



# Cingulate Therapeutics

Developing next-generation therapeutics to address unmet needs in CNS disease

2Q 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, 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.

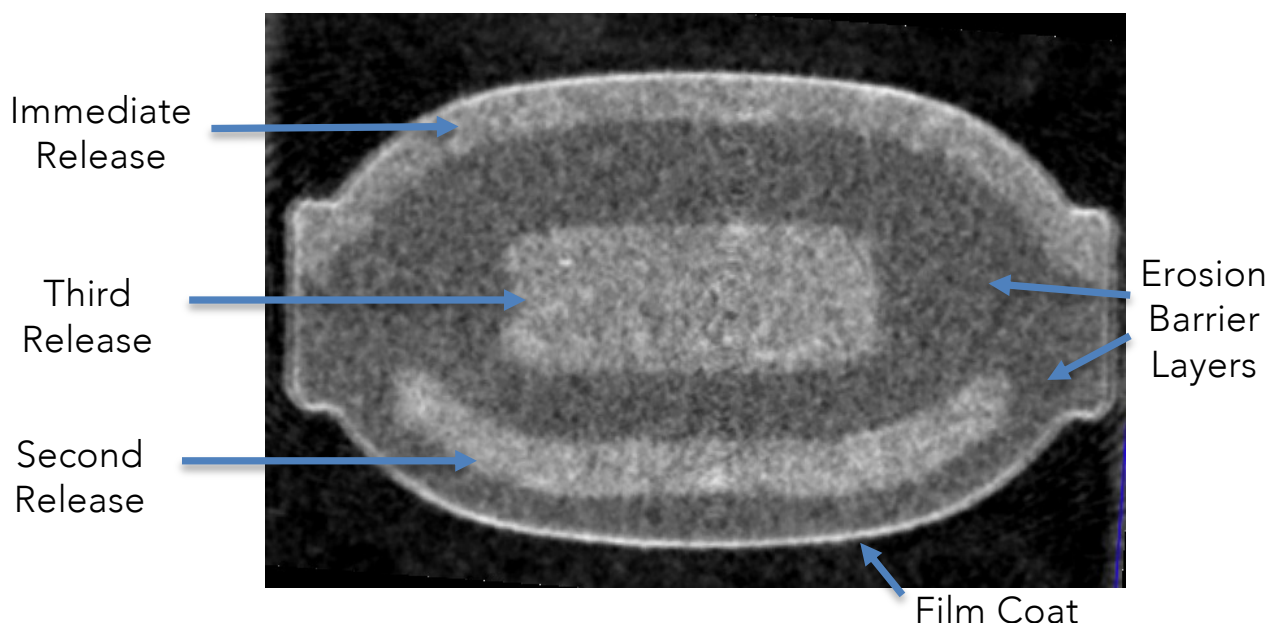
# Company Highlights

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- **Innovative Drug Delivery Platform Focused on CNS** – patented tri-modal Precision Timed Release (“PTR”) technology overcomes many of the shortcomings found in current CNS medicines.
- **Lead Asset CTx-1301 Addresses Multiple Unmet Needs in ADHD** - A once-daily, rapid onset tablet that provides entire active-day efficacy and improved tolerability.
- **Multi-Billion Dollar Market Opportunity** – total ADHD pharmacotherapy sales in 2022 exceeded \$20 billion, with over 90% from the stimulant class.
- **De-risked and Well Understood Clinical Pathway** - The 505(b)(2) clinical pathway is expected to reduce clinical risk and accelerate time to market. In addition, stimulants are well understood by FDA.
- **Strong IP Protection** - a robust patent portfolio covering the PTR drug delivery platform, composition of matter, methods, and their utility in pertinent indications, along with proprietary know-how.
- **Indegene CTx-1301 Commercialization Agreement** – Indegene will be an exclusive ADHD commercialization partner, providing rapidly scalable end-to-end solutions, including medical affairs, pharmacovigilance, pricing, reimbursement and market access services, commercial operations, and marketing services (including field force).
- **Multiple Near-Term Catalysts** – data readout for Phase 3 CTx-1301 adult onset/duration and completion of pivotal Phase 3 pediatrics MASTERY study in 2023

