



# Cingulate Therapeutics

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

1Q - 2023



# Forward-Looking Statements

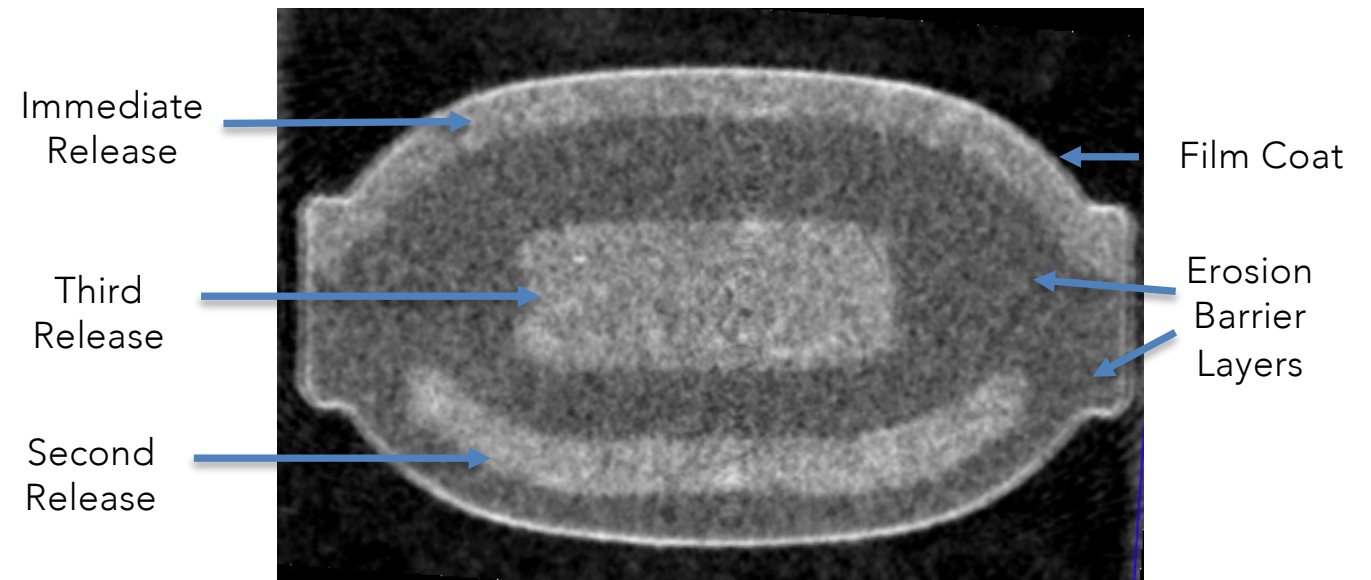
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This presentation contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include all statements, 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](#)

# 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

## ADHD

CTx-1301

CTx-1302

1Q 2023

- Food Effect Clinical Study Report
- CTx-1301 Adult Onset / Duration Efficacy Trial

2Q 2023

- Onset / Efficacy Trial Data
- Initiate Pivotal Phase 3 in Adolescents and Children

