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):
January 5, 2023

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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

On January 5, 2023, Jeff Conroy provided Cingulate Inc. (the "Company") with notice of his resignation from the Board of Directors. Mr. Conroy's decision to resign was not the result of any disagreement with the Company or its management on any matter relating to the Company's operations, policies or practices. Embody, Inc., a company that Mr. Conroy co-founded and for which he serves as Chief Executive Officer, is being acquired. A condition of the acquisition requires Mr. Conroy to step down from all public company boards of directors.

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 99.1 and incorporated by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	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: January 9, 2023

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

CINGULATE®

Cingulate Therapeutics

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

1Q - 2023

CING-US-118-0124

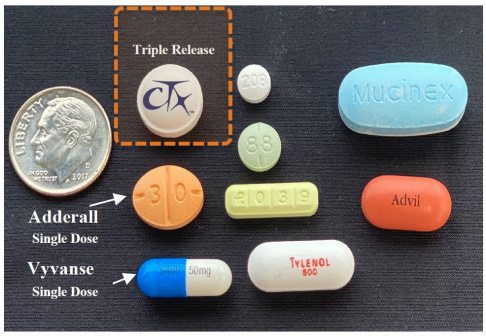
Forward-Looking Statements

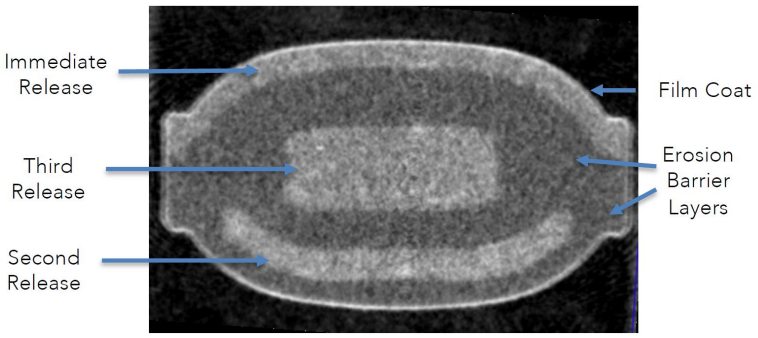
This presentation contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include all statements, other than statements of historical fact, regarding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

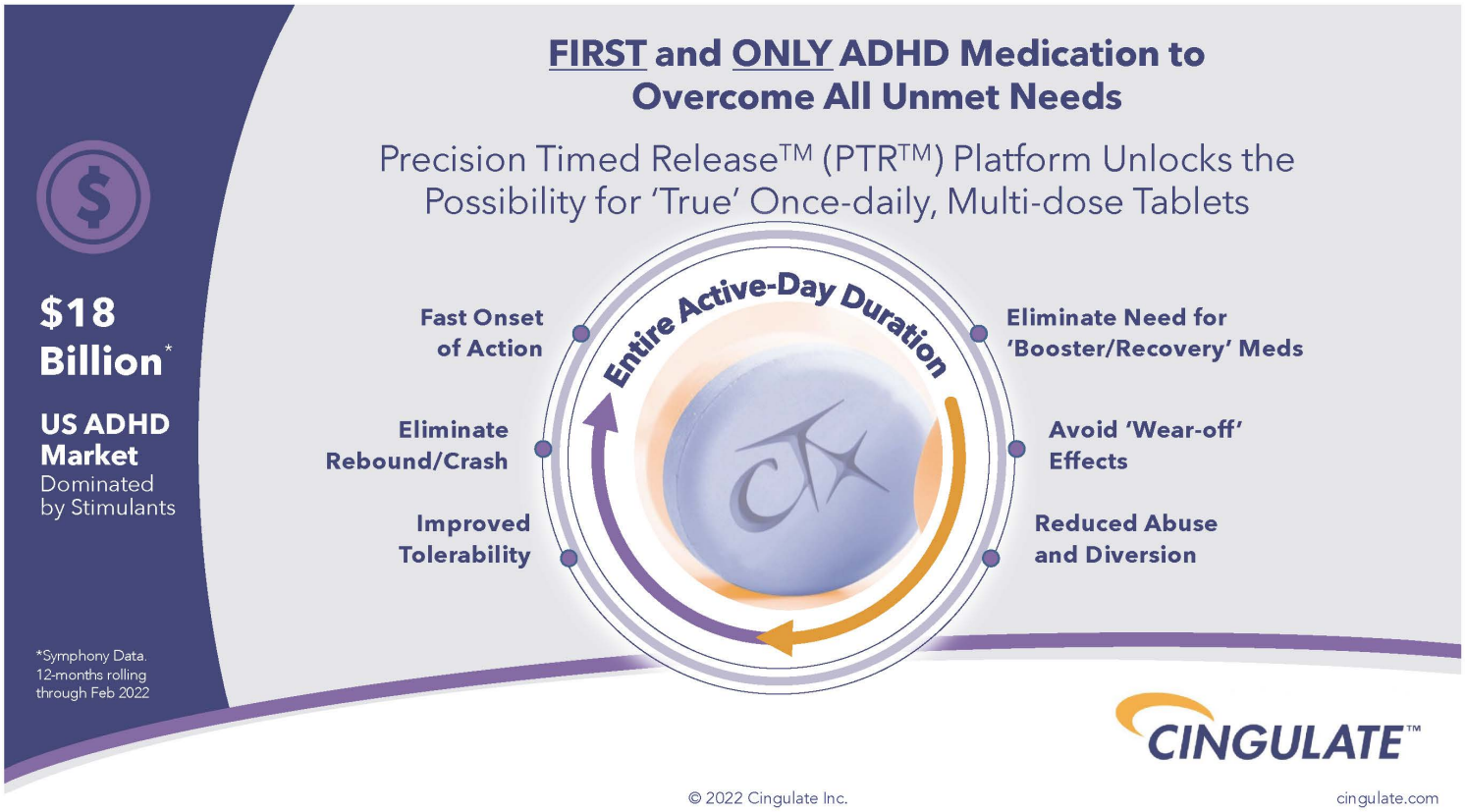
- $5Bn US market
- Buspirone is #1 non-benzodiazepine treatment
- Potential for breakthrough approval
  - PBM rebate offer to improve access
  - Improve patient outcomes
- Streamlined FDA approval pathway

