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):
February 8, 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 7.01. Regulation FD Disclosure.

On February 8, 2022, Cingulate Inc. (the "Company") issued a press release announcing updates to its 2022 clinical program for its lead candidate CTx-1301, an investigational asset for the treatment of Attention Deficit/Hyperactivity Disorder. A copy of the press release is furnished as Exhibit 99.1 and incorporated by reference.

The Company updated its investor presentation to include the updates to the 2022 clincial program for CTx-1301. 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 February 8, 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: February 8, 2022

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

Exhibit 99.1

Cingulate Provides 2022 Clinical Plan for CTx-1301, an Investigational Medication for Attention Deficit/Hyperactivity Disorder (ADHD)

Expedited Clinical Program Reduces Capital Requirements

KANSAS CITY, KS, February 8, 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 updates to its 2022 clinical program for its lead candidate CTx-1301, an investigational asset for the treatment of Attention Deficit/Hyperactivity Disorder (ADHD).

This year, the Company plans to initiate its CTx-1301 Phase 3 clinical studies: a fixed-dose pediatric and adolescent safety and efficacy study, a dose-optimization study extension, and a pediatric safety and efficacy study to assess the onset and duration of efficacy. Specifically, the pivotal, fixed-dose study is slated to begin in the second quarter of 2022. These studies will be conducted in the United States (U.S.) and are instrumental for the filing of the New Drug Application to the U.S. Food and Drug Administration (FDA), expected in the second half of 2023.

Based on feedback from the FDA regarding the CTx-1301 initial Pediatric Study Plan (iPSP), and longstanding guidance on the 505(b)(2) pathway, Cingulate has accelerated its study timeline, with a strong likelihood of reducing capital requirements by condensing the number and design of studies, therefore potentially reducing its time to approval.

“We are determined to bring our lead candidate, CTx-1301, to market as efficiently as possible, within the FDA regulatory pathway for a 505(b)(2) drug. The expedited timeline of our clinical trials will allow us to commercialize our products more quickly, addressing the significant unmet needs in the ADHD market, and ultimately improving patient outcomes,” said Shane J. Schaffer, Cingulate Chairman and Chief Executive Officer. “These studies allow Cingulate to compile a robust data set for our FDA filing, providing clinicians and payers clear evidence of the potential benefits of CTx-1301.”

About Attention Deficit/Hyperactivity Disorder (ADHD)

Attention Deficit/Hyperactivity Disorder (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 percent demonstrating clinical ADHD symptoms that persist into adulthood. Adult ADHD prevalence is estimated at approximately 11 million patients (4.4 percent), double the size of the child and adolescent segment combined, however, only an estimated 20 percent receive treatment.

Although there is no single medical, physical, or genetic test for ADHD, qualified mental health care professionals and physicians can provide a diagnostic evaluation after gathering information from multiple sources, including: ADHD symptom checklists, standardized behavior rating scales, detailed histories of past and current functioning, and information obtained from family members or significant others who know the person well. Some practitioners will also conduct tests of cognitive ability and academic achievement to rule out a possible learning disability.

About Cingulate®

Cingulate Inc. (NASDAQ: CING), 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 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 prospectus filed with the SEC on December 9, 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.

# # #

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Exhibit 99.2

CINGULATE®

Cingulate Therapeutics

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

1Q 2022

CING-US-104-0223

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.

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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 quarter of 2022. New Drug Application expected in the second half of 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

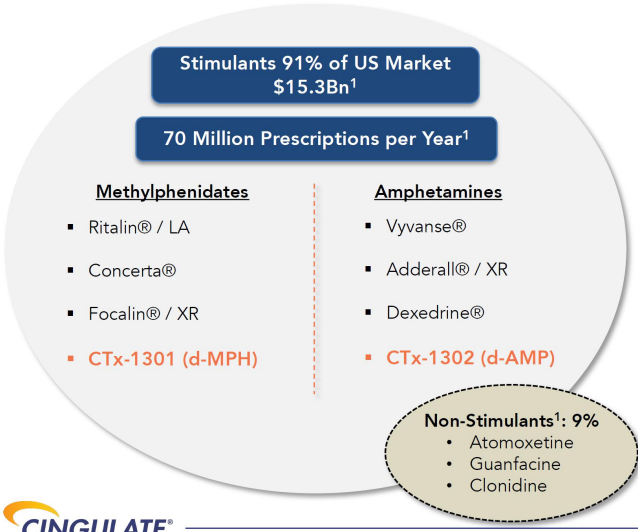
- ~6.4M patients in the US
- 11.0% of the US under 18 population
- ~80% receive treatment

