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):
October 17, 2023

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 October 17, 2023, Cingualte Inc. (the "Company") issued a press release announcing a key opinion leader event on October 23, 2023 at which ADHD, anxiety and the Company's leading, late-stage asset CTx-1301 (dexmethylphenidate), including the results from the Company's Phase 3 adult efficacy and safety trial of CTx-1301 for ADHD, will be discussed. A copy of the press release is attached hereto as Exhibit 99.1.

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.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibits 99.1 and 99.2, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01. Other Events.

On October 17, 2023, the Company issued a press release announcing a key opinion leader event on October 23, 2023 at which ADHD, anxiety and the Company's leading, late-stage asset CTx-1301 (dexmethylphenidate), including the results from the Company's Phase 3 adult efficacy and safety trial of CTx-1301 for ADHD, will be discussed.

Top-line results for the Phase 3 adult trial were released on July 11, 2023 and included in the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2023 and detailed trial results were presented on September 8, 2023 at the 36th Annual Psych Congress in Nashville, Tennessee and included in the Company's Current Report on Form 8-K filed with the SEC on September 11, 2023.

CTx-1301 demonstrated a reduction in Adult ADHD Investigator Symptom Rating Scale (AISRS) scores (-16.3) during the dose-optimization period. During the randomized placebo controlled period, CTx-1301 demonstrated a reduction in AISRS scores (mean difference: -13.1) with an effect size of 5.45 and a p-value of <0.001.

The pivotal Phase 3 fixed-dose pediatric and adolescent safety and efficacy study and a Phase 3 pediatric dose-optimization onset and duration study of CTx-1301 have commenced, with results expected in the first half of 2024.

Assuming the Company receives positive clinical results from its Phase 3 trials, the Company expects to submit the NDA for CTx-1301 in the second half of 2024 under the Section 505(b)(2) pathway.

The Company 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 the second half of 2024 and, if the results from this study are successful, subsequently initiate pivotal Phase 3 clinical trials in all patient segments in 2025.

The Company has embarked on a program to develop CTx-2103 (buspirone) for the treatment of anxiety, which is the most common mental health concern in the U.S. The Company completed a formulation study in which the pharmacokinetics were evaluated for this trimodal tablet providing three precisely timed doses of buspirone versus one immediate release dose. In addition, scintigraphic imaging visualized transit of the tablets through the gastrointestinal tract to confirm both the site and onset of release, which will then be correlated with pharmacokinetic data to establish the full release profile of the CTx-2103 formulation. Based on the pharmacokinetic profile seen in the data, CTx-2103 achieved the desired triple release of buspirone. These results provided the critical information required to allow the Company to request a Pre-IND meeting with the FDA to discuss the design of its clinical and regulatory program for CTx-2103, and the Company expects to receive feedback from the FDA in the fourth quarter of 2023 to allow for a potential IND filing in the first half of 2024.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated October 17, 2023
99.2	Investor Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: October 19, 2023

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

Exhibit 99.1

Cingulate to Host CNS Key Opinion Leader Panel in New York City

Expert Analysis of Cingulate, it's Phase 3 ADHD Adult Data, Anxiety, and PTR™ Drug Delivery Platform Innovations

KANSAS CITY, Kan., October 17, 2023 — **Cingulate Inc. (NASDAQ: CING)**, a biopharmaceutical company utilizing its proprietary Precision Timed Release™ (PTR™) drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products, announced today that it will be hosting a key opinion leader event on the morning of **October 23, 2023**, at the Union League Club in New York City.

The live-streamed event will be held from 10:00am-11:30am EST at the Union League Club in Midtown Manhattan, and will focus on the Company's leading, late-stage asset CTx-1301(dexmethylphenidate), along with ADHD and anxiety-related disorders. For those in the New York area who would like to attend, there will be space for approximately 25-30 guests in the club's Grant Room. Those who wish to watch the event virtually may do so through the link provided **here**, with the passcode **429018**.

What: Cingulate Key Opinion Leader Panel

Where: Union League Club (Grant Room)
39 East 37th Street, New York, NY 10016

When: Monday October 23, 2023, 10am-11:30am EST

Attire: The Union League Club requests that in-person attendees abide by club dress guidelines. For more information, please visit the club's **website**.

The event may be added to calendars through the following links:

Add to Calendar
Add to Google Calendar

Cingulate's Chief Medical Officer, Matthew Brams, M.D., and Chief Science Officer, Raul Silva, M.D., will moderate the discussion.