Catalysts Into 2023

	1Q 2023	2Q 2023	2H 2023
ADHD CTx-1301 CTx-1302	➢ Food Effect Clinical Study Report ➢ 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 Formulation Study 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
Entire Active-Day Duration
Fast Onset of Action
Eliminate Need for 'Booster/Recovery' Meds
Eliminate Rebound/Crash
Avoid 'Wear-off' Effects
Improved Tolerability
Reduced Abuse and Diversion
CINGULATE™
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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

Stimulants 91%
of US Market $15.3Bn[1]

70 Million Prescriptions per Year[1]

Methylphenidates
- Ritalin® / LA
- Concerta®
- Focalin® / XR
- CTx-1301 (d-MPH)

Amphetamines
- Vyvanse®
- Adderall® / XR
- Dexedrine®
- CTx-1302 (d-AMP)

Non-Stimulants[1]: 9%
- Atomoxetine
- Guanfacine
- Clonidine

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-118-0124

Nine Significant Points of Differentiation

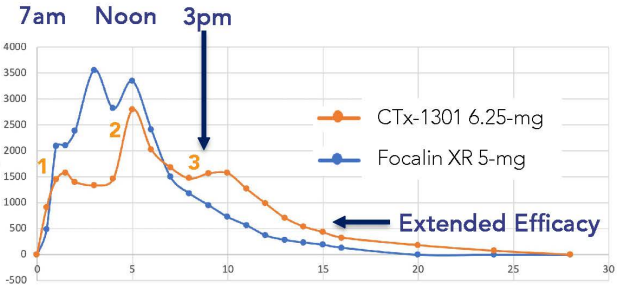
NO ADHD product available today combines all unmet needs.

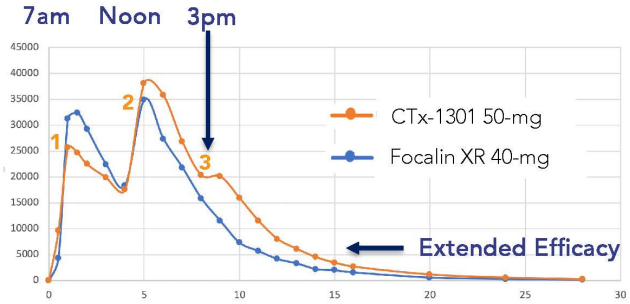
PTR™ technology affords our product candidates the following potential advantages over currently available ADHD treatments:

