 30 Minutes and at Hour 16, Respectively; Currently Available Long-Acting Stimulants Range from 0.5 to 0.9¹

CTx-1301 Demonstrated a Favorable Safety Profile in the Trial Compared to Placebo

KANSAS CITY, KANSAS – September 11, 2023 – **Cingulate Inc. (NASDAQ: CING)**, a biopharmaceutical company utilizing its proprietary Precision Timed Release™ (PTR™) drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products, announced full results from the Phase 3 adult efficacy and safety study of its lead candidate, CTx-1301 (dexamethylphenidate), for the treatment of attention deficit/hyperactivity disorder (ADHD), presented on September 8th at the 36th Annual Psych Congress, in Nashville, TN. A poster describing this data was selected as a finalist for the Psych Congress’s First Annual Poster Awards.

The Phase 3 CTx-1301-022 study ([NCT05631626](#)) assessed efficacy and safety along with onset and duration of CTx-1301 in 21 adults (age range: 18-55 years) with ADHD in an adult laboratory classroom setting. The data from the trial, presented at the 2023 Psych Congress, did not achieve statistical significance on the primary efficacy endpoint but demonstrated a trend toward significance in improving Permanent Product Measure of Performance (PERMP) scores with CTx-1301 compared to placebo. Clinical Global Impression Scale [CGI-S]) scores with CTx-1301 compared to placebo also showed significant improvements even though the study was not powered for statistical significance.

“Even with currently available extended-release formulations of dexamethylphenidate, many patients require longer duration of efficacy and must add a second, or booster, dose to ensure treatment effect over their entire active day. CTx-1301 is designed to release dexamethylphenidate multiple times throughout the day in just one tablet, with the last release happening around the time that plasma concentrations of other stimulants start to wane,” said Ann Childress, M.D., President, Center for Psychiatry and Behavior Medicine, Inc. and lead investigator. “The treatment effect size of CTx-1301 in this trial was notable – starting at 30 minutes and remaining consistent over 16 hours – and demonstrated the ability of CTx-1301 to improve upon ADHD symptoms in patients over an entire active day. If approved, this would allow physicians to avoid prescribing the immediate-release booster doses that over 60 percent of patients are currently using to extend the efficacy of their medications².”

CTx-1301 demonstrated a favorable safety profile in the trial compared to placebo. No patients reported experiencing insomnia during the randomized period.

“Along with a restricted duration of efficacy, another limitation of current stimulant-based treatments for ADHD is the phenomena of crash and rebound they produce. This can result in the recurrence or exaggeration of ADHD symptoms” said Raul Silva, M.D., Chief Science Officer, Cingulate.

“To address this, we designed CTx-1301 to be a once-daily, rapid-onset tablet that is meant to provide entire active-day coverage along with a controlled descent in blood levels to mitigate the crash or rebound by avoiding the precipitous drop in blood levels usually associated with stimulants. We are encouraged by the Phase 3 data which should correlate with CTx-1301’s onset and duration of action, thus improving ADHD symptoms from morning to night, all while offering a favorable safety profile.”

CTx-1301 is a novel, investigational treatment being developed as a true, once-daily stimulant medication for ADHD, upon approval from the U.S. Food and Drug Administration (FDA).

In addition to this Phase 3 adult dose-optimization study, Cingulate initiated its pivotal Phase 3 fixed-dose pediatric and adolescent study in July 2023, as well as a dose-optimization onset and duration trial in pediatric patients in August 2023.

Detailed Results from Phase 3 Adult Safety and Efficacy Trial of CTx-1301 Demonstrate Improvements in ADHD Symptoms with Optimal Onset and Duration

Subjects who were randomized to their optimized dose of CTx-1301 showed improvements on the PERMP scores (effect size 0.88 to 2.60; average of 1.79) compared to subjects randomized to placebo, with a trend towards statistical significance for PERMP ratings over the 16-hour period ($p=0.089$). The treatment effect size of CTx-1301 was 1.41 at 30 minutes and 0.98 at 16 hours, which corresponded to onset and duration of effect. For comparison, a meta-analysis using 11 published studies of long-acting stimulants in adults found the average effect size to be 0.73 (approximately ranging from 0.5 to 0.9)¹.

A key secondary endpoint of the trial was a change in CGI-S scores from baseline (pre-dose) at Visit 2 to Visit 8. CGI-S scores showed significant improvements in severity of illness in patients taking CTx-1301 (-1.2) compared to placebo (0.0), ($p<0.001$). Additionally, CTx-1301 demonstrated a reduction in Adult ADHD Investigator Symptom Rating Scale (AISRS) scores (-16.3).

During the double-blind randomization period, only one treatment-emergent AE (mild) was reported among patients randomized to CTx-1301, while three AEs (one mild, two moderate) were reported among patients randomized to placebo.

About Attention Deficit/Hyperactivity Disorder (ADHD)

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About the CTx-1301 Phase 3 Adult Dose-Optimization Study

The first Phase 3 study (CTx-1301-022, [NCT05631626](#)) for CTx-1301 was a single-center, dose-optimized, double-blind, randomized, placebo-controlled, parallel efficacy and safety adult laboratory classroom (ALC) study of CTx-1301 in 21 adults (age range: 18-55 years) with ADHD. The study was comprised of a screening period, a dose-optimization phase, a double-blind randomized phase, and a seven-day safety follow-up period. Subjects underwent a screening visit prior to entering a five-week dose-optimization phase. During the dose-optimization phase, subjects had weekly visits and were titrated to doses ranging between 25 mg and 50 mg of CTx-1301. Cingulate utilized an ALC, which enabled it to facilitate repeated assessments over the course of a day to evaluate the onset and duration of efficacy provided by CTx-1301. Eligible subjects were randomized to their optimal dose or placebo in a 1:1 ratio after completing a practice visit with four Product Measure of Performance (PERMP) assessments. Subjects took their assigned/randomized dose over the following seven-day period. On the seventh day, subjects completed a full ALC visit. The duration of the full ALC visit was approximately 17 hours. Subjects had an in-clinic safety follow-up visit within seven days after the full ALC visit.

The primary objective of CTx-1301-022 was to evaluate the efficacy of CTx-1301 compared to placebo in treating adults with ADHD in an ALC study. Secondary objectives included determination of the onset and duration of clinical effect of CTx-1301 in treating ADHD in adults in an ALC study and to determine safety and tolerability of CTx-1301 compared to placebo. The study also evaluated the quality and satisfaction of prior medication to CTx-1301. The Phase 3 clinical trial program for CTx-1301 is being conducted in the U.S. and is instrumental for the filing of the NDA to the FDA, expected in the second half of 2024.

About CTx-1301

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References

¹ Faraone SV and Glatt SJ. *J Clin Psychiatry*. 2010;71(6):754-763.

² Thomas E. Brown. 2017. *Outside the Box: Rethinking ADD/ADHD in Children and Adults—A Practical Guide*. American Psychiatric Association Publishing.

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Investor Relations:

Matt Kreps
Darrow Associates
mkreps@darrowir.com
(214) 597-8200

Thomas Dalton
Vice President, Investor & Public
Relations, Cingulate
tdalton@cingulate.com
(913) 942-2301

Media Relations

Melyssa Weible
Elixir Health Public Relations
mweible@elixirhealthpr.com
(201) 723-5805