2H 2023

- 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

CING-US-118-0124

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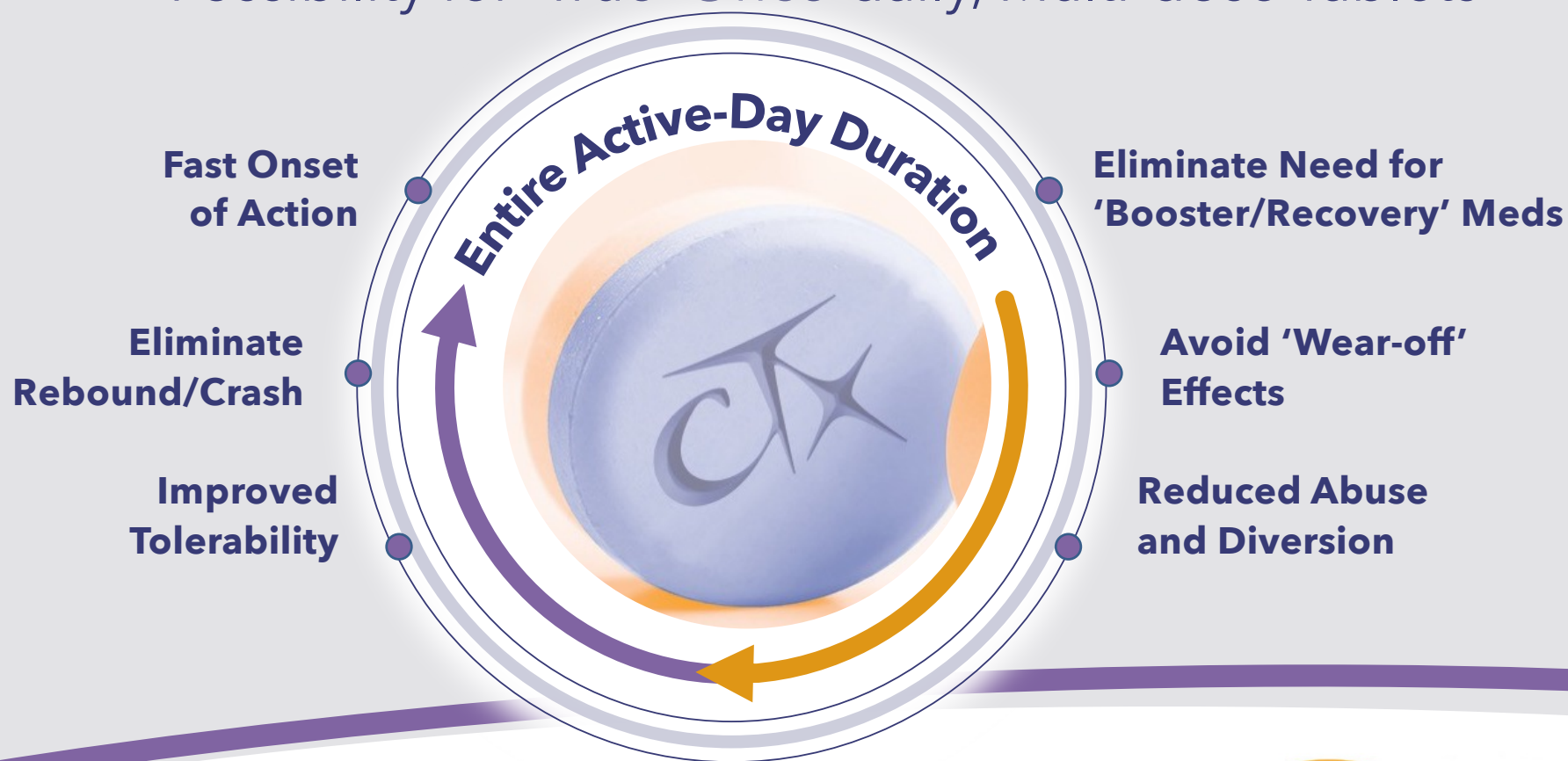
**\$18  
Billion\***

**US ADHD  
Market**  
Dominated  
by Stimulants

\*Symphony Data.  
12-months rolling  
through Feb 2022

## **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



**CINGULATE™**

# 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<sup>1</sup>

**70 Million Prescriptions per Year<sup>1</sup>**

## Methylphenidates

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

## Amphetamines

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

**Non-Stimulants<sup>1</sup>: 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 <sup>1</sup>		UNMET NEEDS <sup>1</sup>			
		Onset	Duration (less onset)	Fast Onset of Action ≤ 30 min	Entire Active-Day Efficacy*	Minimize Crash/Rebound	Avoid Booster <sup>2</sup>
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 (\$)<sup>2</sup>**

\* 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

<sup>1</sup> 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.

<sup>2</sup> 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 <sup>1</sup>		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

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# The Cingulate Solution for ADHD Patients & Providers