# 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 @  
Cingulate.com](https://www.cingulate.com)

# PTR Facilitates a Potential Pipeline Addressing Multiple CNS Indications

## Identified PTR™ Platform Pipeline Opportunities

### In Development

- ADHD (CTx-1301, 1302)
- Anxiety (CTx-2103)

### 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

- \$22+Bn US market\*
- Stimulants dominate prescription volume (90%+)\*
- Top 4 ADHD meds generic at CING launch
  - PBM rebates
  - Generics are expensive and in shortage
  - Cingulate positioned to dominate Share of Voice
- Streamlined FDA approval pathway

## Anxiety

- \$5.2 Bn US market<sup>+</sup>
- Buspirone is #1 non-benzodiazepine treatment\*
- Potential for breakthrough approval
  - PBM rebate offer to improve access
  - Improve patient outcomes
- Streamlined FDA approval pathway

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

<sup>+</sup> Symphony Data.  
12-months rolling  
through Feb 2021

# Multiple Near-Term Milestones Expected

## ADHD

CTx-1301

CTx-1302

1H 2023

- CTx-1301 Phase 1 Food Effect Clinical Data
- CTx-1301 Adult Onset / Duration Efficacy Trial

3Q 2023

- Adult Onset / Efficacy Trial Data
- Initiate Pivotal CTx-1301 Phase 3 Trial in Adolescents and Children
- CTx-1301 Ped/Adolescent Onset / Duration Efficacy Trial

4Q 2023

- Complete CTx-1301 Pivotal Phase 3 Child/Adolescent Onset / Efficacy Trial Data
- Prepare CTx-1302 For Planned Clinical Trials

## Anxiety

CTx-2103

- CTx-2103 Formulation Study Report

- CTx-2103 Potential IND
- Formulation Study Presentation
- FDA Pre-IND Meeting

## PTR™ Platform

- Expand Manufacturing Operations

- Pursue out license opportunity for PTR™ Platform
  - Potential Milestone Payments
  - Potential Royalty Payments
- Potential licensing of CTx-1301, CTx-1302, CTx-2103 outside of the United States
- Expand CING – BDD Partnership
- Expand BD&L Activities w/ PTR™



# The Cingulate Solution for ADHD Patients & Providers





# Targeting Treatment of ADHD - \$22Bn US Market Opportunity

Frequently diagnosed, chronic pattern interfering with functioning / development

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

## Stimulants 90% of Prescriptions

80 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: 10%

- Atomoxetine
- Guanfacine
- Clonidine
- Quelbree®

## 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

<sup>1</sup>Symphony Data. 12-months rolling through Sept 2022

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>1</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	✗

**\$11.6B**  
76%  
Market  
Share (\$)<sup>2</sup>

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

\* 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.

# 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 – Discontinued	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

<sup>1</sup> Information based upon product Package Inserts and Summary Basis of Approvals and  
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**\$22  
Billion\***