The panel will include Ann Childress, M.D., President, Center for Psychiatry and Behavior Medicine, Inc., and lead investigator of Cingulate's recently completed Phase 3 adult dose-optimization study, as well as Greg Mattingly, M.D., Founding Partner, St. Charles Psychiatric Associates.

"The Cingulate team thanks Dr. Childress and Dr. Mattingly for their participation in this event. We believe this will be an excellent opportunity for healthcare providers, patients, advocacy groups, and the investor community to hear the Cingulate story and take a deeper look at our most recent Phase 3 data with two of the top key opinion leaders in ADHD and CNS disorders," said Cingulate Chairman & CEO Shane J. Schaffer.

About Attention Deficit/Hyperactivity Disorder (ADHD)

ADHD is a chronic neurobiological and developmental disorder that affects millions of children 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 65-90 percent demonstrating clinical ADHD symptoms that persist into adulthood. Adult ADHD prevalence is estimated at approximately 11 million patients (4.4 percent), almost double the size of the child and adolescent segment combined, however, only an estimated 20 percent receive treatment.

About Anxiety

Anxiety disorders are the most common mental health concern in the U.S.[1] Anxiety is the feeling of fear that occurs when faced with threatening or stressful situations or can be endogenous and not have an identified stressor. It can be a normal response when confronted with danger, but, if severe and chronic and affects functioning, it could be regarded as an anxiety disorder. An estimated 31 percent of U.S. adults experience an anxiety disorder at some time in their lives.[2] People may live with anxiety for years before they are diagnosed or treated. The global COVID-19 crisis has exacerbated the diagnosis and treatment of anxiety and anxiety related disorders and as a result is a priority within the class of unmet medical needs in mental health.

About CTx-1301

Cingulate's lead candidate, CTx-1301, utilizes Cingulate's proprietary PTR drug delivery platform to create a breakthrough, multi-core formulation of the active pharmaceutical ingredient dexmethylphenidate, a compound approved by the FDA for the treatment of ADHD. Dexmethylphenidate is part of the stimulant class of medicines and increases norepinephrine and dopamine activity in the brain to affect attention and behavior. While stimulants are the gold-standard of ADHD treatment due to their efficacy and safety, the long-standing challenge continues to be providing patients entire active-day duration of action. CTx-1301 is designed to precisely deliver three releases of medication at the predefined time, ratio, and style of release to optimize patient care in one tablet. The result is a rapid onset and entire active-day efficacy, with the third dose being released around the time when other extended-release stimulant products begin to wear off.

About Precision Timed Release™ (PTR™) Platform Technology

Cingulate is developing ADHD and anxiety disorder product candidates capable of achieving true once-daily dosing using Cingulate's innovative PTR drug delivery platform technology. It incorporates a proprietary Erosion Barrier Layer (EBL) providing control of drug release at precise, pre-defined times with no release of drug prior to the intended release. The EBL technology is enrobed around a drug-containing core to give a tablet-in-tablet dose form. It is designed to erode at a controlled rate until eventually the drug is released from the core tablet. The EBL formulation, Oralogik™, is licensed from BDD Pharma. Cingulate intends to utilize its PTR technology to expand and augment its clinical-stage pipeline by identifying and developing additional product candidates in other therapeutic areas in addition to Anxiety and ADHD where one or more active pharmaceutical ingredients need to be delivered several times a day at specific, predefined time intervals and released in a manner that would offer significant improvement over existing therapies. To see Cingulate's PTR Platform click **here**.

About Cingulate Inc.

Cingulate Inc. (NASDAQ: CING), is a biopharmaceutical company utilizing its proprietary 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 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 Annual Report on Form 10-K filed with the SEC on March 10, 2023. 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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CINGULATE®

Cingulate Inc.

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

4Q 2023

CING-US-127-0724

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.

CINGULATE®

Efficacy

Boosters

Cost (s)

Current Medication Options Do Not Deliver Acceptable Outcomes for Patients, Providers, and Payors

Tolerability

Compliance

Onset / Duration

Abuse / Diversion

CINGULATE®

✓ Efficacy

✓ Boosters

✓ Cost (s)

✓ Tolerability

✓ Compliance

Cingulate's PTR™ Platform could Solve these issues affecting Millions of Patients

✓ Onset / Duration

✓ Abuse / Diversion

Why Cingulate (Nasdaq: CING)

Completed & Near-Term Catalysts (CTx-1301)

