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):
November 14, 2022

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

Delaware	**001-40874**	**86-3825535**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(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 2.02. Results of Operations and Financial Condition.

On November 14, 2022, Cingulate Inc. (the "Company") issued a press release announcing its financial results for the third quarter of 2022 and providing a clinical and business update. A copy of the press release is furnished as Exhibit 99.1 and incorporated by reference.

Item 7.01. Regulation FD Disclosure.

The Company updated its investor presentation to be used at investor conferences and in investor meetings. A copy of the presentation is furnished as Exhibit 99.2 and incorporated by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 14, 2022
99.2	Investor Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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: November 14, 2022

By: */s/ Louis G. Van Horn*
Name: Louis G. Van Horn
Title: Chief Financial Officer

Cingulate Inc. Reports Third Quarter 2022 Financial Results and Provides Clinical and Business Update

Phase 3 Trial Initiation for Lead ADHD Candidate CTx-1301 in December 2022

Executed Manufacturing Agreement with Societal CDMO

2022 Psych Congress Presentation Demonstrated Ability of Anxiety Candidate CTx-2103 to Deliver a Single Administration of Triple-Release Buspirone

KANSAS CITY, Kan., November 14, 2022 — 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, today announced its financial results for the quarter ended September 30, 2022 and provided a clinical and business update. Highlights include a newly executed Master Services Agreement (MSA) and multiple clinical program updates on its lead Attention Deficit / Hyperactivity Disorder (ADHD) candidate, CTx-1301 (dexmethylphenidate), as well as anxiety asset CTx-2103 (buspirone HCl).

"The third quarter of 2022 marked multiple inflection points for Cingulate, during which we initiated and completed a food effect study to meet the New Drug Application pharmacology requirement for our lead ADHD candidate, CTx-1301, and finalized plans for a Phase 3 adult dose-optimization study that will commence in the coming weeks," said Shane J. Schaffer, Cingulate Chairman and CEO.

"Our agreement with Societal CDMO secures the manufacturing capacity and operational expertise to support our products at each and every scale as we advance our clinical trial activities toward the commercialization of these next-generation products designed to improve patient outcomes ."

Cingulate Announces Partnership with Societal CDMO

Cingulate announced it has executed an MSA with Societal CDMO, Inc. (NASDAQ: SCTL), a contract development and manufacturing organization (CDMO) dedicated to solving complex formulation and manufacturing challenges in small molecule therapeutic development.

With capabilities spanning pre-Investigational New Drug (IND) development to commercial manufacturing and packaging for a wide range of therapeutic dosage forms, Societal CDMO will manufacture all clinical, registration, and commercial batches of Cingulate's lead ADHD candidate CTx-1301, an investigational medication for the treatment of ADHD. Societal CDMO will dedicate a specific manufacturing suite within its Gainesville, GA facility and outfit it with proprietary equipment owned by Cingulate.

Clinical Update

- **CTx-1301:** Cingulate advanced its clinical program for CTx-1301 on the expedited approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. As part of that effort:

  In order to meet the pharmacology requirement for the CTx-1301 New Drug Application (NDA) submission, the Company initiated a food effect study in September 2022 which was completed in October of 2022, with results expected to be available in December 2022.

A Phase 3 adult dose-optimization study to assess the onset and duration of efficacy and safety of CTx-1301 in adults with ADHD will commence in December 2022.

With the newly executed MSA with Societal CDMO, the CTx-1301 Phase 3 fixed-dose pediatric and adolescent safety and efficacy study is expected to commence in mid-2023 after the final two dosage strengths for this study are manufactured. Results from the fixed-dose study are expected in late 2023.

Upon positive clinical results from the Phase 3 trials and food effect study, the Company plans to submit the NDA for CTx-1301 in the first half of 2024 under the Section 505(b)(2) pathway.

- **CTx-2103:** Cingulate is constructing a clinical program for CTx-2103 toward an expedited approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. As part of that effort:

  Cingulate presented results from the human formulation study of its lead anxiety candidate, CTx-2103 (buspirone), in September 2022 at the annual Psych Congress. Pharmacokinetics were evaluated for this trimodal tablet providing three (3) precisely timed doses of buspirone versus one immediate release dose. In addition, scintigraphic imaging visualized transit of the tablets through the gastrointestinal tract to confirm both the site and onset of release, which will then be correlated with pharmacokinetic data to establish the full release profile of the CTx-2103 formulation.

