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):
May 12, 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 May 12, 2022, Cingulate Inc. (the "Company") issued a press release announcing its financial results for the first 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.

The Company updated its investor presentation to be used at investor conferences and in investor meetings. A copy of the investor 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 May 12, 2022
99.2	Investor Presentation
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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: May 12, 2022

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

Exhibit 99.1

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

Announcement of First Subject Dosing for Anxiety Candidate CTx-2103 to Extend the Application of the Precision Timed Release™ Platform (PTR™)

KANSAS CITY, Kan., May 12, 2022 — Cingulate Inc. (NASDAQ: CING), a clinical-stage 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 three months ended March 31, 2022, and provided a clinical and business update, which includes the announcement of first subject dosing in its human formulation study of CTx-2103 (buspirone) for the treatment of anxiety.

"At its core, Cingulate has maintained a primary focus on addressing patients' suboptimal treatment outcomes and overcoming unmet needs due to the limitations of current standard of care treatments," said Cingulate Chief Science Officer Raul Silva, M.D. "Anxiety affects millions of individuals every day, and many of the available treatments are either addicting or abusable, of abbreviated duration, and need to be taken up to three times daily. CTx-2103 has the potential to address and remedy these shortcomings through a precise, single-dose therapeutic approach."

Clinical and Business Update

CTx-2103: Cingulate has embarked on a program to develop CTx-2103 (buspirone), which would expand the PTR platform into the anxiety therapeutic category and extend the potential of PTR technology in another indication where multiple daily doses are required and the timing, style, and ratio of this medication delivery is paramount. The Company initiated a human formulation study for CTx-2103 in May 2022 and has dosed the first subject. Results from the study are expected in July 2022, and the site for the study is BDD Pharma, Glasgow, Scotland, UK.

Buspirone is the first nonbenzodiazepine anxiolytic introduced for the treatment of generalized anxiety disorder, first synthesized in 1968 and originally patented in 1975. The original indication was for the management of anxiety disorders or the short-term relief of anxiety. The efficacy of buspirone has been demonstrated in generalized anxiety disorder (GAD) and may also be used for the treatment of other neurological and psychiatric disorders.

CTx-2103 will be designed as a once-daily, multi-dose tablet with what the Company believes will be clear differentiation and compelling advantages over standard treatment options. In 2021, the US anxiety market exceeded $5.5 Bn with buspirone sales of nearly $2Bn.

CTx-1301: Cingulate has designed its clinical program for CTx-1301 (dexmethylphenidate), the Company's lead investigational asset for the treatment of Attention Deficit/Hyperactivity Disorder (ADHD), based on U.S. Food and Drug Administration (FDA) feedback regarding its CTx-1301 initial Pediatric Study Plan (iPSP), and longstanding guidance on the accelerated approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

Cingulate plans to commence two CTx-1301 Phase 3 clinical studies in 2022: (1) a fixed-dose pediatric and adolescent safety and efficacy study, with dosing of the first patient targeted in the second half of 2022, and (2) a pediatric safety and efficacy dose-optimization study to assess the onset and duration of efficacy, also targeted to begin in the second half of 2022. Cingulate has experienced certain manufacturing delays; its contract manufacturing organization (CMO) has experienced operational resource issues in the manufacturing and delivery of clinical supply for the CTx-1301 fixed-dose study. This has delayed the first patient dosed, initially targeted for the second quarter of 2022. Manufacturing of the final two dosage strengths is expected to begin in the second or third quarter of this year. Results from the fixed-dose study are expected in late 2022/early 2023. Assuming Cingulate receives positive clinical results from its Phase 3 trials, the Company still plans to submit a New Drug Application (NDA) for CTx-1301 in late 2023 under the Section 505(b)(2) pathway.

In order to achieve the filing of our NDA for CTx-1301 in late 2023 for potential FDA approval, Cingulate believes that it will need approximately $21.5 million of additional capital, which amount has increased approximately $6.5 million from the original estimate due primarily to an estimated six months of additional operating expenses resulting from the manufacturing delay described above. Inflation and additional clinical site expenses and manufacturing costs are also expected. Cingulate will also need additional capital to advance its other programs. The Company is evaluating alternatives to raise additional capital, including equity and debt financing and non-dilutive strategic collaborations in the U.S. and abroad. In addition, Cingulate continues to evaluate commercial collaborations and strategic relationships with established pharmaceutical companies, which would provide more immediate access to marketing, sales, market access and distribution infrastructure.