- Commercialization Strategy & Execution in Place
- Impressive Phase 3 Adult Effect Size
- Phase 3 Pediatric & Adolescent Trials Underway
  - On Target Completion and Data in 1H'24
- Planned NDA Submission in 2H'24 (on target)

Multiple Long-Term Revenue Streams

- 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

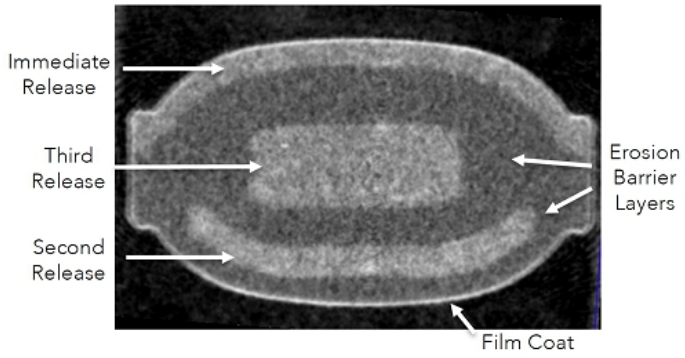
- Proven C-Suite and Management team possessing big and small pharma expertise
- Seasoned Board of Directors – Pharma, Securities, PubCo, Finance, M&A, PRMA
- Indegene Commercial Partnership provides instant launch and scalable commercial readiness

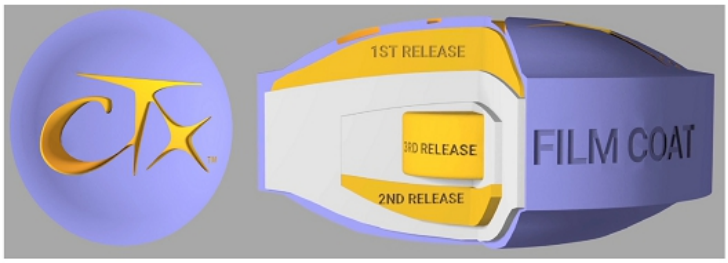
Multiple Near-Term Milestones Expected and Achieved

	1H 2023	3Q 2023	4Q 23 / 1H 24
ADHD CTx-1301 CTx-1302	✓ CTx-1301 Phase 1 Food Effect Clinical Data ✓ CTx-1301 Adult Onset / Duration Efficacy Trial	✓ Adult Onset / Efficacy Trial Data ✓ Initiate Both Phase 3 Trials in Children and Adolescents ✓ FDA CMC Meeting	Child / Adolescent CTx-1301 Pivotal Phase 3 Trial Completion & Data Child Onset/Duration Trial Completion & Data Prepare CTx-1302 IND
Anxiety CTx-2103	✓ CTx-2103 Formulation Study Report	✓ Formulation Study Presentation	Prepare & File CTx-2103 IND 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™	