  Based on the dissolution profile seen in the data, the CTx-2103 30 mg tablet achieved the solubility required to deliver a triple release of buspirone. The tablet was also able to deliver the intended doses at three precise time points. These results provide critical information as Cingulate moves forward with designing the clinical program for CTx-2103 in anxiety, the most common mental health concern in the U.S.

- **CTx-1302:** A Phase 1/2 bioavailability study in ADHD patients for CTx-1302 (dextroamphetamine), Cingulate's second asset for the treatment of ADHD, is planned for the first half of 2024. If results from this study are successful, pivotal Phase 3 clinical trials in all patient segments for CTx-1302 will begin in 2024.

Third Quarter 2022 Results

- **Cash Position:** As of September 30, 2022, Cingulate had $9.8 million in cash and cash equivalents, as compared to $16.5 million in cash and cash equivalents as of December 31, 2021. Based on the Company's current operating plan, Cingulate expects its cash and cash equivalents will enable the Company to fund its research and development and general and administrative expenditures through the first quarter of 2023. Cingulate is evaluating alternatives to raise additional capital, including equity and debt financing.

- **Research & Development (R&D) Expenses:** R&D expenses were $2.1 million for the three months ended September 30, 2022, compared to $5.8 million for the same period in 2021. R&D expenses were $7.1 million for the nine months ended September 30, 2022, as compared to $7.1 million for the same period in 2021. The Company incurred a one-time non-cash compensation charge to R&D totaling $4.6 million for the modification of profits interest units in the third quarter of 2021. This charge was partially offset by increased development activity in 2022 as compared to 2021 as the Company began conducting a food effect study for CTx-1301 during the third quarter of 2022 as well as study start-up activities for a Phase 3 fixed-dose pediatric and adolescent safety and efficacy study for CTx-1301 during the first nine months of 2022. In addition, manufacturing of the Phase 3 clinical supply for the fixed-dose study began in the first quarter of 2022 with continued activity through the third quarter of 2022. The Company has also incurred costs in 2022 relating to a human formulation study for CTx-2103.

- **General and Administrative (G&A) Expenses:** G&A expenses were $1.8 million for the three months ended September 30, 2022, compared to $9.4 million for the same period in 2021. G&A expenses were $5.9 million for the nine months ended September 30, 2022, as compared to $10.9 million for the same period in 2021. These decreases primarily relate to a one-time non-cash compensation charge to G&A totaling $8.1 million for the modification of profits interest units in the third quarter of 2021, partially offset by certain costs which have increased for the Company operating as a public company, including directors' and officers' insurance, audit and other professional fees and added personnel.

- **Net Loss:** Net loss was $4.0 million for the three months ended September 30, 2022, compared to $15.3 million for the same period in 2021. Net loss was $13.1 million for the nine months ended September 30, 2022, as compared to $18.1 million for the same period in 2021. These decreases in net loss primarily relate to a one-time non-cash compensation charge totaling $12.7 million for the modification of profits interest units in the third quarter of 2021, partially offset by increased development activity as well as the increase in G&A expenses relating to additional costs to operate as a public company in 2022, both described above.

About Cingulate®

Cingulate Inc. is 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, designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. With an initial focus on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD), Cingulate is identifying and evaluating additional therapeutic areas where its PTR technology may be employed to develop future product candidates, such as anxiety disorders.

Cingulate is headquartered in Kansas City, KS. For more information visit Cingulate.com.

About Societal CDMO

Societal CDMO (NASDAQ: SCTL) is a bi-coastal contract development and manufacturing organization (CDMO) with capabilities spanning pre-Investigational New Drug (IND) development to commercial manufacturing and packaging for a wide range of therapeutic dosage forms with a primary focus in the area of small molecules. With an expertise in solving complex manufacturing problems, Societal CDMO is a leading CDMO providing therapeutic development, end-to-end regulatory support, clinical and commercial manufacturing, aseptic fill/finish, lyophilization, packaging and logistics services to the global pharmaceutical market.

In addition to our experience in handling DEA controlled substances and developing and manufacturing modified-release dosage forms, Societal CDMO has the expertise to deliver on our clients' pharmaceutical development and manufacturing projects, regardless of complexity level. We do all of this in our best-in-class facilities, which total 145,000 square feet, in Gainesville, Georgia and San Diego, California.

Societal CDMO: Bringing Science to Society. For more information about Societal CDMO's customer solutions, visit societalcdmo.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 28, 2022. 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.