CTx-1302: Cingulate plans to initiate a Phase 1/2 bioavailability study in ADHD patients for CTx-1302 (dextroamphetamine), its second investigational asset for the treatment of ADHD, in 2023 and, if the results from this study are successful, the Company plans to initiate pivotal Phase 3 clinical trials in all patient segments for CTx-1302 in late 2023 with results expected in late 2024.

First Quarter Results

Cash Position: As of March 31, 2022, Cingulate had $12.6 million in cash and cash equivalents, as compared to $16.5 million in cash and cash equivalents as of December 31, 2021. Cash and cash equivalents as of March 31, 2022, reflect the net proceeds of the Company's IPO of approximately $20.4 million, which closed on December 10, 2021, less development and operating expenses which occurred in late 2021 and the first quarter of 2022. Based on the Company's current operating plan, Cingulate expects its cash and cash equivalents as of March 31, 2022, will enable the Company to fund its research and development and general and administrative expenditures through late 2022.

R&D Expenses: Research and development expenses were $2.8 million for the three months ended March 31, 2022, compared to $0.6 million for the same period in 2021. Development activity has been increasing since late 2021 as the Company is active in study start-up phase of a Phase 3 clinical study, the fixed-dose pediatric and adolescent safety and efficacy study for CTx-1301. In addition, manufacturing the Phase 3 clinical supply for this study began in the first quarter of 2022. The Company has also incurred costs in the first quarter of 2022 relating to a human formulation study for CTx-2103.

G&A Expenses: General and administrative expenses were $2.2 million for the three months ended March 31, 2022, compared to $0.8 million for the same period in 2021. This increase relates to 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 $5.0 million for the three months ended March 31, 2022, compared to $1.3 million for the same period in 2021. This increase relates to the increased development activity as well as the increase in G&A expenses relating to additional costs to operate as a public company, both described above.

About Cingulate®

Cingulate Inc. is a clinical-stage 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.

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

	March 31, 2022	Dec. 31, 2021
Cash, cash equivalents and short-term investments	$ 12,615,113	$ 16,493,678
Working capital	12,942,662	17,705,601
Total assets	18,432,681	22,886,257
Total liabilities	2,414,080	2,042,715
Accumulated deficit	(56,735,775)	(51,732,264)
Total stockholders' equity	16,018,601	20,843,542

Cingulate Inc.
Consolidated Statements of Operations

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 2,762,284	$ 562,519
General and administrative	2,247,060	767,645
Operating loss	**(5,009,344)**	**(1,330,164)**
Interest and other income (expense), net	5,833	(3,759)
Loss before income taxes	(5,003,511)	(1,333,923)
Income tax benefit (expense)	-	-
Net loss	$ (5,003,511)	$ (1,333,923)
Net loss per share of common stock, basic and diluted	$ (0.44)	N/A
Weighted average number of shares used in computing net loss per share of common stock, basic and diluted	11,309,412	N/A

Investor Relations

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CINGULATE®

Cingulate Therapeutics

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

May 2022

CING-US-107-0523

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.

Cingulate Mission

Cingulate will develop, shape market acceptance, and prepare to commercialize next-generation drug candidates in markets where currently prescribed standard-of-care treatments result in suboptimal outcomes for all stakeholders

Achievement Drives Shareholder and Team Member Value

- ✓ Proprietary Precision Timed Release™ (PTR™) platform unlocks the possibility for 'true' once-daily, multi-dose tablets
- ✓ Lead pipeline candidates target $15.3Bn* ADHD stimulant market designed to provide substantial benefits addressing the shortcomings of currently available therapies by offering:
  - ✓ **'Entire active-day'** duration and **fast onset of action**
  - ✓ **Elimination** of need for a **'booster/recovery' dose** of short-acting stimulant medication
  - ✓ **Improved tolerability** including minimization or **elimination of rebound/crash** symptoms associated with early medication **'wear-off,'** and
  - ✓ **Reduced abuse and diversion** by eliminating the need for short-acting stimulant booster doses
- ✓ CTx-1301, pivotal, fixed-dose study is slated to begin in the second half of 2022. New Drug Application expected in the late 2023 via 505(b)(2) development pathway
- ✓ PTR™ pipeline candidates to leverage technology in multitude of other $1Bn+ potential indications