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

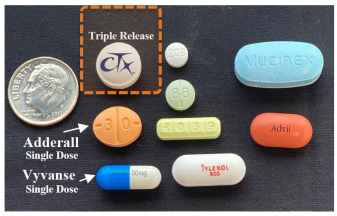
ACCOMPLISH® CTx-1302

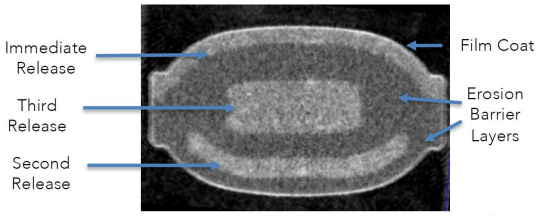
CING-US-104-0223

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





Unmet Needs Persist in ADHD

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

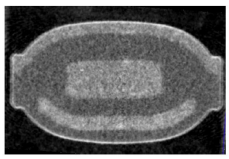
PTR technology affords our product candidates the following potential advantages over currently available ADHD treatments

- ✓ 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 (dMPH) and CTx-1302 (dAMP)

Ideal Design Provides Exclusive Ability to Overcome Unmet Needs

CINGULATE	TARGET ATTRIBUTES		RELEASE PROFILES		
	Onset	Duration (less onset)	DOSE 1 / STYLE / TIME	DOSE 2 / STYLE / TIME	DOSE 3 / STYLE /TIME
CTx-1301	30 mins	14-16 hours	35% IMMEDIATE RELEASE	45% SUSTAINED RELEASE OVER 90 MINUTES AT HOUR 3	20% IMMEDIATE RELEASE AT HOUR 7
CTx-1302	30 mins	14-16 hours	45% IMMEDIATE RELEASE	35% SUSTAINED RELEASE OVER 90 MINUTES AT HOUR 3	20% IMMEDIATE RELEASE AT HOUR 7

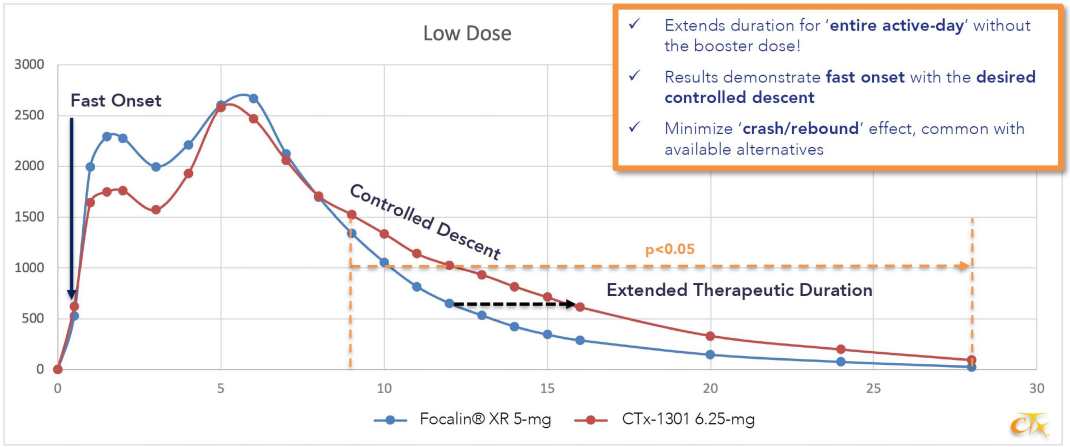


6.25-mg 12.5-mg 18.75-mg 25-mg

31.25-mg 37.5-mg 43.75-mg 50 mg

CTx-1301 Clinical Phase 2 Study Results

Plasma dexmethylphenidate (dMPH) Concentration vs Time

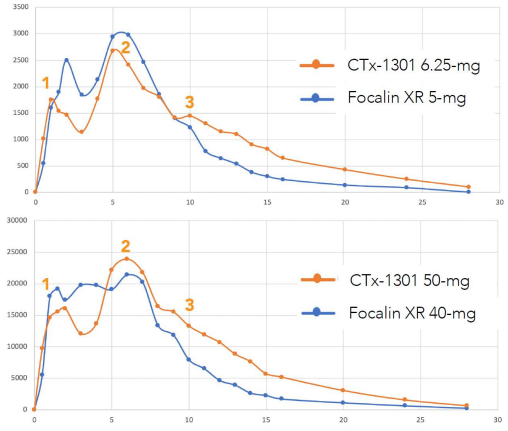


- ✓ Extends duration for '**entire active-day**' without the booster dose!
- ✓ Results demonstrate **fast onset** with the **desired controlled descent**
- ✓ Minimize '**crash/rebound**' effect, common with available alternatives

