



Cingulate Inc.

Developing Next-Generation Therapeutics to Address Unmet Needs in Billion Dollar Markets

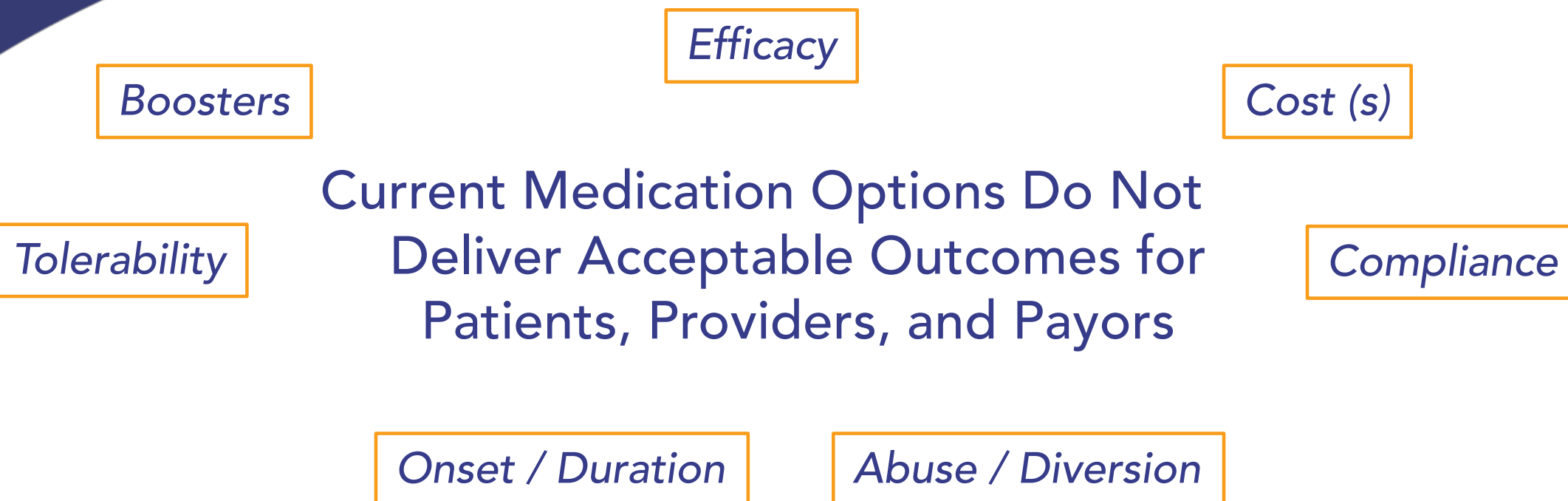
March 2024

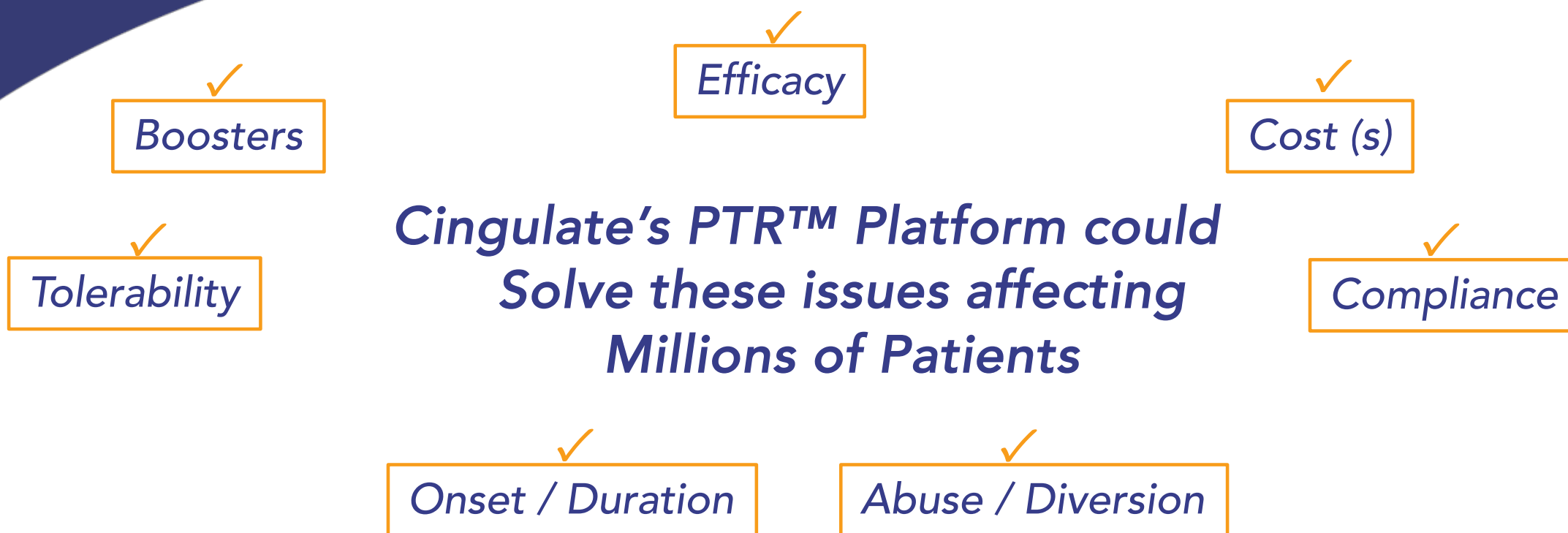


Forward-Looking Statements

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, 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.