CINGULATE®

*Symphony Data. 12-months rolling through Feb 2021

Targeting Treatment of ADHD - $18Bn US Market Opportunity

Frequently diagnosed, chronic pattern interfering with functioning / development

~17 Million US ADHD Patients

Adult ADHD

- ~11M patients in the US and growing (65% of children with ADHD become Adults with ADHD)
- 4.4% of the US adult population
- ~20% receive treatment

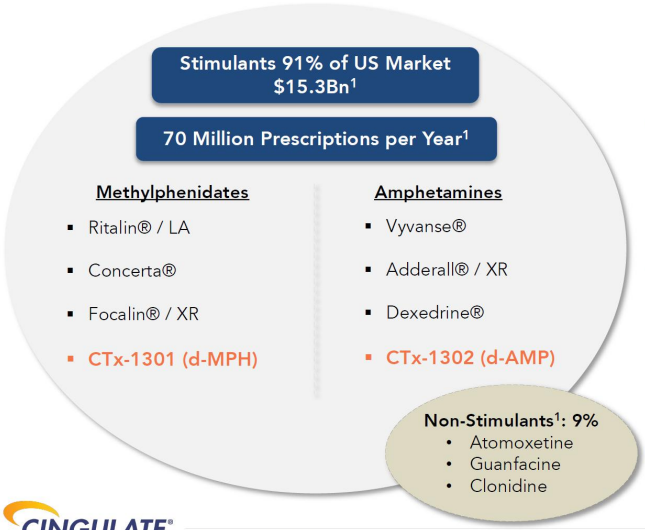
Children & Adolescents

- ~6.4M patients in the US
- 11.0% of the US under 18 population
- ~80% receive treatment

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.

$18 Billion US ADHD Market Dominated by Stimulants



- ✓ Despite multitude of options, patients' needs are still not being met even by the most widely prescribed extended-release ADHD medications
- ✓ 2017 IQVIA Survey of ADHD market found over 60% of providers were currently unsatisfied with available treatment options[3]

[1] Symphony Data. 12-months rolling through Feb 2021
[2] Outside the Box: Rethinking ADD/ADHD in Children and Adults A Practical Guide; First Edition, p. 185 Thomas E. Brown, PhD
[3] Unmet Needs in the Treatment of Pediatric and Adult ADHD, J. Rakesh MD et al, Psych Congress, Sept 2017, New Orleans, LA

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	✗

$11.6B
76%
Market Share ($)[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 Feb 2021

ADHD Market Leaders Do Not Provide "Built-In Booster"

Market Leaders Stop Delivery of Medication 4-5 Hours After Administration

ADHD BRANDS	ATTRIBUTES[1]		RELEASE PROFILES[1]		
	Onset	Duration (less onset)	DOSE 1 / STYLE / TIME	DOSE 2 / STYLE / TIME	DOSE 3 / STYLE /TIME
Vyvanse®	2 hours	12 hours	100% PRODRUG SUSTAINED RELEASE OVER 2 – 3 HOURS	0	0
Adderall® XR (and generics)	1 ½ hours	10 ½ hours	50% IMMEDIATE RELEASE	50% IMMEDIATE RELEASE AT HOUR 4	0
Concerta® (and generics)	2 hours	10 hours	22% IMMEDIATE RELEASE	78% SUSTAINED RELEASE OVER 4-5 HOURS	0
Focalin® XR (and generics)	30 mins	11½ hours	50% IMMEDIATE RELEASE	50% IMMEDIATE RELEASE AT HOUR 4	0

[1] Information based upon product Package Inserts, and Summary Basis of Approvals

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

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Source: Outside the Box: Rethinking ADD/ADHD in Children and Adults A Practical Guide; First Edition, p. 185 Thomas E. Brown, PhD