Cingulate Inc.
Consolidated Balance Sheet Data

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 9,795,570	$ 16,492,745
Working capital	$ 5,428,411	$ 17,705,601
Total assets	$ 15,376,675	$ 22,886,257
Total liabilities	$ 7,010,143	$ 2,042,715
Accumulated deficit	$ (64,803,469)	$ (51,732,264)
Total stockholders' equity	$ 8,366,532	$ 20,843,542

Cingulate Inc.
Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 2,123,114	$ 5,791,407	$ 7,063,626	$ 7,147,513
General and administrative	1,845,248	9,488,082	5,963,067	10,884,759
Operating loss	**(3,968,362)**	**(15,279,489)**	**(13,026,693)**	**(18,032,272)**
Interest and other income (expense), net	(58,885)	(10,559)	(44,512)	(23,994)
Loss before income taxes	(4,027,247)	(15,290,048)	(13,071,205)	(18,056,266)
Income tax benefit (expense)	-	-	-	-
Net loss	(4,027,247)	(15,290,048)	(13,071,205)	(18,056,266)
Net loss per share of common stock, basic and diluted	$ (0.36)	-	$ (1.16)	-

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Investor Relations

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CINGULATE®

Cingulate Therapeutics

Developing next-generation therapeutics where standard-of-care treatments result in suboptimal outcomes

4Q - 2022

CING-US-117-1123

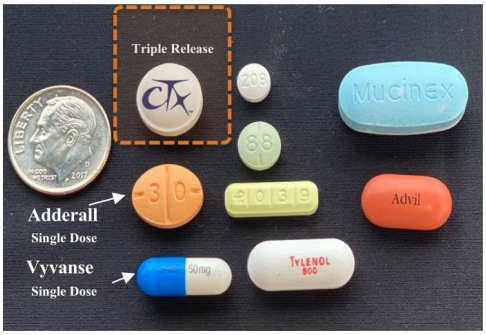
Forward-Looking Statements

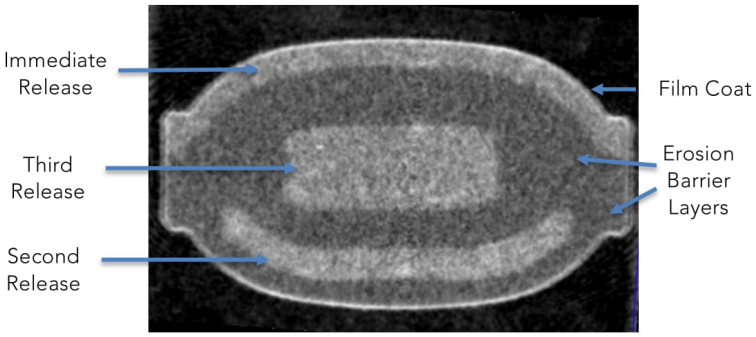
This presentation contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include all statements, other than statements of historical fact, regarding 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 for the year ended December 31, 2021. 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.

Next-Generation Medications in Billion-Dollar Markets

Precision Timed Release™ (PTR™) Platform Unlocks the Possibility for 'True' Once-daily, Multi-dose Tablets





[See the PTR™ Platform in Action]

*Symphony Data. 12-months rolling through Jun 2022

Pipeline of Next-Generation Medications in Billion-Dollar Markets

Identified PTR™ Platform Pipeline Opportunities

In Development

- ADHD
- Anxiety

Near-Term

- Insomnia
- Depression
- Bipolar Disorder
- Parkinson's Disease
- Cardiovascular Disorders
- Xerostomia (dry mouth)

Future Therapeutic Areas

- Migraine
- Hypothyroidism
- Oral Oncology Medicines
- Psychosis
- Alzheimer's Disease
- Pain (Non-Opioid)

Market Dynamics in ADHD & Anxiety

ADHD

- $18Bn US market
- Stimulants dominate (90%+)
- Top 4 ADHD meds generic at CING launch
  - PBM rebates going away
  - Cingulate will dominate Share of Voice
- 100% of stimulants have been approved over last 50 years
- Streamlined FDA approval pathway
- IQVIA Survey: over 60% of providers unsatisfied with current options

Anxiety

- $5Bn US market
- Buspirone is #1 non-benzodiazepine treatment
- Potential for breakthrough approval
  - PBM rebate offer to improve access
  - Improve patient outcomes
- Streamlined FDA approval pathway