# Nine Significant Points of Differentiation

**NO ADHD** product available today combines all unmet needs.

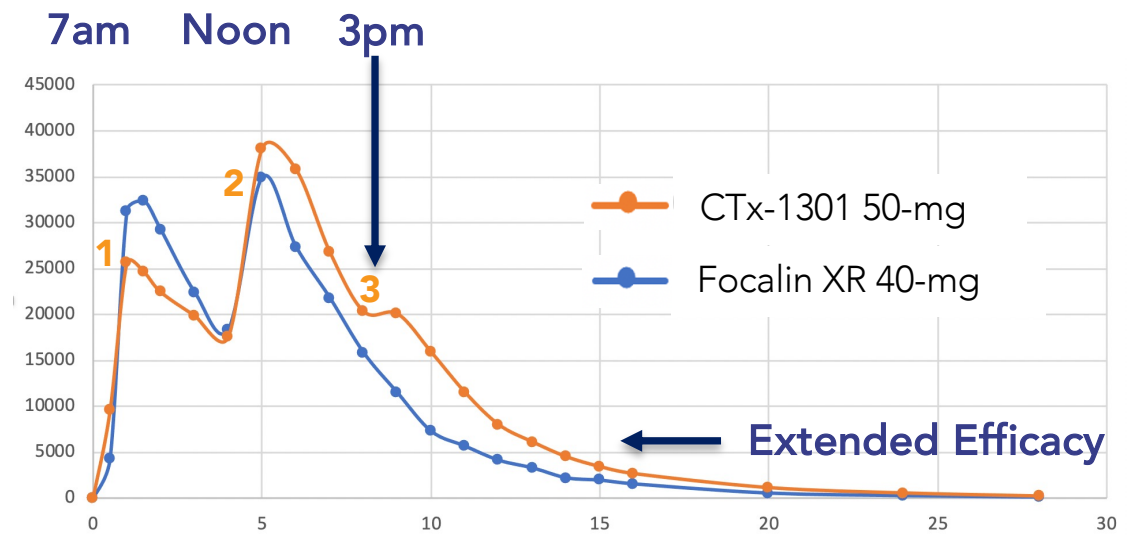
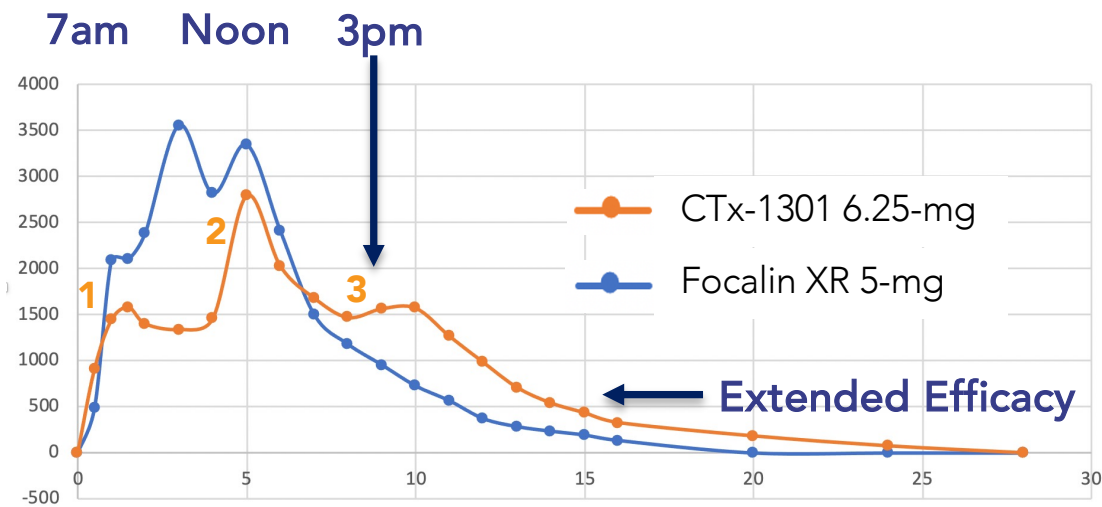
**PTR™ technology affords our product candidates the following potential advantages over currently available ADHD treatments:**