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

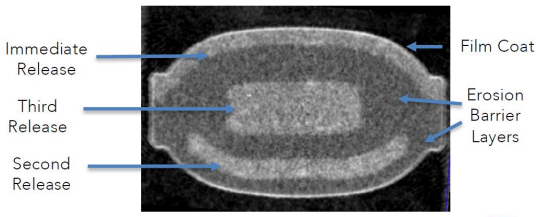
ACCOMPLISH® CTx-1302

CING-US-107-0523

Cingulate's Precision Timed Release™ Platform Technology

Disruptive Technology Changing the Paradigm of Oral Drug Delivery

- Our current pipeline candidates contain three releases of active pharmaceutical ingredient combined into one small tablet dosage form, smaller than many single dose ADHD products
- Each release is separated with a proprietary Erosion Barrier Layer (EBL), providing precise erosion that yields a consistent, predictable, and controlled drug release at prespecified time intervals
- Each of our current pipeline candidates are created using our proprietary specialized compression technology
- Manufacturing process capable of delivering real-time product release and distribution



See PTR in Action

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

CTx-1301 (d-MPH) and CTx-1302 (d-AMP)

Ideal Design Provides Exclusive Ability to Overcome Unmet Needs

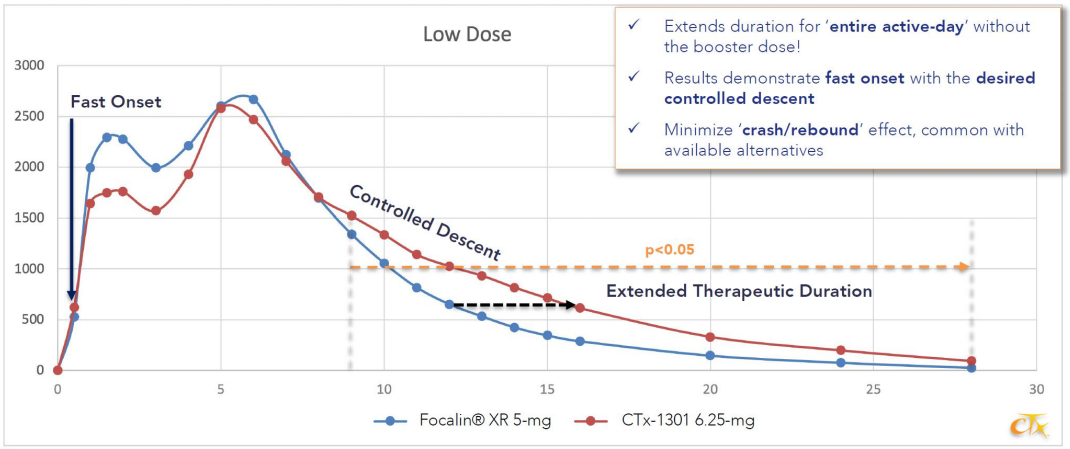
CINGULATE	TARGET ATTRIBUTES		RELEASE PROFILES		
	Onset	Duration	DOSE 1 / STYLE / TIME	DOSE 2 / STYLE / TIME	DOSE 3 / STYLE /TIME
CTx-1301 (d-MPH)	30 mins	Up to 16 hours	35% IMMEDIATE RELEASE	45% SUSTAINED RELEASE OVER 90 MINUTES AT HOUR 3	20% IMMEDIATE RELEASE AT HOUR 7
CTx-1302 (d-AMP)	30 mins	Up to 16 hours	45% IMMEDIATE RELEASE	35% SUSTAINED RELEASE OVER 90 MINUTES AT HOUR 3	20% IMMEDIATE RELEASE AT HOUR 7

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 Clinical Phase 2 Study Results

Plasma dexmethylphenidate (dMPH) Concentration vs Time

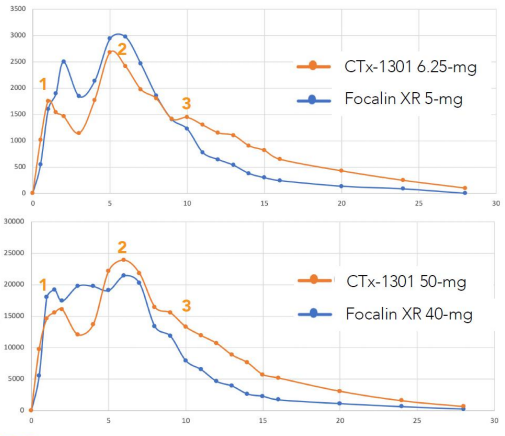


- ✓ Extends duration for '**entire active-day**' without the booster dose!
- ✓ Results demonstrate **fast onset** with the **desired controlled descent**
- ✓ Minimize '**crash/rebound**' effect, common with available alternatives