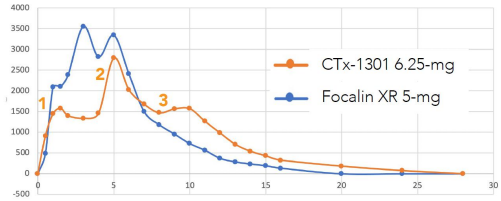
At the Individual Level, Tri-modal Delivery is Clear

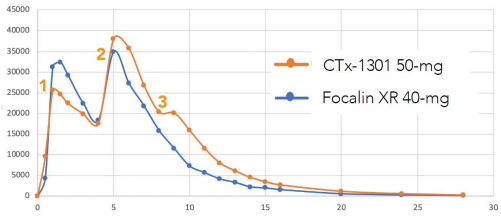
Entire Active-Day Efficacy, Stop the Crash & Rebound, Eliminate the Booster Dose

Subject ID: 01-504



Subject ID: 01-510





CTx-1301 Demonstrated Significantly Lower Adverse Events

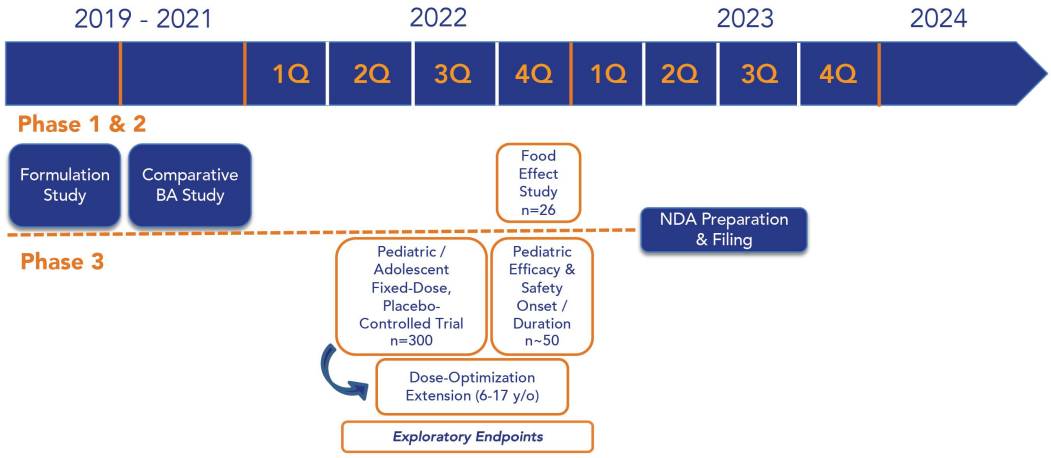
28.6% reduction in TEAE's related to CTx-1301 versus Focalin XR (14.3% difference)

	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 Strategy

Changing dynamics in ADHD commercial landscape

- Vyvanse loss of exclusivity ~August 2023
- Concerta, Adderall XR, Focalin XR are all off-patent with no promotion
- New entrants lack major promotional efforts, field forces and revenue
- PBM's driven by rebate guarantees to payers; estimated at $3B last year*

ADHD is a high brand utilization market with high-cost generics at 55-90% of branded drug cost*

Cingulate goal:

- **Branded product of choice ~ Clinicians & Payers**
- **Dominate share of voice**
- **Strategic partnership with an established pharma player**
  - Psychiatry / Neurology & Pediatrics / Family Practice encompass 84% of ADHD market*
  - Specialty sales force of 125-150 professionals to communicate with neurology and psychiatry prescribers
  - Additional 125-150 professionals required, especially at launch, to communicate with pediatricians and family practice

*Symphony Data. 12-months rolling through Feb 2021

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)
- Two (2) 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
• Anxiety	• Migraine
• Insomnia	• Hypothyroidism
• Depression	• Oral Oncology Medicines
• Bipolar Disorder	• Psychosis
• Parkinson's Disease	• Alzheimer's
• Cardiovascular Disorders	• Pain (Non-Opioid)

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

- ✓ Ensure the Company has the financial resources to execute our key corporate drivers
  - ✓ $15M in additional capital provides ability for Cingulate to submit New Drug Application for its lead asset, CTx-1301
  - ✓ Strategic partnership, Outside US licensing, equity raise, debt, etc.
- ✓ Further validate the Precision Timed Release™ (PTR™) Platform to drive immediate and future success
- ✓ Execute the CTx-1301 Regulatory and Clinical Trial Plan
- ✓ Enlighten the ADHD and Financial Markets to the Cingulate Value Propositions