- **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



Subject ID: 01-510

	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)**

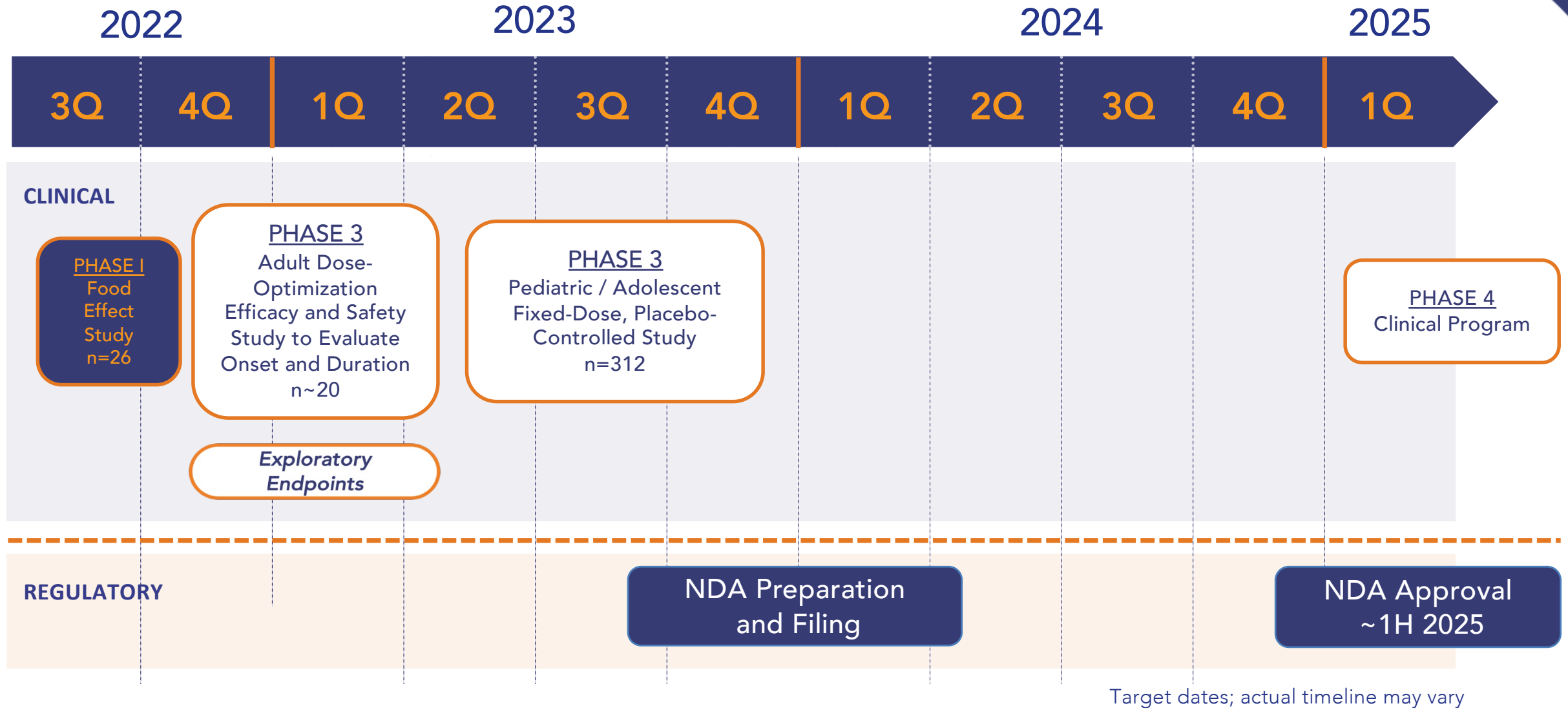
	Focalin XR 5 mg (n=41)	CTx-1301 6.25 mg (n=39)	Focalin XR 40 mg (n=43)	CTx-1301 50 mg (n=42)	All CTx-1301 (n=42)	All Focalin XR (n=44)
Patients with at least one						
Treatment Emergent Adverse Events	7 (17.1%)	4 (10.3%)	22 (51.2%)	14 (33.3%)	17 (40.5%)	25 (56.8%)
Mild	7 (17.1%)	4 (10.3%)	20 (46.5%)	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
<b>TEAE Related to Study Drug</b>	<b>5 (12.2%)</b>	<b>3 (7.7%)</b>	<b>20 (46.5%)</b>	<b>13 (31.0%)</b>	<b>15 (35.7%)</b>	<b>22 (50.0%)</b>
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<sup>®</sup> CTx-1301 Clinical and Regulatory Timeline