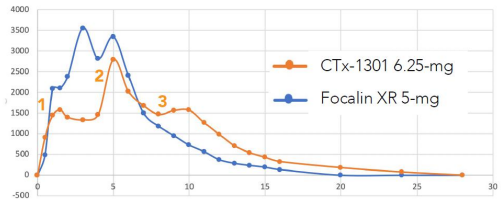
At the Individual Level, Tri-modal Delivery is Clear

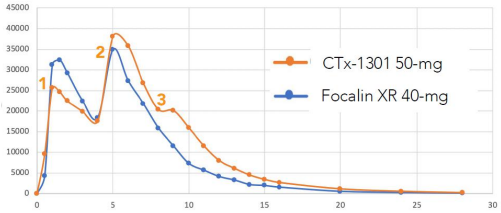
Entire Active-Day Efficacy, Stop the Crash & Rebound, Eliminate the Booster Dose

Subject ID: 01-504



Subject ID: 01-510





CTx-1301 Demonstrated Significantly Lower Adverse Events

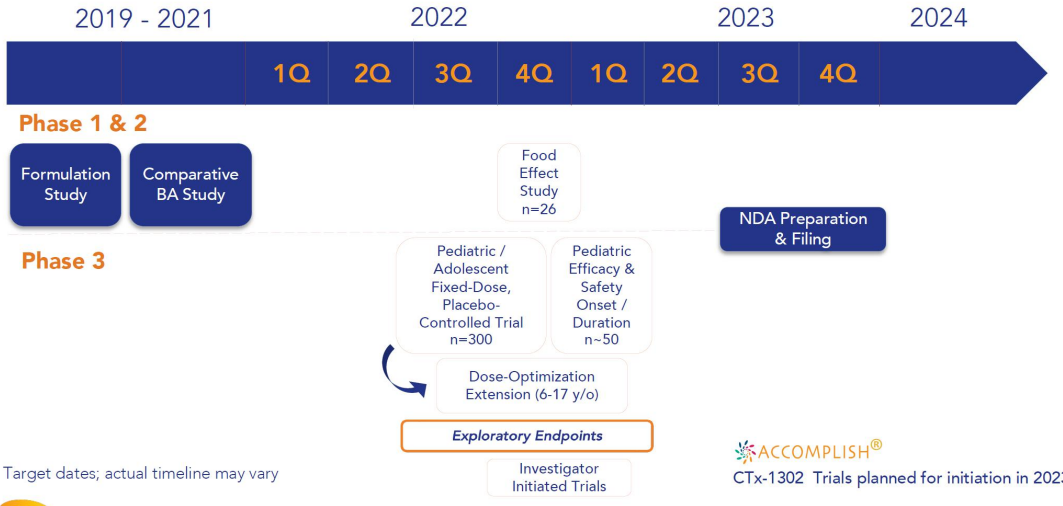
28.6% reduction in TEAE's related to CTx-1301 versus Focalin XR (14.3% difference)

	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® Planned Phase 3 Trials



Target dates; actual timeline may vary

ACCOMPLISH®
CTx-1302 Trials planned for initiation in 2023

CINGULATE®

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

- Efficacy, tolerability, 1 vs 2 Rx's, Abuse/Diversion
- *REBATES*
- 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 ~ Clinicians, Patients, & 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 Feb 2022

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

Vast Pipeline of Next-Generation Medications Beyond ADHD

- ✓ Leverage our PTR platform in other therapeutics areas
- ✓ Market Criteria:
  - $1Bn+ in peak sales
  - Next-generation mediations with significant improvement over existing therapies

Identified PTR™ Platform Pipeline Opportunities

Near-Term Focus	Future Therapeutic Areas
• CTx-2103 (buspirone) – Anxiety	• Migraine
• Insomnia	• Hypothyroidism
• Depression	• Oral Oncology Medicines
• Bipolar Disorder	• Psychosis
• Parkinson's Disease	• Alzheimer's
• Cardiovascular Disorders	• Pain (Non-Opioid)

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®

Appendix

Senior Management Team

Proven, Experienced Pharmaceutical Industry Team

Leadership team brings extensive expertise in ADHD, clinical trials, pharmaceutical development, manufacturing, commercialization, market access, and patient care. Team has led 200+ clinical trials, 300+ publications, 30+ FDA drug approvals and the management of several billion-dollar brands.