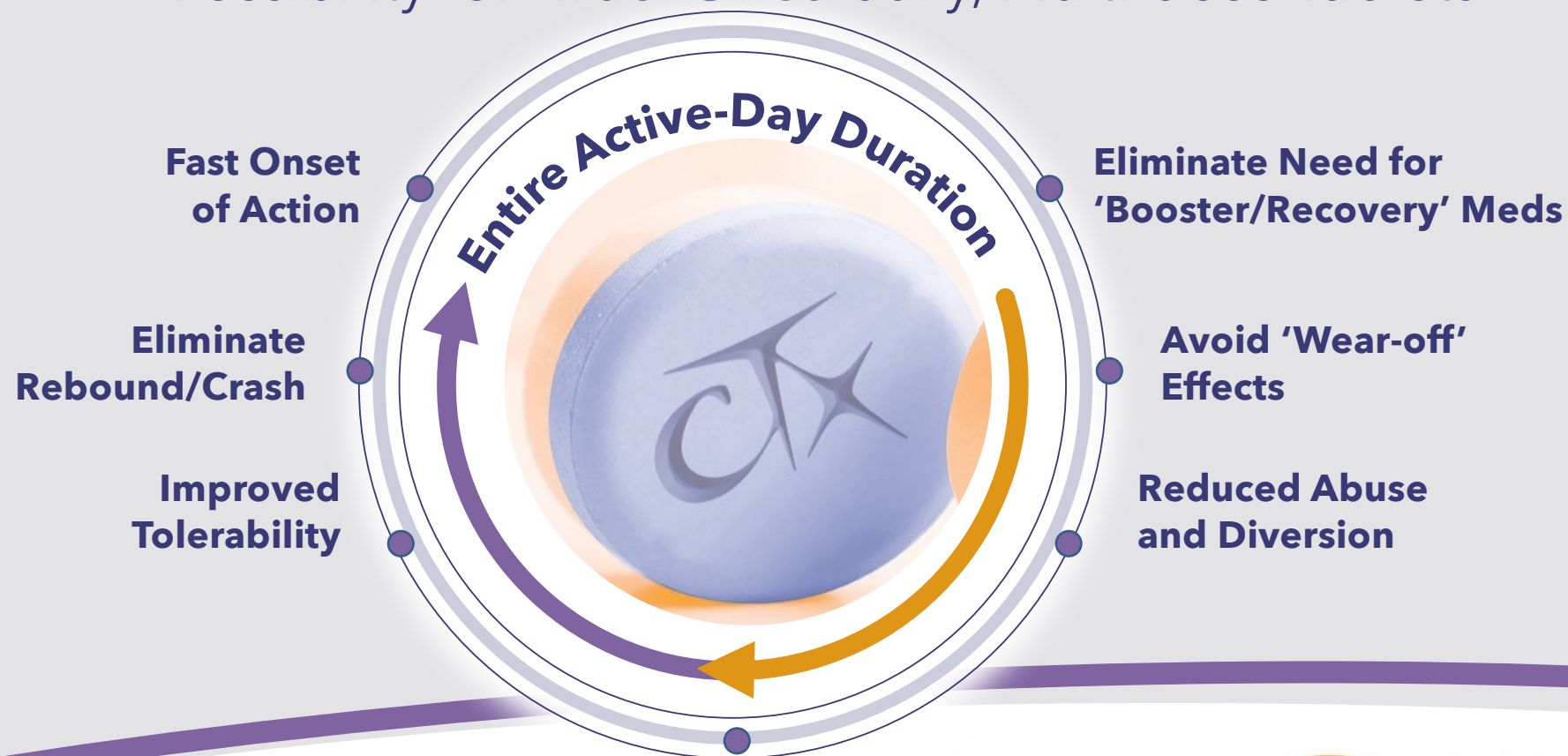
**US ADHD  
Market**

Dominated  
by Stimulants

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

## The ADHD Medication to Provide Daily Durability

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

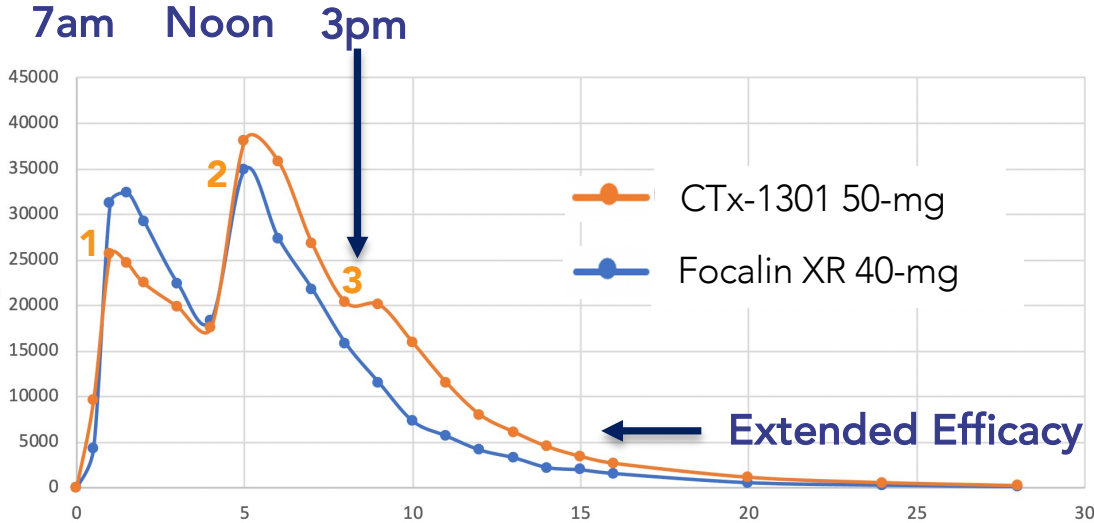