Why Cingulate (Nasdaq: CING)

Completed & Near-Term Catalysts (CTx-1301) Multiple Long-Term Revenue Streams

- Commercialization Strategy & Execution in Place
- Impressive Phase 3 Adult Effect Size Data
- Phase 3 Pediatric & Adolescent Trials Enrollment Closed
- Planned NDA Submission in 1H'25
- PTR™ Platform: CING Assets & Out license Value
- ADHD Market \$20+ Bn in US
- Anxiety Market \$5+ Bn in US
- Ex-US License Opportunities
- IP & Exclusivity: First LOE in 2035

Experienced Leadership Team

- Proven C-Suite and Management team possessing big and small pharma expertise
- Seasoned Board of Directors – Pharma, Securities, PubCo, Finance, M&A, PRMA
- Indegene Commercial Partnership provides instant launch and scalable commercial readiness



Cingulate Business Development & Licensing

- Current Status
 - Ex-US
 - Major UK pharma company is in final stages to execute UK agreement; \$5M potential with additional \$5-10M with additional EU territories
 - EU/Middle East/Latin America pharma company nearing term sheet exchange
 - Brazilian pharma company nearing term sheet exchange
 - US
 - Commercialization agreement executed with Indegene for full service Go-To-Market and Launch execution
 - Term sheet imminent with US based company for 50/50 copromote partnership

Multiple Near-Term Milestones Expected

ADHD

CTx-1301

CTx-1302

1H 2024

- Complete Phase 3 Clinical Development Plan
- Complete Registration Batches for NDA Filing
- Ex-US Licensing

2H 2024

- NDA Preparation
- Registration Stability Data
- US Licensing BD&L

1H 2025

- File CTx-1301 New Drug Application
- Prepare CTx-1302 IND

Anxiety

CTx-2103

- US & Ex-US Licensing

- Manufacture IND-enabling clinical study supply

- Prepare & File CTx-2103 IND

- FDA Pre-IND Meeting

PTR™ Platform

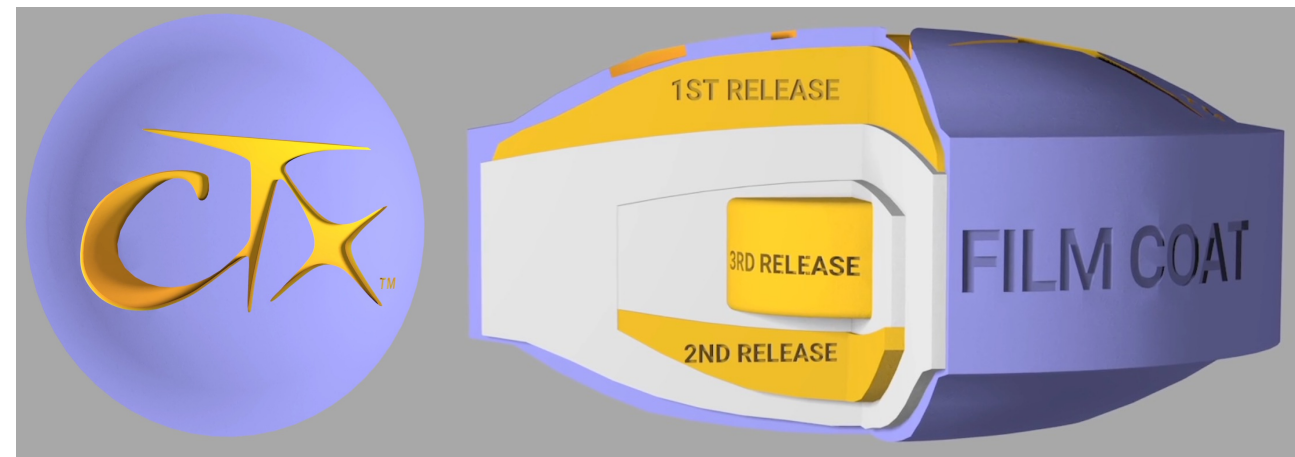
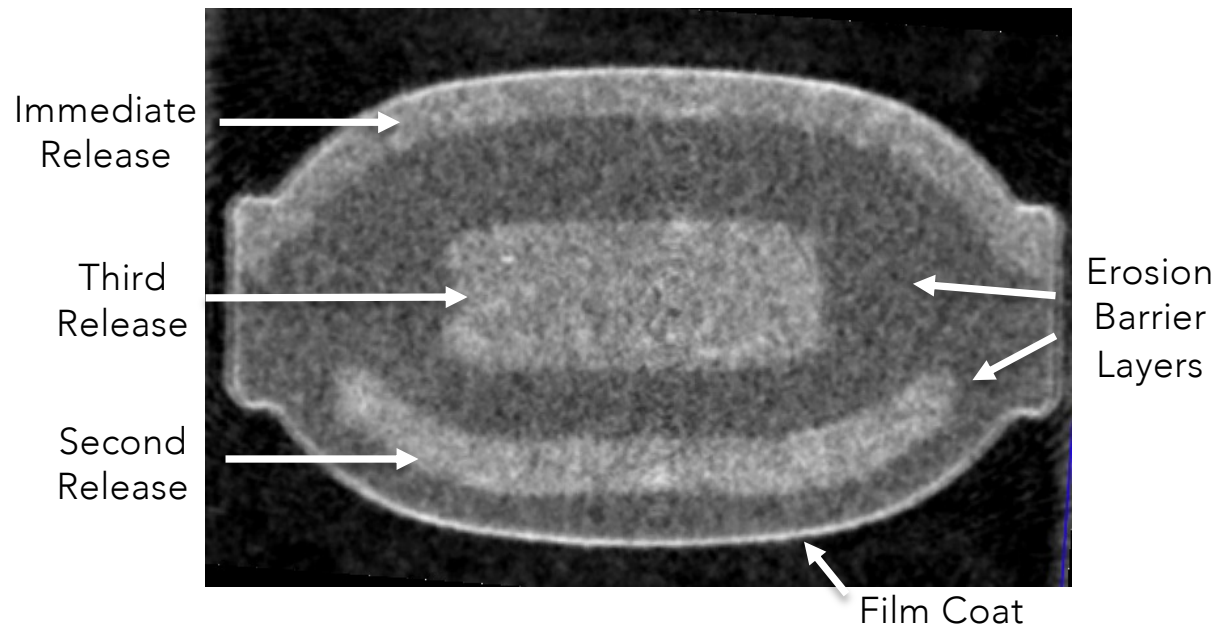
- Manufacturing Operations Expanded for Current and Future PTR™ Platform Assets

- Pursue out license opportunity for PTR™ Platform
- Expand CING – BDD Partnership
- Expand BD&L Activities w/ PTR™



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 Indications

Identified Targets for PTR™ Platform Pipeline



In Development

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



Near-Term Targets Identified

- Insomnia
- Depression
- Bipolar Disorder
- Movement Disorders
- Cardiovascular Disorders
- Xerostomia (dry mouth)



Future Therapeutic Areas

- Migraine
- Hypothyroidism
- Oral Oncology Medicines
- Psychosis
- Alzheimer's Disease
- Pain (Non-Opioid)