# 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



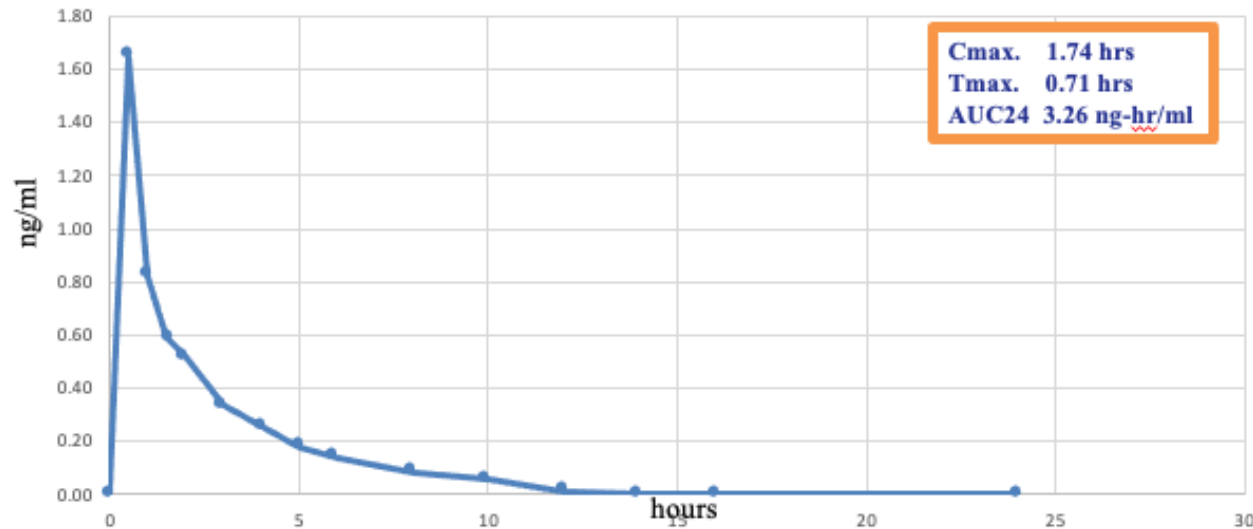


# The Cingulate Solution for Anxiety Patients & Providers

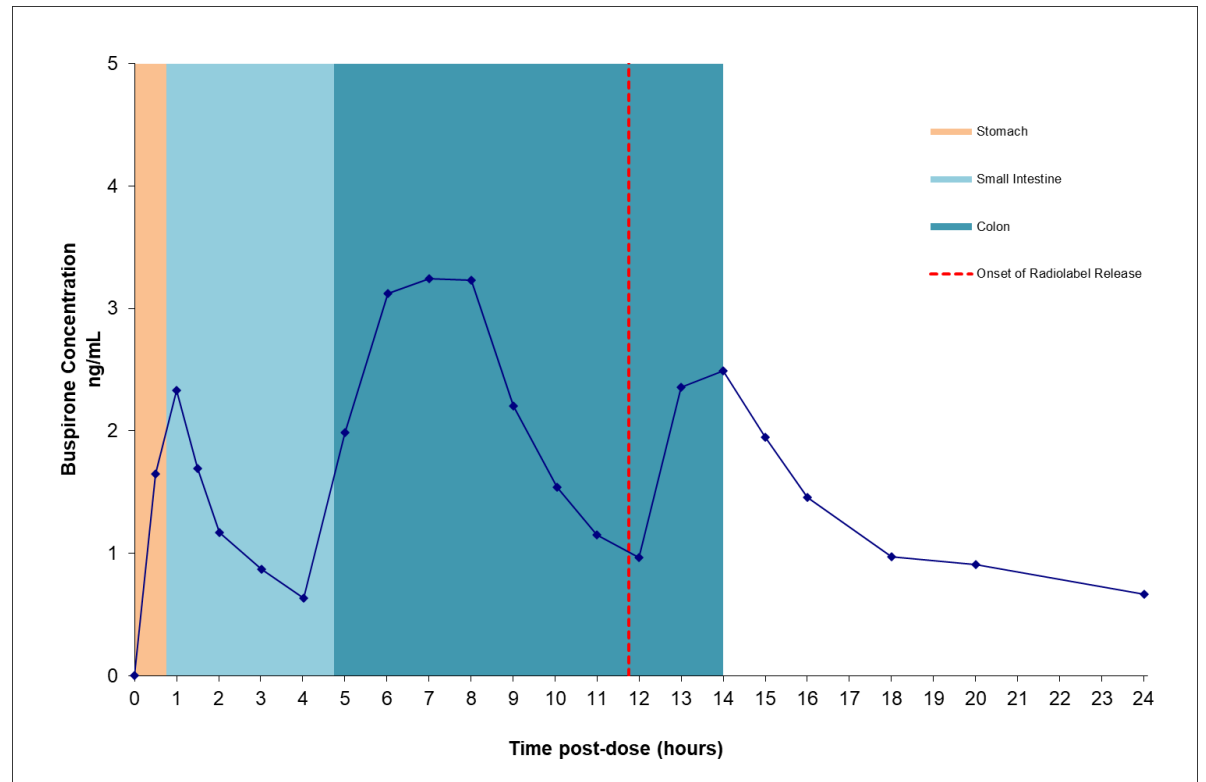
# CTx-2103 – Buspirone HCl for the Treatment of Anxiety

Next-Generation Buspirone designed to Improve Patient Outcomes  
CTx-2103 Trimodal Tablet

## Single Dose Buspirone 10 mg- Immediate Release



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



# 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
  - Pharmacodynamics
  - Trimodal release of API
  - 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

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- ✓ 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***





Thank You