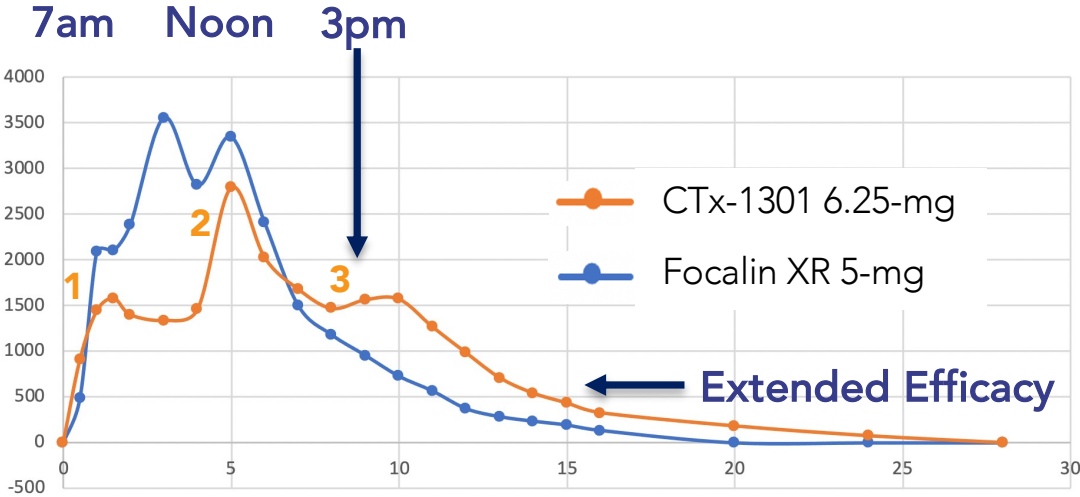


**8 Dosage Strengths at Launch to  
Optimize Treatment**


**CINGULATE™**

# One Product Designed to Overcome 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-1302 (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)**