Shane J Schaffer, PharmD
Chairman & Chief Executive Officer

Pfizer · NOVARTIS · SANOFI

Matthew N Brams, MD
Chief Medical Officer

Baylor College of Medicine · Bayou City Research

Laurie A Myers, PhD MBA
Chief Operating Officer

Pfizer · NOVARTIS · DUPONT · SANOFI

Louis G Van Horn, MBA
Chief Financial Officer

EMD · Kings Entertainment · pwc

Raul R Silva, MD
Chief Science Officer

NEW YORK UNIVERSITY CHILD STUDY CENTER

Craig S Gilgallon, Esq
General Counsel & Chief Compliance Officer

Davis Polk · PGR

Board of Directors

Experienced and Accomplished Directors

Shane J Schaffer, PharmD

Chairman & Chief Executive Officer

Pfizer · NOVARTIS · SANOFI

Gregg Givens

DST MASTER COMPLEXITY™ · pwc

Jeff Hargroves

PROPHARMA GROUP®

Peter J Werth

CHEMWERTH

Jeff Conroy

EMBODY

Patrick Gallagher, MBA CFA

LAIDLAW & COMPANY

Curt Medeiros, MBA ChemE

OPTUM® · ontrak better, together

CINGULATE®

100% of Stimulants Have Been Approved

30 stimulant product approvals in ADHD over last 50+ years

Methylphenidates	Status	Approval Date
Azstarys*	**APPROVED**	March 2021
Adhansia XR*	**APPROVED**	February 2019
Jornay PM*	**APPROVED**	August 2018
Cotempla XR ODT*	**APPROVED**	June 2017
Quillichew ER*	**APPROVED**	December 2015
Quillivant XR*	**APPROVED**	September 2012
Aptensio XR*	**APPROVED**	April 2015
Daytrana*	**APPROVED**	April 2006
Focalin XR	**APPROVED**	May 2005
Methylin Chewable Tablets*	**APPROVED**	April 2003
Ritalin LA	**APPROVED**	June 2002
Focalin	**APPROVED**	November 2001
Metadate CD*	**APPROVED**	April 2001
Concerta	**APPROVED**	August 2000
Metadate ER*	**APPROVED**	June 1988
Desoxyn	**APPROVED**	Pre-1984
Ritalin	**APPROVED**	Pre-1984

Amphetamines	Status	Approval Date
Evekeo ODT*	**APPROVED**	January 2019
Evekeo	**APPROVED**	August 2018
Adzenys ER*	**APPROVED**	September 2017
Mydayis	**APPROVED**	June 2017
Adzenys XR/ODT*	**APPROVED**	January 2016
Dyanavel XR	**APPROVED**	October 2015
Zenzedi	**APPROVED**	May 2013
Procentra	**APPROVED**	January 2008
Vyvanse	**APPROVED**	February 2007
Adderall XR	**APPROVED**	October 2001
Adderall	**APPROVED**	February 1996
Dextrostat	**APPROVED**	Pre-1984
Dexedrine Spansule	**APPROVED**	Pre-1984
TRN-110 (Tris Pharma)	Phase 3 (Oct. 2019)	Projected 2021
Amphetamine Transdermal System (Noven)	Phase 2 (March 2013)	Projected 2022
ADAIR (Abuse Deterrent Amphetamine IR - Vallon)*	Phase 2 (June 2017)	Projected 2023

References: ClinicalTrials.gov, FDA Summary of Approvals, Noven Pharmaceuticals, Tris Pharma, and Vallon Pharmaceuticals

Note: Asterisks indicate stimulants used / plan to use the 505(b)2 regulatory pathway for approval