Next-Generation Medications in Billion-Dollar Markets

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

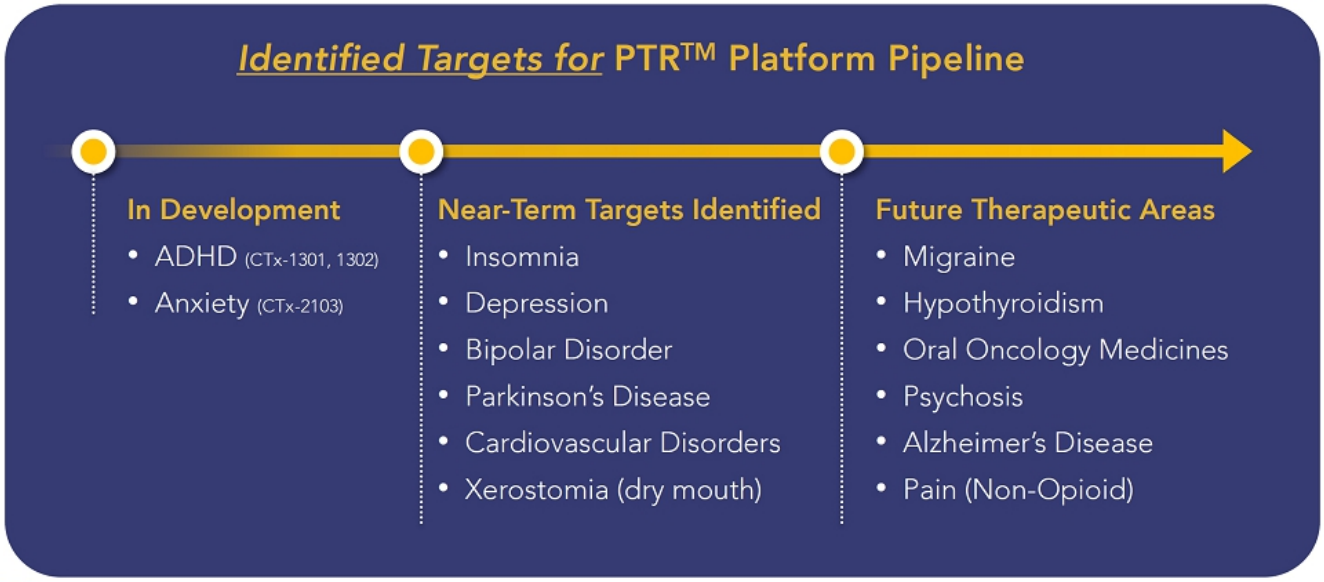




[See the PTR™ Platform in Action @ Cingulate.com]

*Symphony Data. 12-months rolling through Jun 2022

PTR Facilitates a Potential Pipeline Addressing Multiple Indications



CINGULATE®

The Cingulate Solution for ADHD Patients & Providers

MASTERY® CTx-1301

ACCOMPLISH® CTx-1302

CING-US-127-0724

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 Year[1]

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

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

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
  - Psych Congress finalist at poster award reception
  - ***Effect size 2, 3, 5 x greater**** than available ADHD treatments (**real-world impact**)
  - Efficacy starting at 30 minutes and providing Entire Active-Day Duration (14-16 hrs)

- 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.

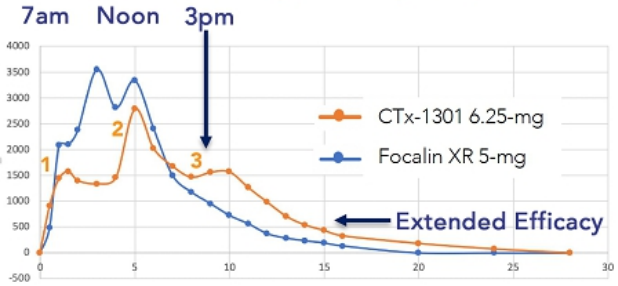
Why is Effect Size Important?

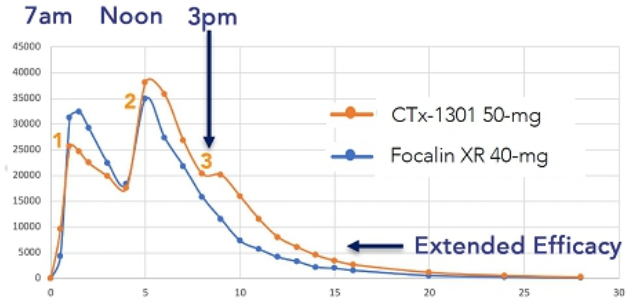
- Conveys Clinical Significance versus Statistical Significance
- Not Reliant on Sample Size
- Allows for Comparison Across Trials
  - p-value is not translational

McGough JJ, Faraone SV. Estimating the size of treatment effects: moving beyond p values. Psychiatry (Edgmont). 2009 Oct;6(10):21-9. PMID: 20011465; PMCID: PMC2791668.