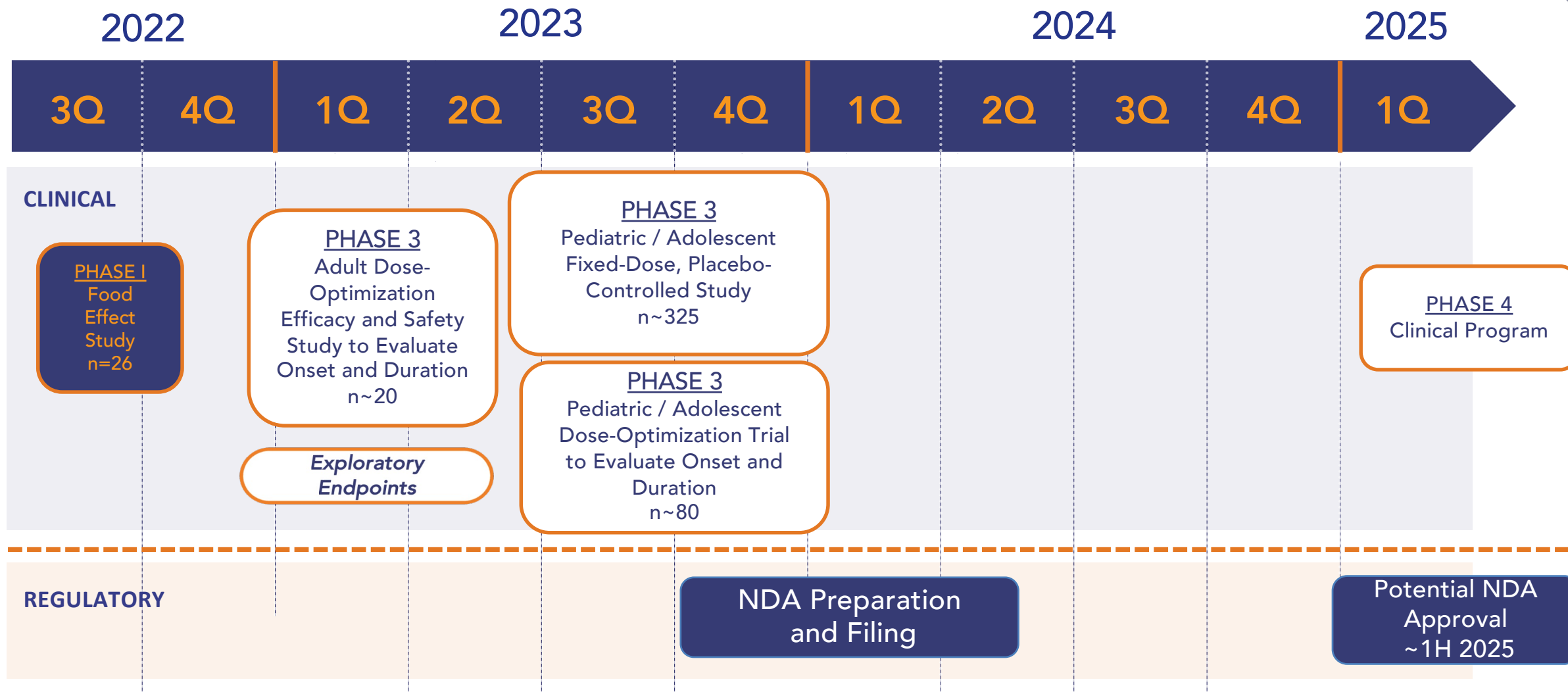
	Focalin XR 5 mg (n=41)	CTx-1301 6.25 mg (n=39)	Focalin XR 40 mg (n=43)	CTx-1301 50 mg (n=42)	All CTx-1301 (n=42)	All Focalin XR (n=44)
Patients with at least one						
Treatment Emergent Adverse Events	7 (17.1%)	4 (10.3%)	22 (51.2%)	14 (33.3%)	17 (40.5%)	25 (56.8%)
Mild	7 (17.1%)	4 (10.3%)	20 (46.5%)	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

15



Target dates; actual timeline may vary



# Commercialization Strategy

Best in Class Market Preparation and Execution





# Traditional Pharmaceutical Commercialization Is Increasingly Challenged

1 in 5

products reach peak U.S. sales of \$1B<sup>1</sup>

62%

of products launched in the last 15 years have underperformed pre-launch forecasts<sup>1</sup>

50%

of products fail to reach peak U.S. sales of \$250M<sup>1</sup>

Furthermore, a recent McKinsey study<sup>2</sup> indicated that...

50%

of Providers never plan to see a sales rep again

50%

will see a sales rep once or twice a year, three times at most

<sup>1</sup> Data on File. Indegene Inc. 2021-2022.

<sup>2</sup> McKinsey & Company, The future of HCP engagement. Supporting information from U.S. HCP research. October 2021.

# A Scalable, Comprehensive Commercial Model Represents A Better Way

## Flexible & Strategic

- Partner who shares in strategy and drives execution
- Capabilities scale up and down as needed

## Capital Efficient Model

- Minimize balance sheet investment
- Lower infrastructure costs (people, process & tech)
- Mutually Aligned Success!!!



Infrastructure



Technology



People



Data



Patient ID &  
Trial Enrollment  
Services



Regulatory  
Affairs



Medical  
Affairs &  
Medical  
Information



Safety/  
PV



Pricing,  
Market  
Access,  
Payers  
(PRMA)