Catalysts Into 2023

	4Q 2022	1H 2023	2H 2023
ADHD CTx-1301 CTx-1302	➢ Food Effect Clinical Study Report ➢ Initiate CTx-1301 Adult Onset / Duration Efficacy Trial	➢ Onset / Efficacy Trial Data ➢ Initiate Pivotal Phase 3 in Adolescents and Children	➢ Complete CTx-1301 Pivotal Phase 3 ➢ CTx-1302 IND
Anxiety CTx-2103	➢ CTx-2103 Formulations Study Clinical Report	➢ FDA Discussion regarding clinical development plan	➢ CTx-2103 IND

PTR™ Platform	➢ Expand Manufacturing Operations	➢ Out license opportunity for PTR™ Platform
		  ➢ Milestones
		  ➢ Royalty
		➢ Potential OUS licensing of CTx-1301, CTx-1302, CTx-2103
		➢ Expand CING – BDD Partnership
		➢ Expand BD&L Activities w/ PTR™	

Target dates; Actual time to achievement may vary

FIRST and ONLY ADHD Medication to Overcome All Unmet Needs

Precision Timed Release™ (PTR™) Platform Unlocks the Possibility for 'True' Once-daily, Multi-dose Tablets

$18 Billion*

US ADHD Market
Dominated by Stimulants

*Symphony Data. 12-months rolling through Feb 2022

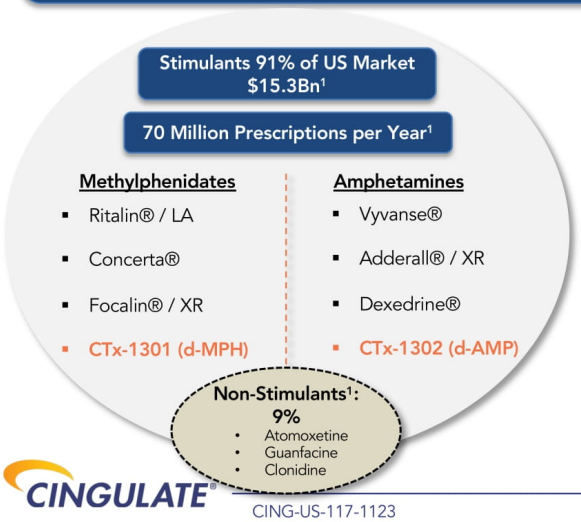
CINGULATE™

cingulate.com

Targeting Treatment of ADHD - $18Bn US Market Opportunity

Frequently diagnosed, chronic pattern interfering with functioning / development

17 Million US ADHD Patients
11M Adults & 6M Children/Adolescents



Societal Impact of ADHD
Estimated annual incremental costs of $143 to $266 billion in the United States
Earn ~ 30% less and 10% less likely to be employed
>40% higher rate of car accidents
2x greater divorce rate
2x greater incidence of accidental death
2x higher incarceration rate

References: https://www.cdc.gov/ncbddd/adhd/data.html
Doshi et al. J Am Acad Child Adolesc Psychiatr. 2012;51(10):990-1002.

ADHD Market Currently Dominated by 4 Stimulant Products

Major Unmet Medical Needs Persist

ADHD BRANDS	APPROVED	ATTRIBUTES[1]		UNMET NEEDS[1]			
		Onset	Duration (less onset)	Fast Onset of Action ≤ 30 min	Entire Active-Day Efficacy*	Minimize Crash/Rebound	Avoid Booster[2]
Vyvanse®	2007	2 hours	12 hours	✗	✗	Data Not Available	✗
Adderall® XR	2001	1 ½ hours	10 ½ hours	✗	✗	Data Not Available	✗
Concerta®	2000	2 hours	10 hours	✗	✗	Data Not Available	✗
Focalin® XR	2005	30 mins	11½ hours	✓	✗	Data Not Available	✗

60% use short-acting 'booster' dose *every day!*

$11.6B 76% Market Share ($)[2]

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

[1] Information based upon product Package Inserts, and Summary Basis of Approvals for the approved products in chart and Ann C. Childress, Nathalie Beltran, Carl Supnet & Margaret D. Weiss (2021) Reviewing the role of emerging therapies in the ADHD armamentarium, Expert Opinion on Emerging Drugs, 26:1, 1-16.
[2] Symphony Data. 12-months rolling through Jun 2022