One Product Designed to Overcome All Unmet Needs

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



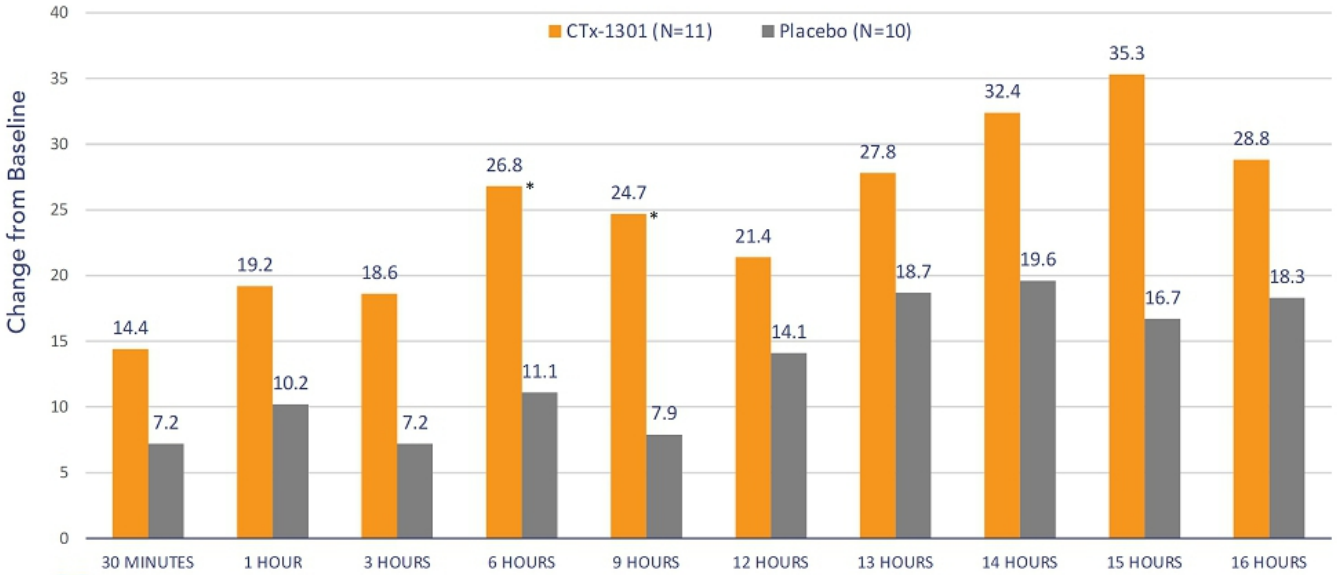


CINGULATE	TARGET ATTRIBUTES		UNMET NEEDS			
	Onset	Duration	Fast Acting (≤ 30 min)	Entire Active-Day Efficacy	Avoid Crash/Rebound	Avoid Booster
CTx-1301 (d-MPH)	30 mins	Up to 16 hours	✓	✓	✓	✓
CTx-1302 (d-AMP)	30 mins	Up to 16 hours	✓	✓	✓	✓

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

Data on file, Cingulate Inc. 1301-022 NCT 05631626



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

* p<0.05

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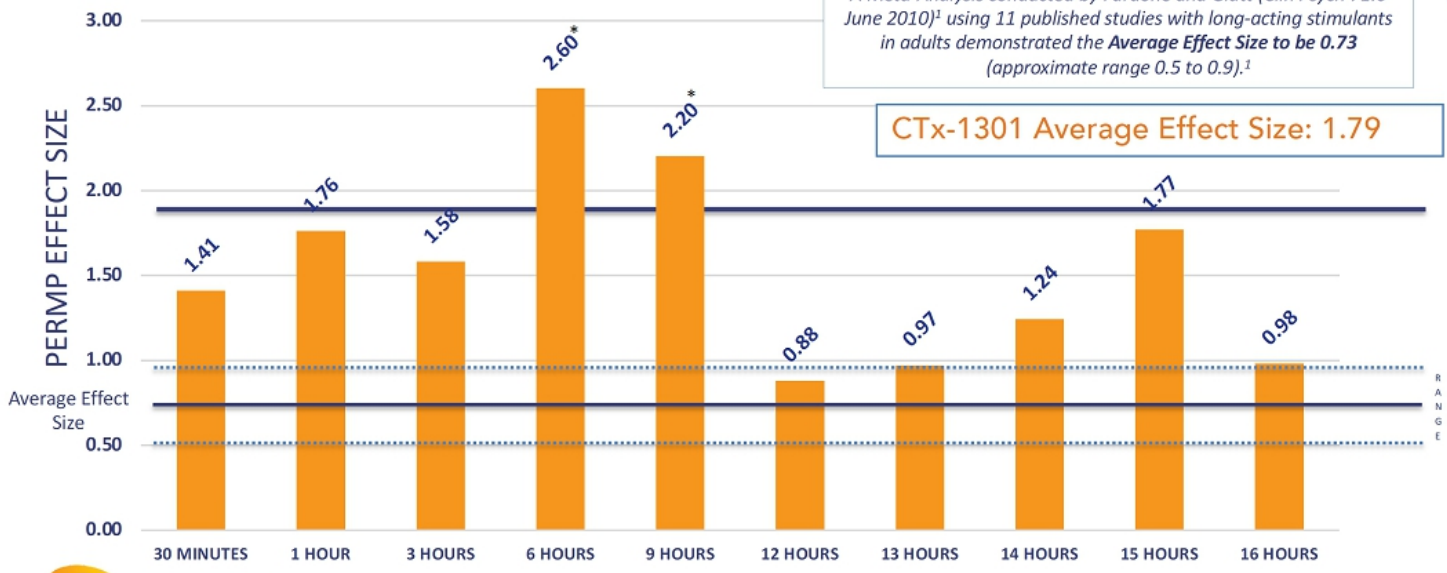
PERMP Effect Size over 16 hours