Brand Strategy  
& Omnichannel  
Marketing



Field Force  
& Training



3PL  
Distribution



AOR:  
Creative &  
Content  
Services



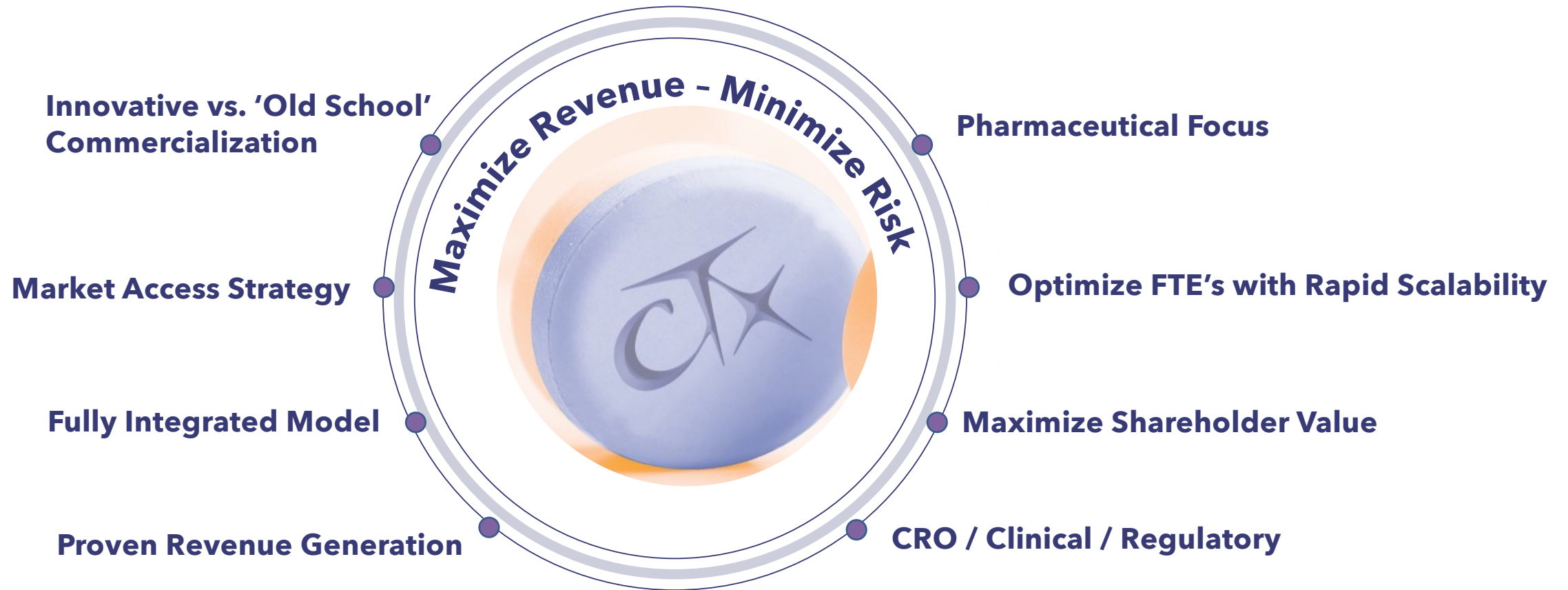
Commercial  
Operations:  
Analytics



Patient  
Services/  
Hub

# Key Decision-making Metrics

## Emerging Commercial Model



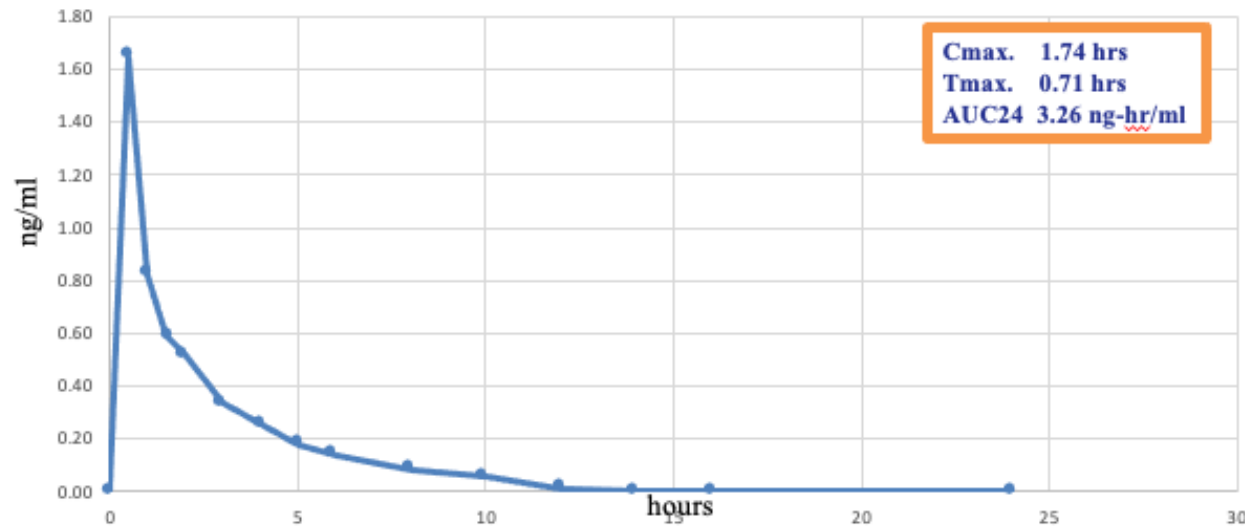


# The Cingulate Solution for Anxiety Patients & Providers

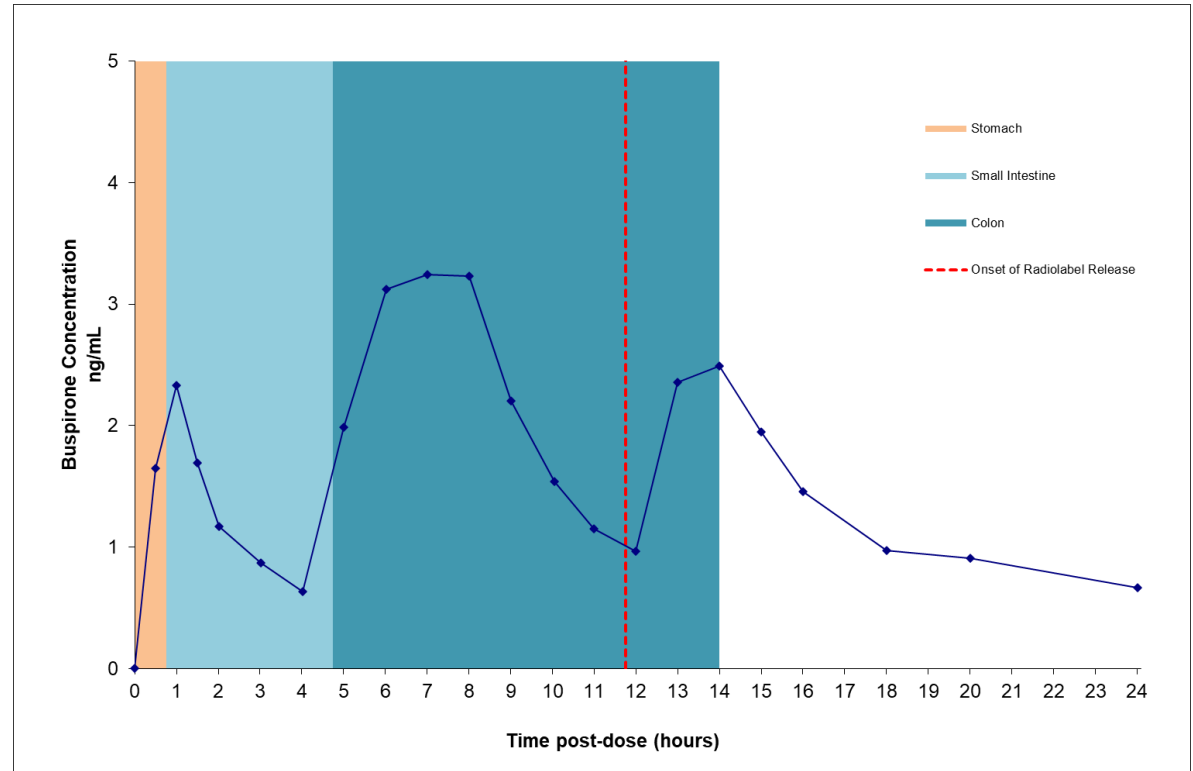
# CTx-2103 – Buspirone HCl for the Treatment of Anxiety

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

## Proprietary Know-How

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



# Why Cingulate (\$CING)

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- ✓ Near and Long-Term Future Revenue Streams
- ✓ CING is a Real Company with Multiple Assets that Solve Real Problems
- ✓ Commercialization is Built and Ready for Scale

➡ *Achievement Drives Shareholder Value*





Thank You