The Cingulate Solution for ADHD Patients & Providers



Targeting Treatment of ADHD - \$20+Bn 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 Year¹

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
- Quinelbree®

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

¹Symphony 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 ¹		UNMET NEEDS ¹			
		Onset	Duration (less onset)	Fast Onset of Action ≤ 30 min	Entire Active-Day Efficacy*	Minimize Crash/Rebound	Avoid Booster ¹
Vyvanse®	2007	1 ½ - 2 hours	8-9 hours	✗	✗	Data Not Available	✗
Adderall® XR	2001	1 ½ hours	7-8 hours	✗	✗	Data Not Available	✗
Concerta®	2000	2 hours	6-7 hours	✗	✗	Data Not Available	✗
Focalin® XR	2005	30 mins	7-8 hours	✓	✗	Data Not Available	✗

60%
use short-acting
'booster' dose
every day!²

* Entire-active day efficacy defined as less than or equal to a 30 min onset of action with true 12 hours of duration vs. baseline

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

Why is Effect Size Important?

Statistical Significance (p value)^{1,2}

- Probability that both groups are equal
- Doesn't measure magnitude
- Not usable in comparisons

Clinical Effect ^{1,2}

'Clinical effect is used to determine if newer therapies are important enough to warrant clinical use and/or formulary decisions'²

- Independent of Sample Size
- Allows for Comparison Across Trials
- Examples: Effect Size, Number Needed to Treat...

¹ McGough, J. J., & Faraone, S. V. (2009). Estimating the size of treatment effects: moving beyond p values. *Psychiatry (Edgmont (Pa. : Township))*, 6(10), 21–29.

² Faraone S. V. (2008). Interpreting estimates of treatment effects: implications for managed care. *P & T : a peer-reviewed journal for formulary management*, 33(12), 700–711.

What Has CTx-1301 Clinical Data Shown Us?

Impressive Effect Size in the Treatment of ADHD

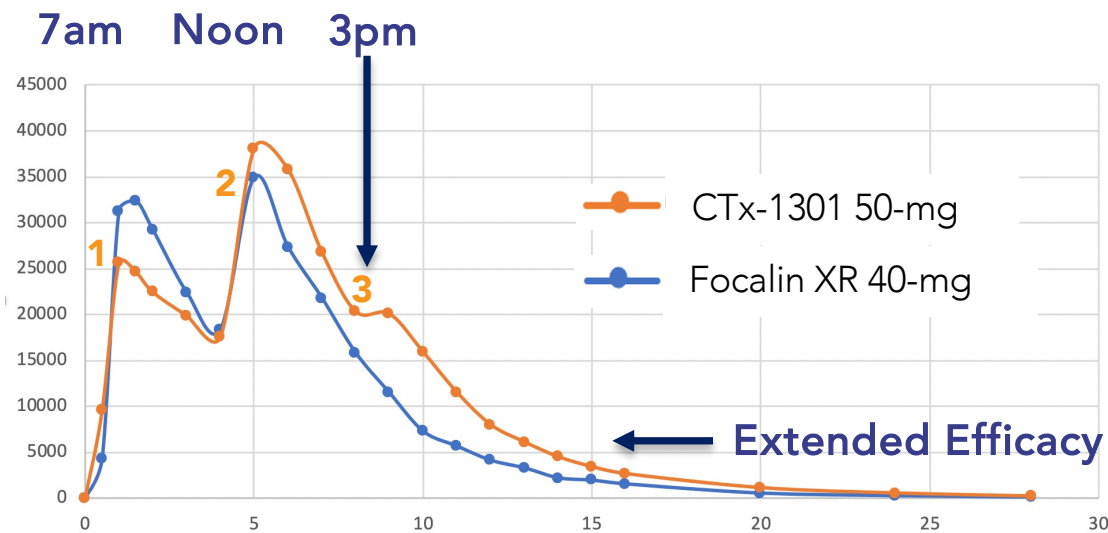
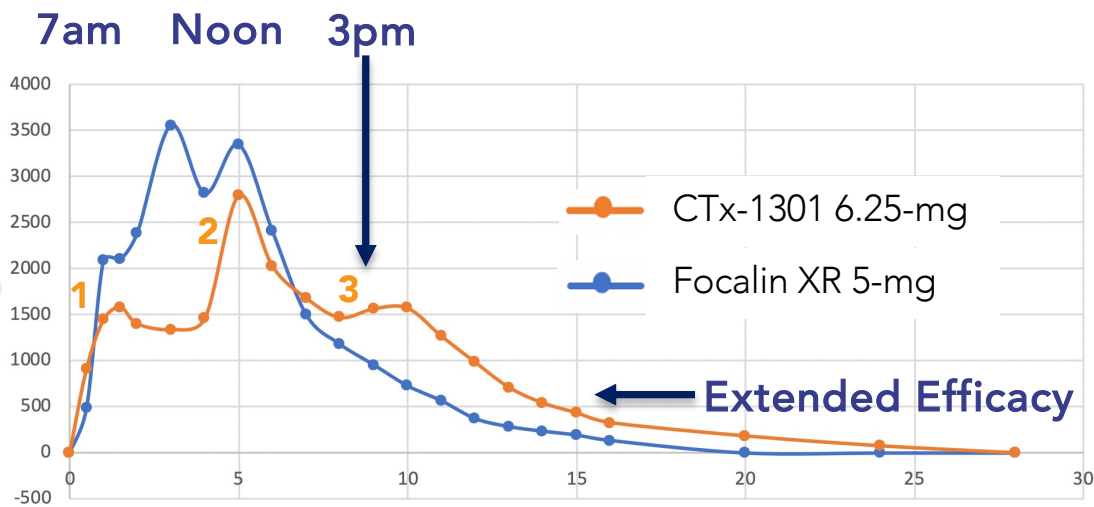
- Ideal product profile with 3 precisely timed, ratioed, and styled releases of medication
- Phase 3 adult study
 - Effect size 2 - 5 x greater* than available ADHD treatments (real-world impact)
 - Efficacy starting at 30 minutes and providing Entire Active-Day Duration (14-16 hrs)
 - Psych Congress finalist at poster award reception
- Improved side effect profile
 - Phase 3 adult study: 1 Side effect (n=11) on CTx-1301, 3 side effects (n=10) on Placebo
 - Head-to-head vs Focalin XR: 28.6% reduction in treatment emergent adverse events
 - All 6 trials completed consistently demonstrated this tolerability




* Effect Size data from published clinical trial results, calculations, and data on file Cingulate Inc. including PERMP, AISRS, ADHD-RS, WREMB-R scales.