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

CINGULATE®

CTx-1301 Demonstrated Significantly Lower Adverse Events

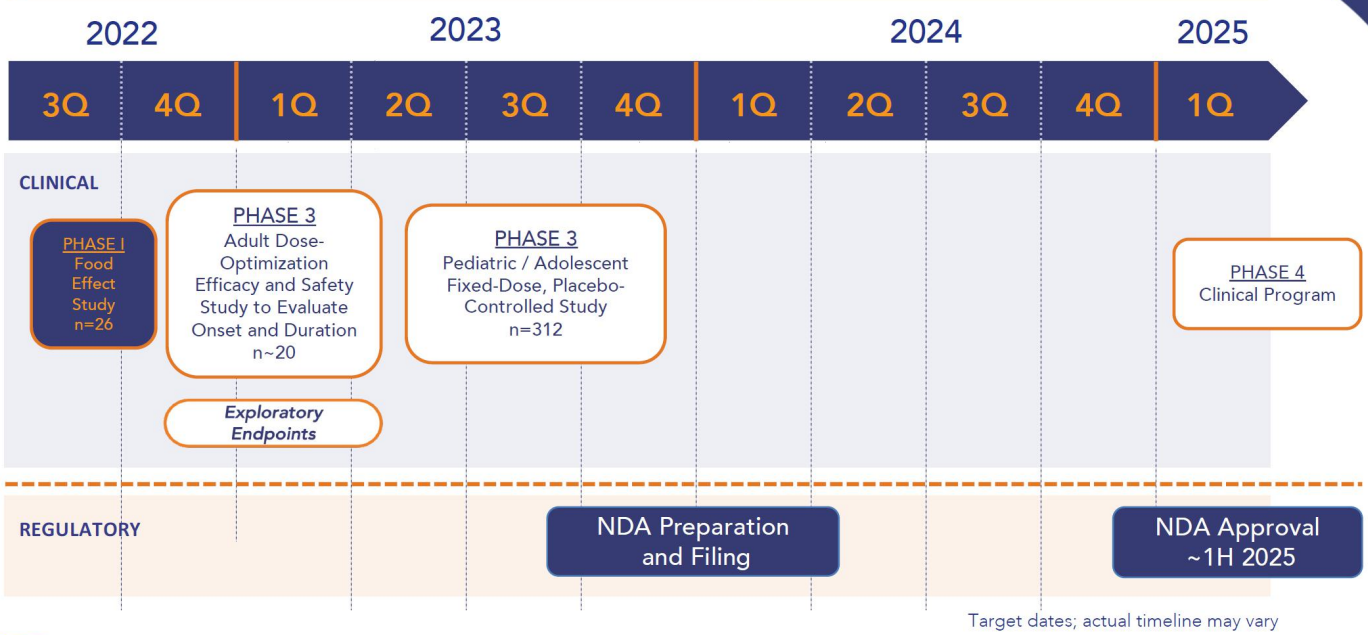
28.6% reduction in TEAE's related to CTx-1301 versus Focalin XR (14.3% difference)

	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



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

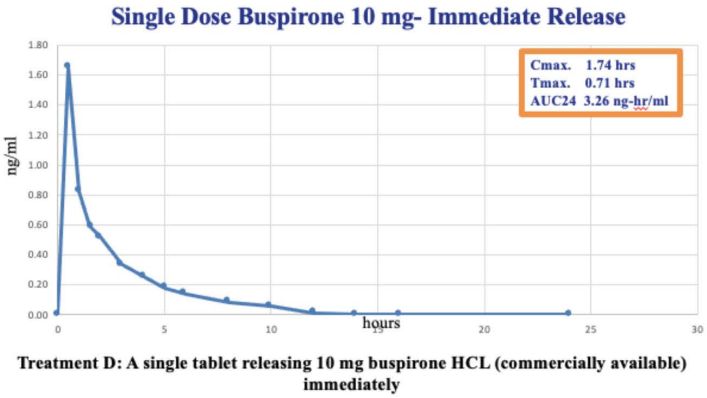
CINGULATE®

The Cingulate Solution for Anxiety Patients & Providers

CING-US-118-0124

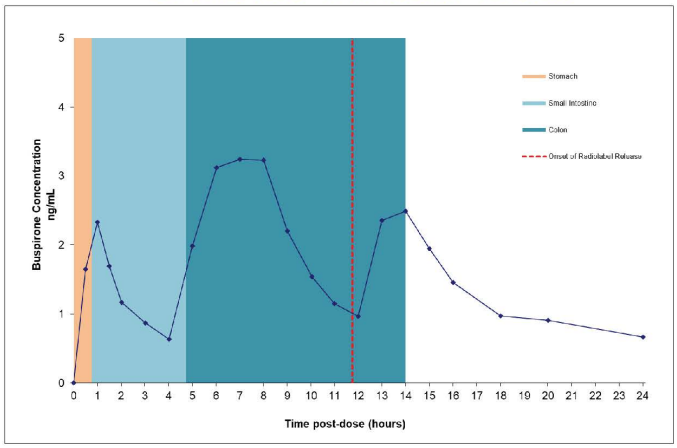
CTx-2103 – Buspirone HCl for the Treatment of Anxiety

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