*A Meta-Analysis conducted by Faraone and Glatt (Clin Psych 71:6 June 2010)[1] using 11 published studies with long-acting stimulants in adults demonstrated the **Average Effect Size to be 0.73** (approximate range 0.5 to 0.9).[1]*

CTx-1301 Average Effect Size: 1.79



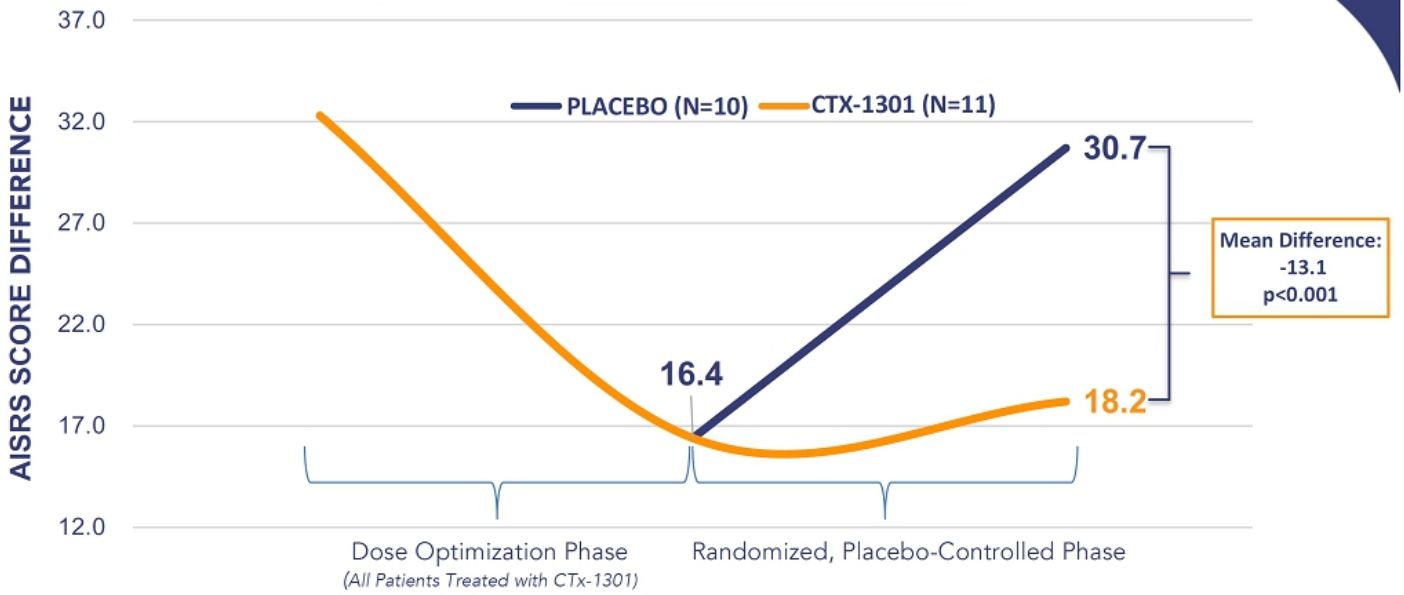
CINGULATE®

p-value (30 min- 16 hour): 0.089 * p<0.05

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



AISRS: Adult ADHD Investigator Symptom Rating Scale DOP: Dose Optimization Phase RPCP: Randomized, Placebo-controlled Phase

Adult ADHD Investigator Symptom Rating Scale

CTx-1301 AISRS Effect Size (Cohen's d)

All subjects treated with CTx-1301

	Mean Starting Baseline	Mean Baseline Visit 7 (pre-dose)	Mean Visit 8	LS Mean CFB (Visit 7 to Visit 8)	p-value	Effect Size (*Cohen's d*)
CTx-1301-022	32.7 (5.06)	16.4 (4.86)	18.2 (7.59)	1.9 ±1.66	**<0.001**	**5.45**
Placebo	31.9 (3.45)	15.6 (3.17)	30.7 (4.37)	15.0 ±1.74	--	--

CFB: Change From Baseline; LS: Least Squares, Standard Deviation: (SD), ±: Standard Error