Recent Launches Lack Meaningful Clinical Innovation

Niche Delivery Platforms – Designed to Fail in ADHD

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

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

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

CINGULATE®

The Cingulate Solution for ADHD Patients & Providers

MASTERY® CTx-1301

ACCOMPLISH® CTx-1302

CING-US-117-1123

Nine Significant Points of Differentiation

NO ADHD product available today combines all unmet needs

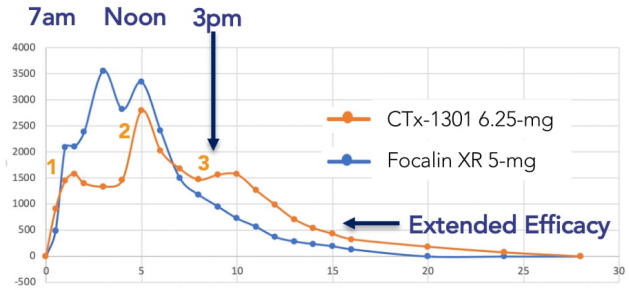
- ✓ **Provide 'Entire Active-Day' Efficacy**
- ✓ Fast onset of action
- ✓ Eliminate need for booster / recovery dose
- ✓ Avoid crash and rebound effect

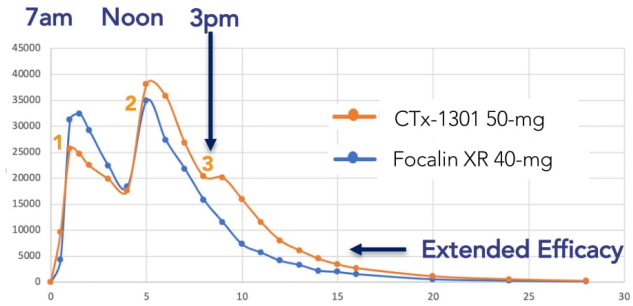
PTR™ technology affords our product candidates the following potential advantages over currently available ADHD treatments

- ✓ Reduce abuse / diversion by eliminating booster
- ✓ Significantly improved tolerability
- ✓ Lower costs to patients, providers, and payers
- ✓ Ability to optimize with 8 dosage strengths
- ✓ Single-enantiomer API selection

One Product Overcomes All Unmet Needs

Entire Active-Day Efficacy, Stop the Crash & Rebound, Eliminate the Booster Dose





CINGULATE	TARGET ATTRIBUTES		UNMET NEEDS			
	Onset	Duration	Fast Acting (≤ 30 min)	Entire Active-Day Efficacy	Avoid Crash/Rebound	Avoid Booster
CTx-1301 (d-MPH)	30 mins	Up to 16 hours	✓	✓	✓	✓
CTx-1301 (d-AMP)	30 mins	Up to 16 hours	✓	✓	✓	✓

6.25-mg 12.5-mg 18.75-mg 25-mg 31.25-mg 37.5-mg 43.75-mg 50-mg

CTx-1301 Demonstrated Significantly Lower Adverse Events

28.6% reduction in TEAE's related to CTx-1301 versus Focalin XR (14.3% difference)

	Focalin XR 5 mg (n=41)	CTx-1301 6.25 mg (n=39)	Focalin XR 40 mg (n=43)	CTx-1301 50 mg (n=42)	All CTx-1301 (n=42)	All Focalin XR (n=44)
Patients with at least one						
Treatment Emergent Adverse Events	7 (17.1%)	4 (10.3%)	22 (51.2%)	14 (33.3%)	17 (40.5%)	25 (56.8%)
Mild	7 (17.1%)	4 (10.3%)	20 (46.5%)	14 (33%)	17 (40.5%)	23 (52.3%)
Moderate	0	0	2 (4.7%)	0	0	2 (4.5%)
Severe	0	0	0	0	0	0
TEAE Related to Study Drug	**5 (12.2%)**	**3 (7.7%)**	**20 (46.5%)**	**13 (31.0%)**	**15 (35.7%)**	**22 (50.0%)**
AE Leading to Study or Drug Withdrawal	1 (2.4%)	0	1 (2.3%)	0	0	2 (4.5%)

There were no serious adverse events.

Source: CSR CTx-1301-001 Listing 16.2.7.1

MASTERY® CTx-1301 Clinical and Regulatory Timeline

CLINICAL

- PHASE I Food Effect Study n=26
- PHASE 3 Adult Dose-Optimization Efficacy and Safety Study to Evaluate Onset and Duration n~20
  - *Exploratory Endpoints*
- PHASE 3 Pediatric / Adolescent Fixed-Dose, Placebo-Controlled Study n=312
- PHASE 4 Clinical Program