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

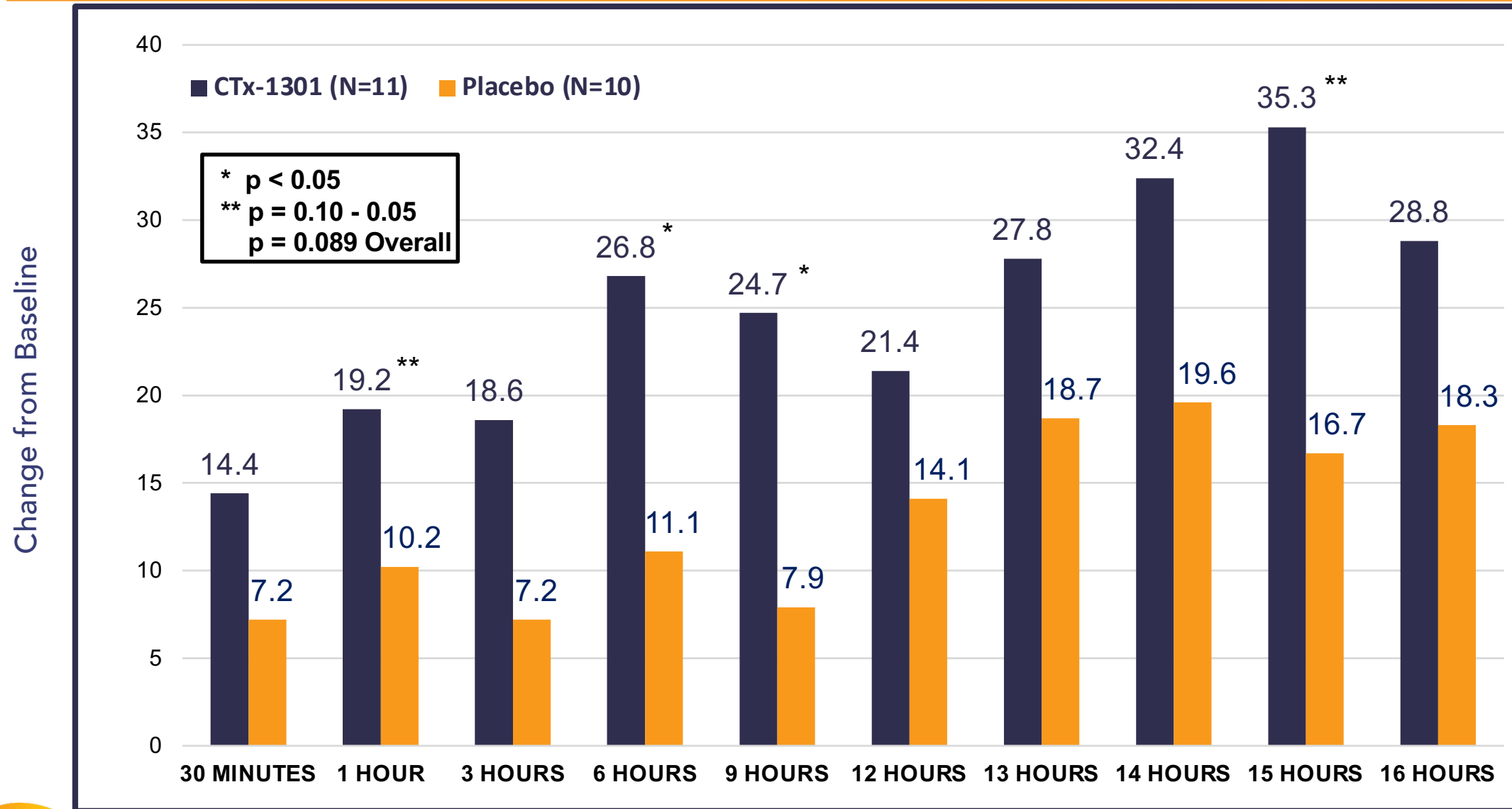
 31.25-mg

 37.5-mg

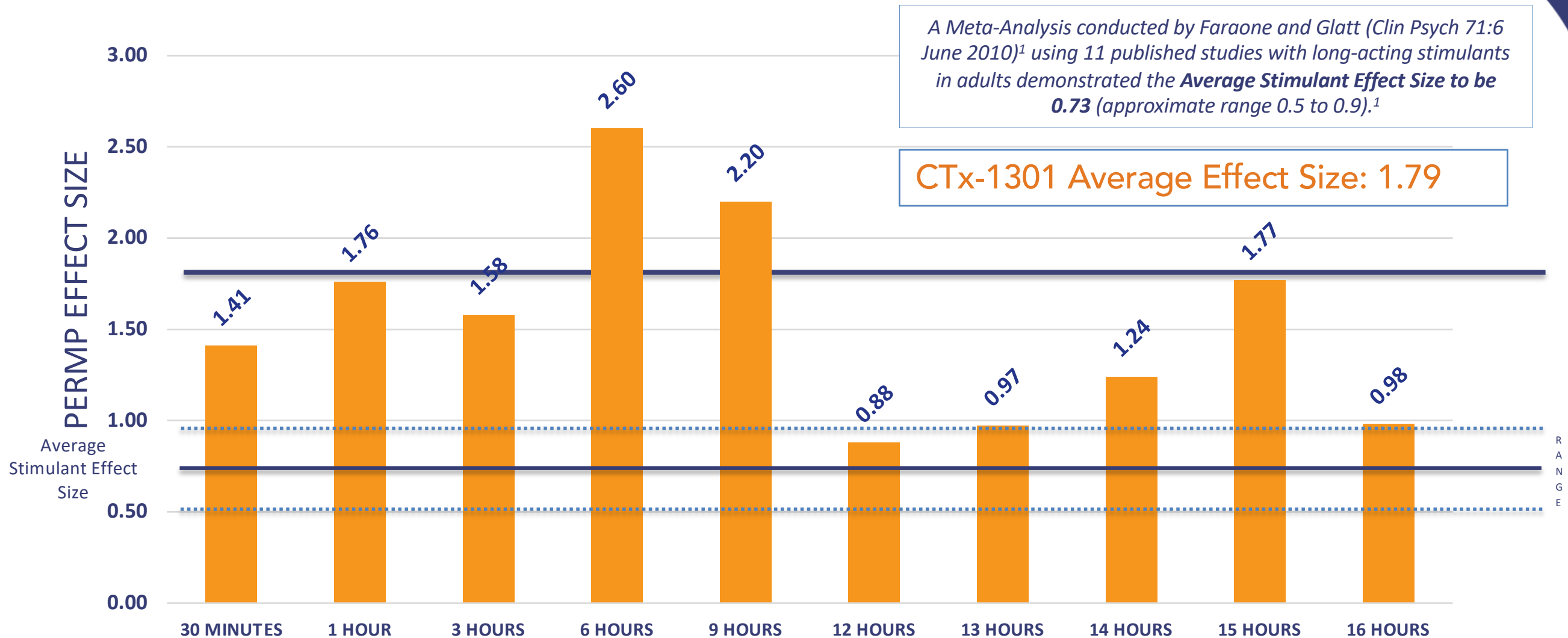
 43.75-mg

 50-mg

PERMP CTx-1301 & Placebo Adult Laboratory Classroom



CTx-1301 PERMP Effect Size over 16 hours



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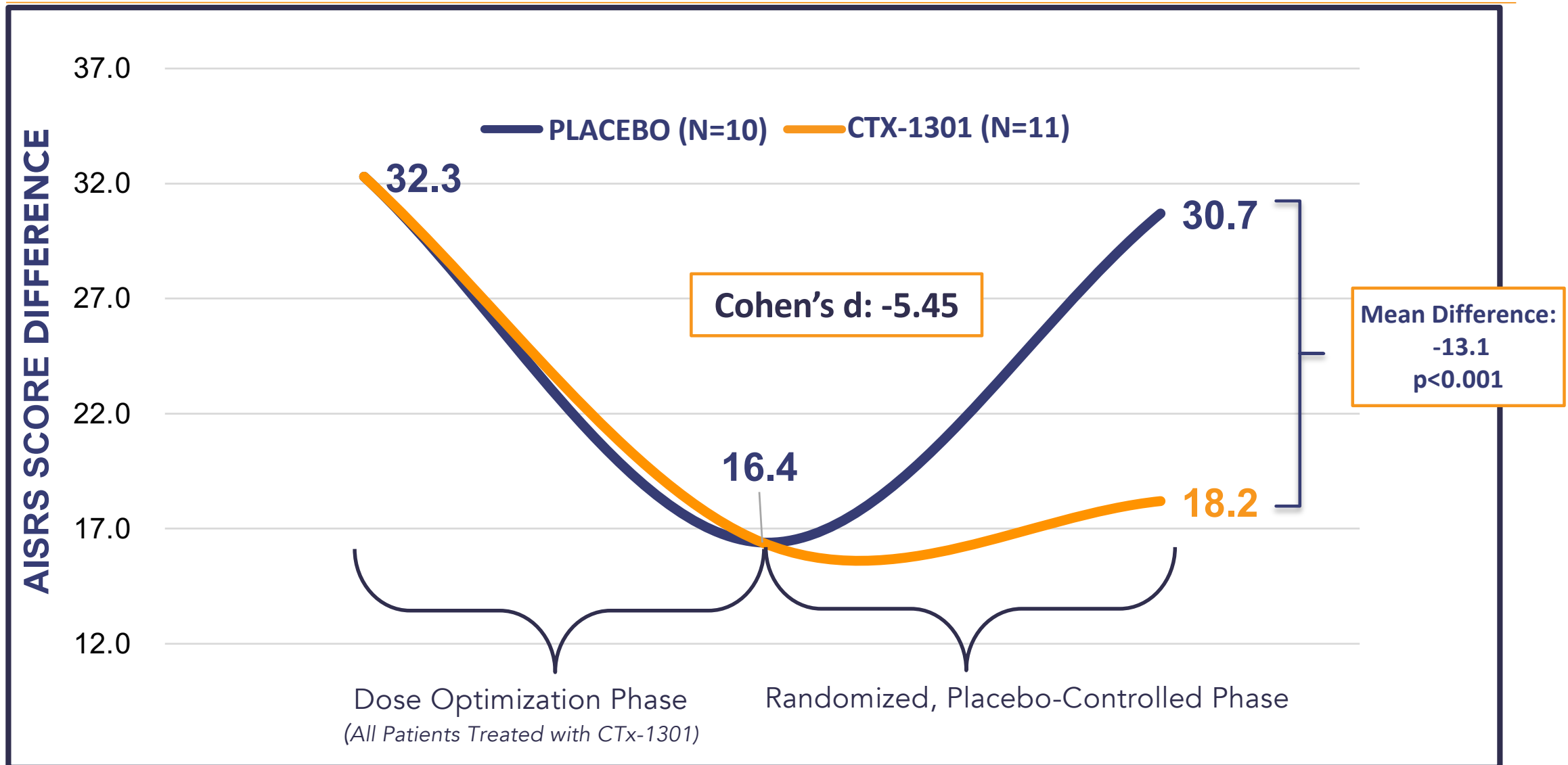
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p-value (30 min- 16 hour): 0.089

Cingulate.com

Data on file. 1301-022 [NCT05631626](#), ¹ Faraone et al. J Clin Psych 2010;71(6) 754-763.

AISRS: CTx-1301 Delivered Ongoing Reduction in ADHD Severity



ADHD Effect Size Comparison*

ADHD Products & Candidate	Peak Effect Size** (Cohen's d)	p-value	Percentiles (Cohen's d)
CTx-1301***	5.45 & 1.79 @ 1 week	<0.001 & 0.089	<u>96 - 99.9%</u>
Concerta ®	0.42 @ 6 weeks	<0.001	~69%
Vyvanse ®	0.94 @ 10 weeks	<0.001	~84%
Focalin XR ®	0.5 @ 6 months	<0.001	~69%
Azstarys ®	0.49 @ 4 weeks	0.003	~69%
Adderall® XR	0.80 @ 4 weeks	<0.001	79%
Mydayis® XR	1.11 @ 4 weeks	<0.001	~85%
Strattera®	0.48 @ 6 months	≤0.012	~69%
Qelbree ®	0.28; 0.312 @ 6 Weeks	0.004; N/A	~54%

* Data from published clinical trial results, calculations, and data on file Cingulate Inc. ** AISRS, ADHD-RS, WREMB-R, PERMP scales. *** CTx-1301 is currently in Phase 3 of clinical development and not an approved product.