Effect Size Inattentive: 5.03, p-value <0.001

Effect Size Hyperactive-Impulsive: 3.14, p-value 0.006

Cohen's d	Percentiles*
0.0	50
0.2	54
0.5	69
0.8	79
1.0	84
2.0	98
3.0	99.9

*Percentage of active medication subjects who would have a score above the average subject in the experimental group

ADHD Effect Size Comparison*

ADHD Products & Candidate	Peak Effect Size** (*Cohen's d*)	p-value	Percentiles (*Cohen's d*)
CTx-1301***	5.45 @ 1 week	<0.001	99.9%+
Concerta ®	0.42 @ 6 weeks	<0.001	~69%
Vyvanse ®	0.94 @ 10 weeks	<0.001	~84%
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 scales. *** CTx-1301 is currently in Phase 3 of clinical development and not an approved product.

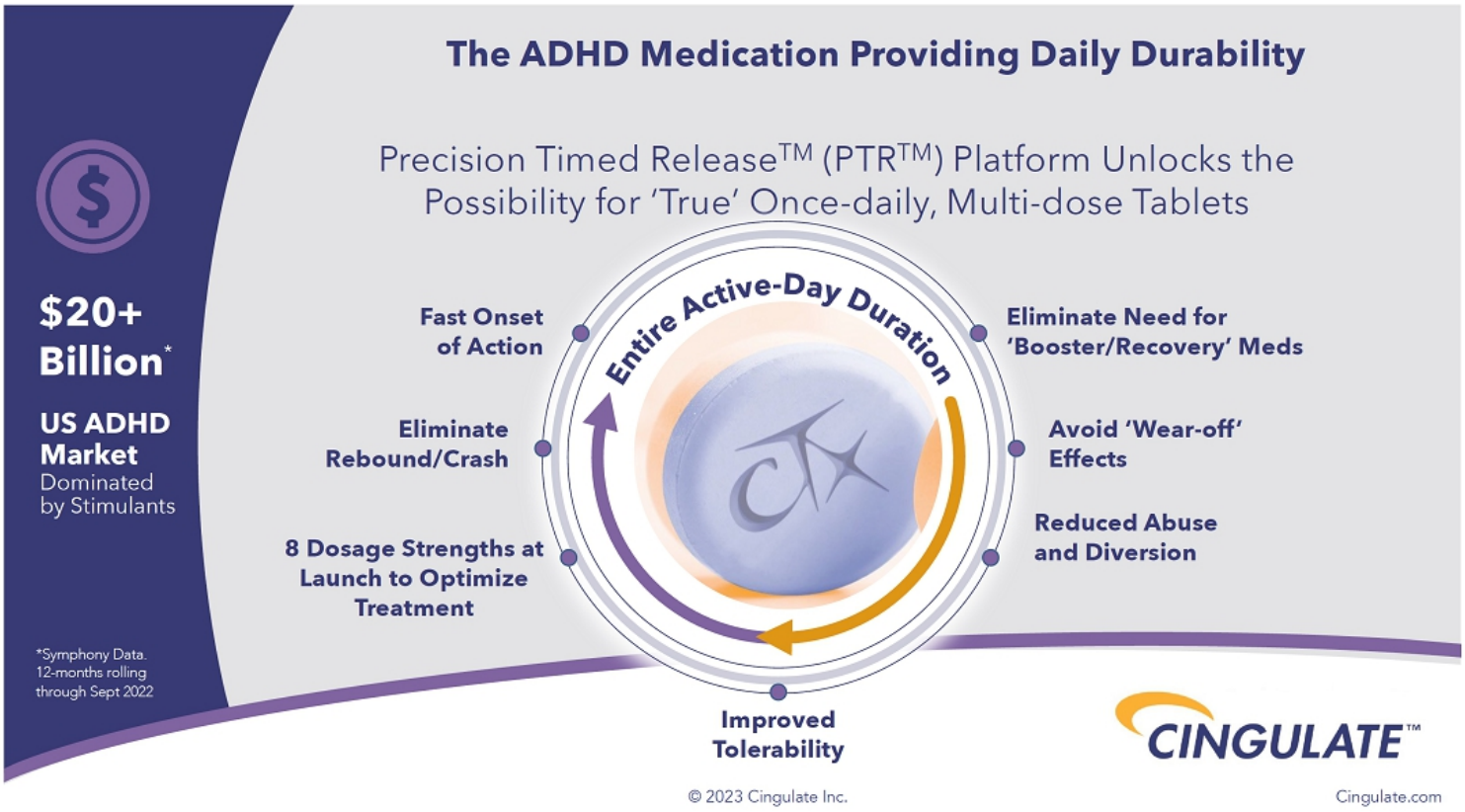
CTx-1301 Demonstrated Significantly Lower Adverse Events