REGULATORY

- NDA Preparation and Filing
- NDA Approval ~1H 2025

Target dates; actual timeline may vary

Commercialization to Drive Revenue

Changing dynamics in ADHD commercial landscape

- Ability to dominate share of voice
  - Concerta, Adderall XR, Focalin XR are all off-patent with no promotion
  - Vyvanse loss of exclusivity ~August 2023
- New entrants lack major promotional efforts, field forces, and revenue

Maximize Access for Patients and Providers

- Clinical, Practical, and Societal Story:
  - Efficacy and Tolerability
  - One versus Two Prescriptions
  - Abuse & Diversion
- *Rebates & Net to Plan Cost*
  - PBM's driven by rebate guarantees to payers; estimated >$2B last year*
  - ADHD is a high brand utilization market with high-cost generics at 55-90% of branded drug cost*

Cingulate's Comprehensive Commercial Model

- **Branded product of choice ~ Patients, Providers, & Payers**
- **Strategic partnership to maximize market access, distribution, promotion across all channels**
  - Psychiatry / Neurology & Pediatrics / Family Practice encompass 84% of ADHD market*
  - Maximize and retain NPV to Cingulate

*Symphony Data. 12-months rolling through Jun 2022

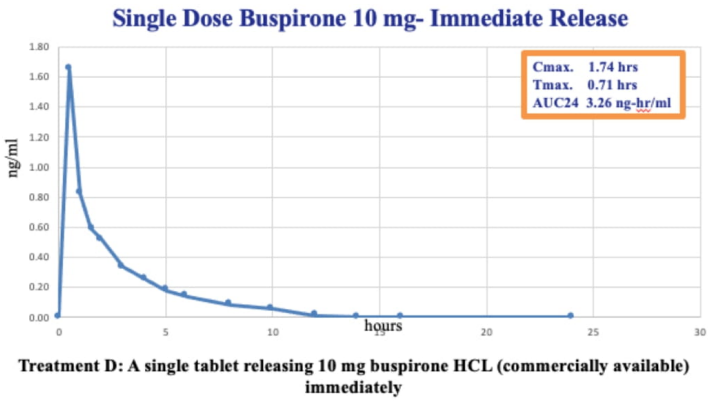
CINGULATE®

The Cingulate Solution for Anxiety Patients & Providers

CING-US-117-1123

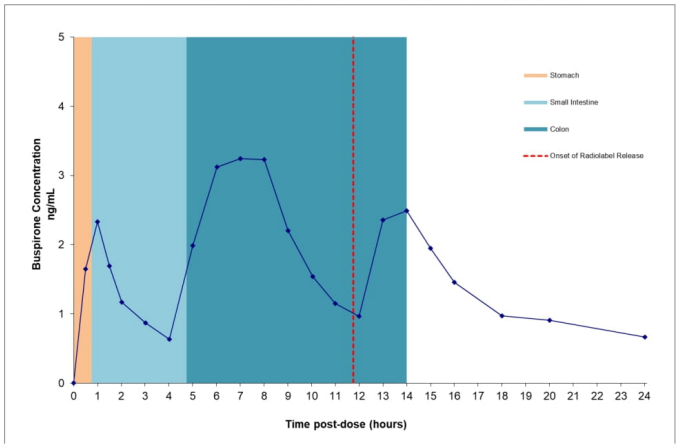
CTx-2103 – Buspirone HCl for the Treatment of Anxiety

Next-Generation Buspirone designed to Improve Patient Outcomes



Treatment D: A single tablet releasing 10 mg buspirone HCL (commercially available) immediately

CTx-2103 Trimodal Tablet



Exclusivity: IP, Agreements, and Trade Secrets

Intellectual property rights expected to provide exclusivity through 2035 at a minimum

- OralogiK™ Erosion Barrier Layer
  - Five (5) patents granted (US & Global) expiry dates ranging from 2031 to 2035,
  - One (1) OralogiK™ patent pending (US, Europe)
- Three (3) Cingulate product specific patents under prosecution with USPTO and global entities
  - Pharmacokinetics
  - Trimodal release of API
  - Pharmacodynamics
  - Formulation, Precise Timing, Ratio of API

Exclusivity agreements

- Compression technology exclusivity for branded Cingulate products
- Significant modifications and exclusive process technologies incorporated

Trade Secrets

- Methods, tools, processes, designs, and equipment trade secrets

Cingulate Mission

Develop…

Shape market acceptance, and…

Prepare to commercialize next-generation drug candidates…

Where currently prescribed standard-of-care treatments result in suboptimal outcomes for all stakeholders

Achievement Drives Shareholder and Team Member Value

CINGULATE®

Thank You