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

The ADHD Medication Providing Daily Durability

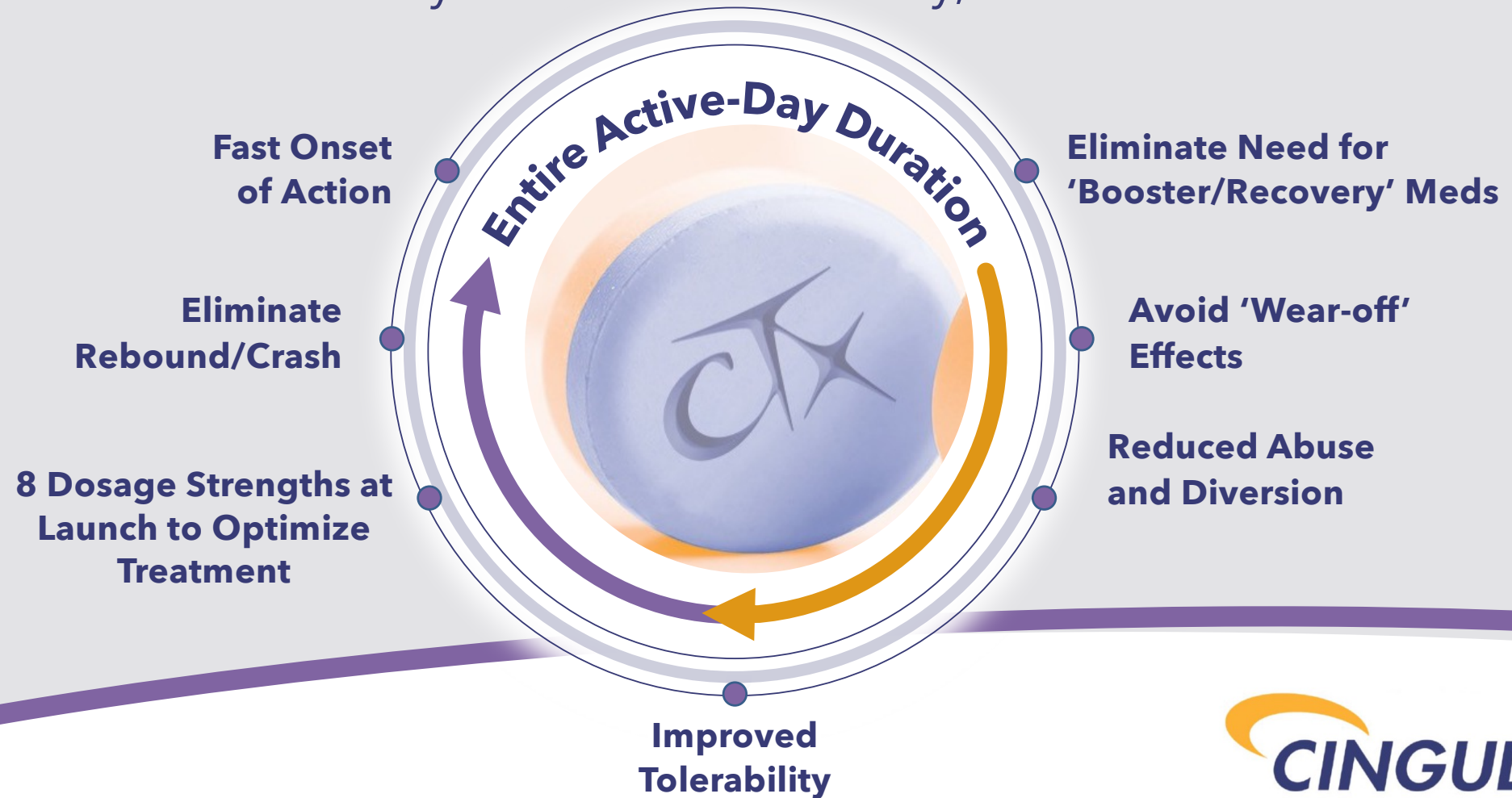
Precision Timed Release™ (PTR™) Platform Unlocks the Possibility for 'True' Once-daily, Multi-dose Tablets



\$20+ Billion*

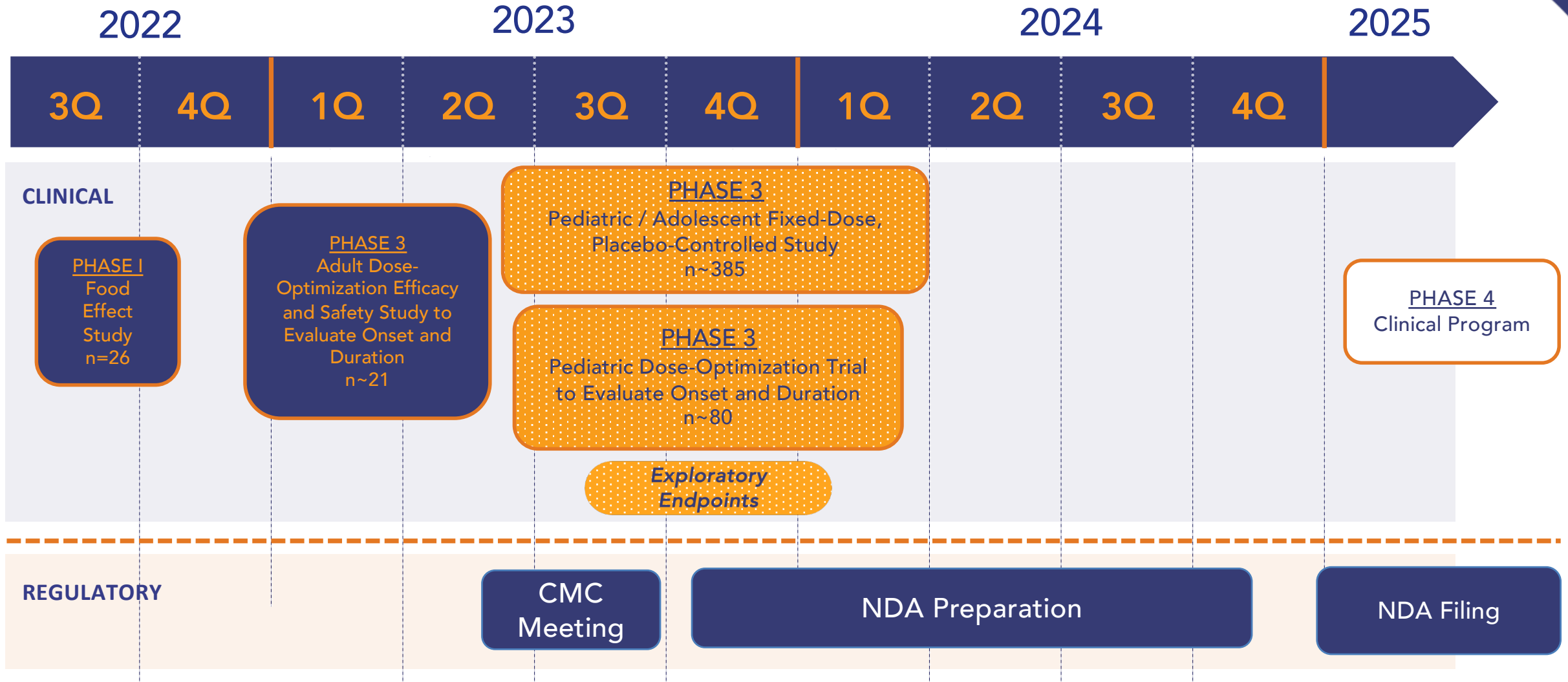
US ADHD Market
Dominated by Stimulants

*Symphony Data.
12-months rolling
through Sept 2022



CINGULATE™

MASTERY[®] CTx-1301 Clinical and Regulatory Timeline



Target dates; actual timeline may vary



The Cingulate Solution for Anxiety Patients & Providers

CTx-2103 – Buspirone HCl for the Treatment of Anxiety

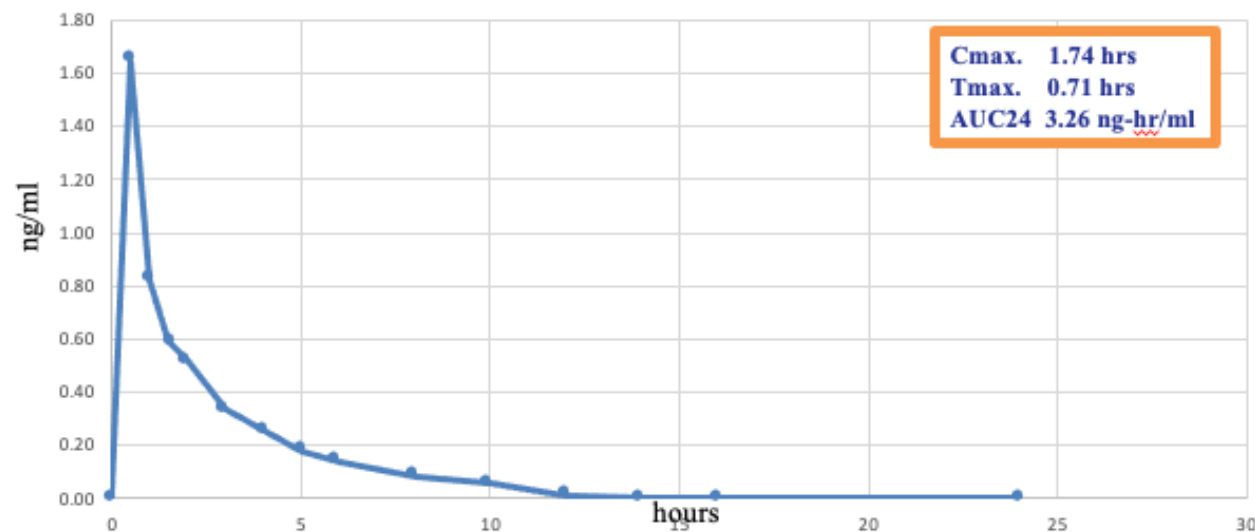
Next-Generation Buspirone designed to Improve Patient Outcomes

Three Times a Day

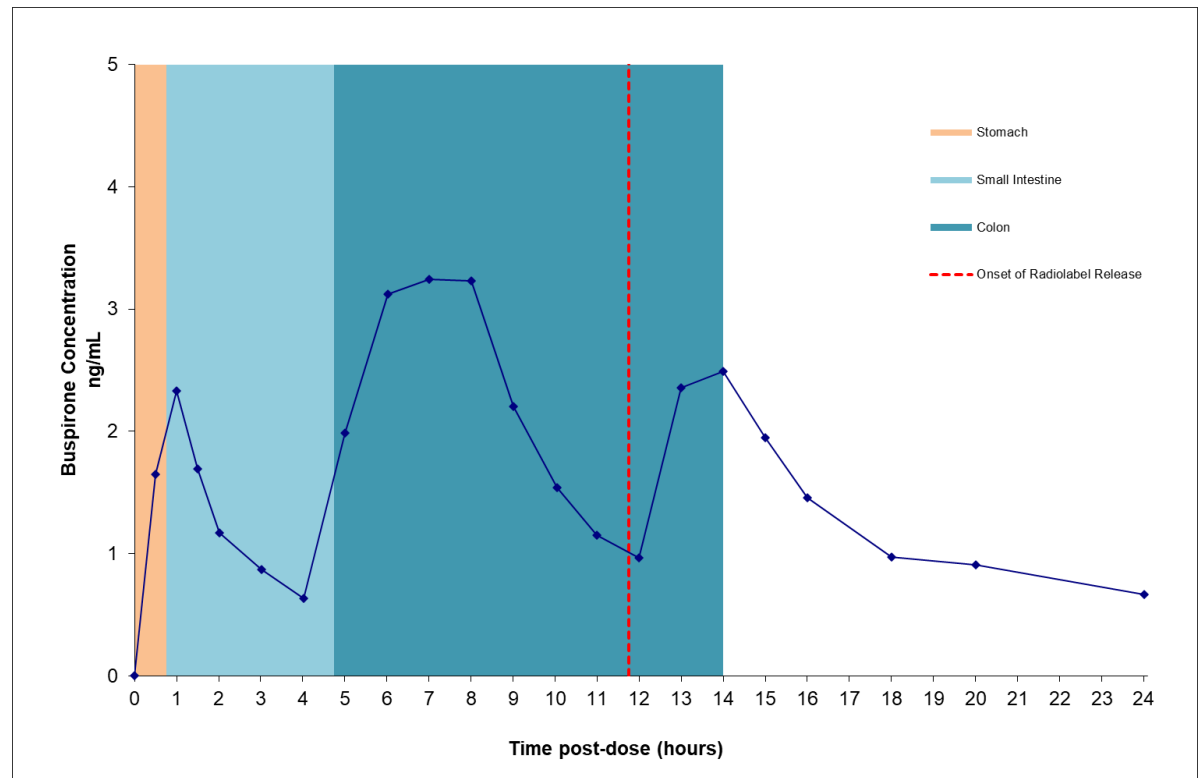
versus

Once a Day

Single Dose Buspirone 10 mg- Immediate Release



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





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 \$1B¹

62%

of products launched in the last 15 years have underperformed pre-launch forecasts¹

50%

of products fail to reach peak U.S. sales of \$250M¹

Furthermore, a recent McKinsey study² indicated that...

50%

of Providers never plan to see a sales rep again

50%

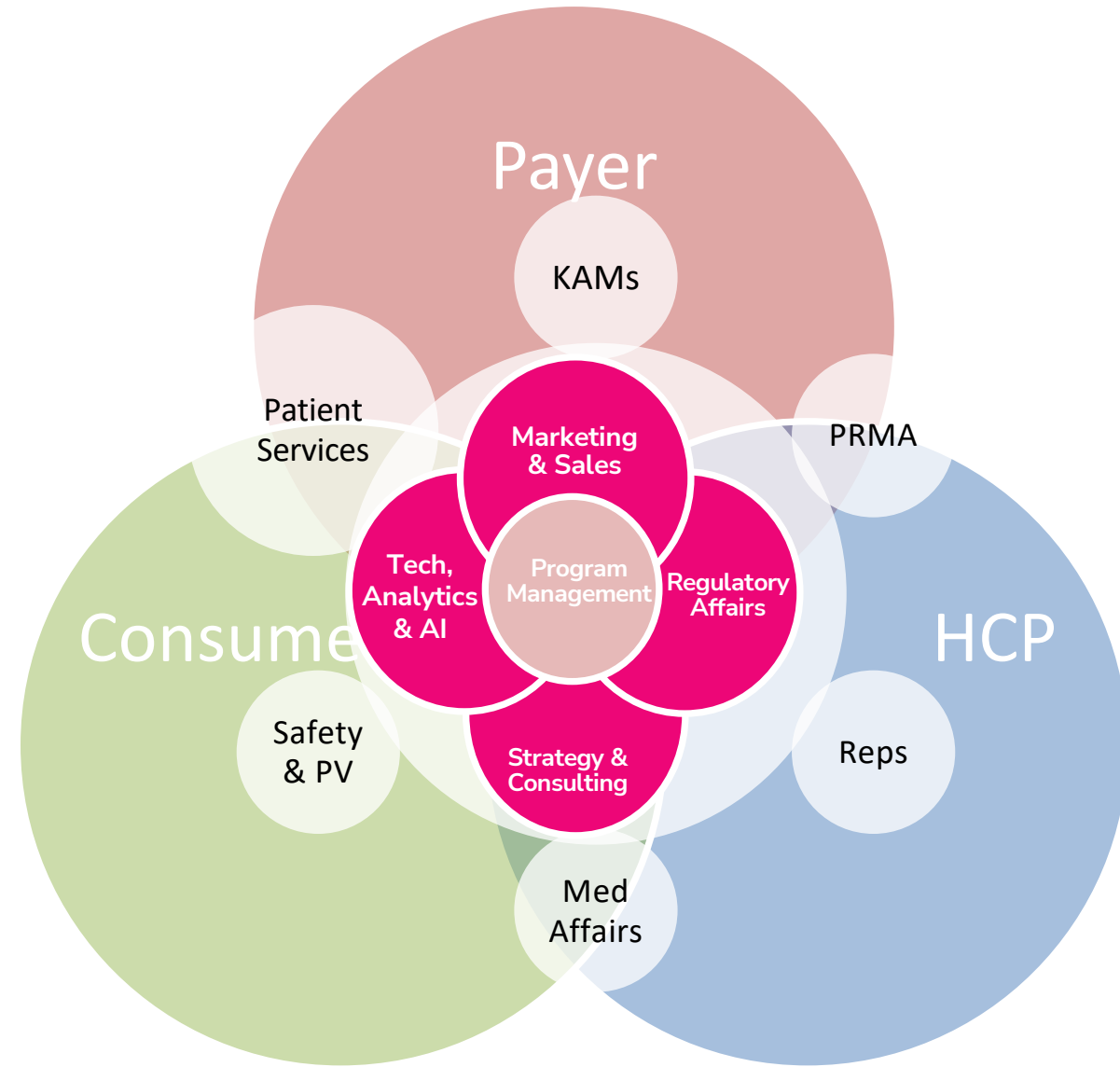
will see a sales rep once or twice a year, three times at most

¹ Data on File. Indegene Inc. 2021-2022.

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

Cingulate & Indegene Integrated GTM Solution

Customer focused, integrated solutions model allows for more effective commercialization and higher revenue generation than traditional commercial options



Value Maximizing Commercial Model

Leverage AI and ML to build a commercial model based on the best mix to drive revenue



Traditional Model

- Hundreds of reps target inaccessible HCPs (60-75%)
- Expensive, inefficient and ineffective
- Reps and individual channels are not integrated



Cingulate & Indegene Model

- Proprietary AI & ML identify best mix of channels with highest probability of driving return
- Positioned to maximize revenue and ROI
- Sales reps and AI **drive** traditional and nontraditional channels with integration
- Market Access (PRMA) Strategy
- Optimize capital with scalability

Why Cingulate (Nasdaq: CING)

30

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



Thank You