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
Entire Active-Day Duration
Fast Onset of Action
Eliminate Need for 'Booster/Recovery' Meds
Eliminate Rebound/Crash
Avoid 'Wear-off' Effects
Reduced Abuse and Diversion
8 Dosage Strengths at Launch to Optimize Treatment
Improved Tolerability
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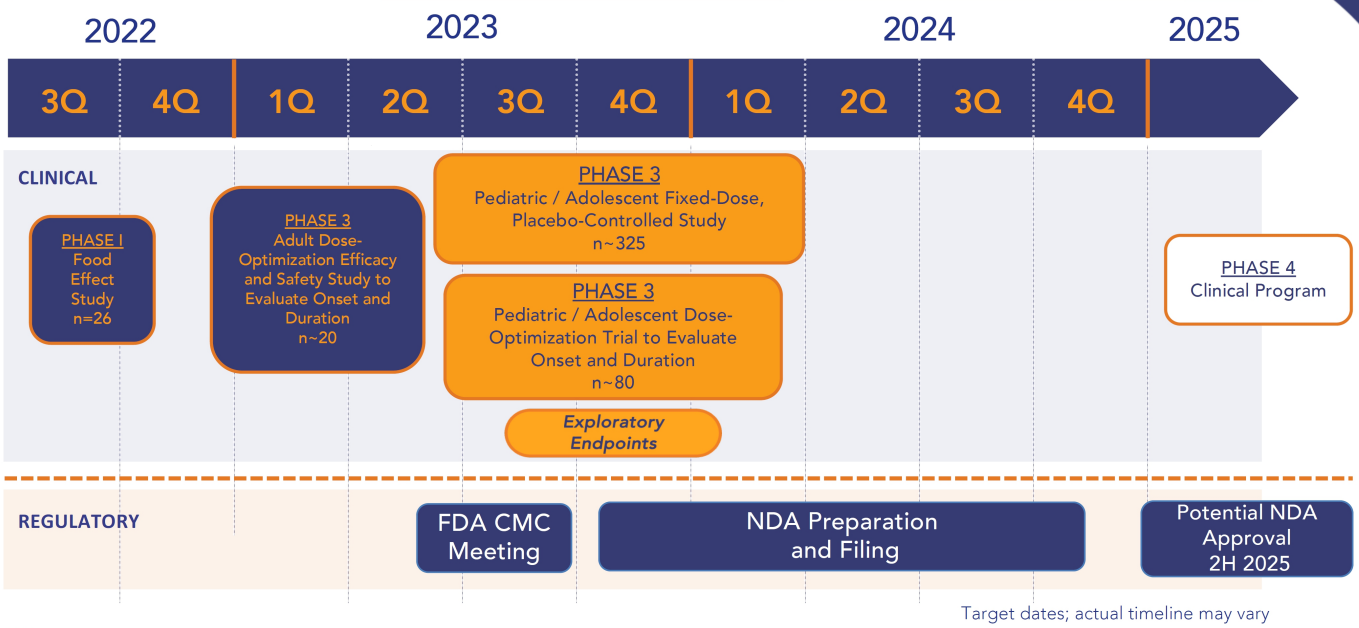
MASTERY® CTx-1301 Clinical and Regulatory Timeline



Target dates; actual timeline may vary

CINGULATE®

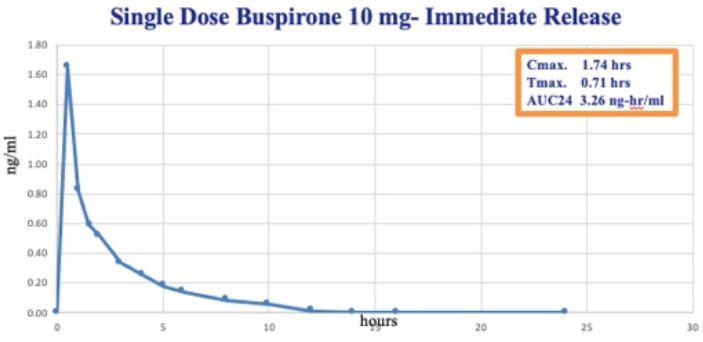
The Cingulate Solution for Anxiety Patients & Providers

CING-US-127-0724

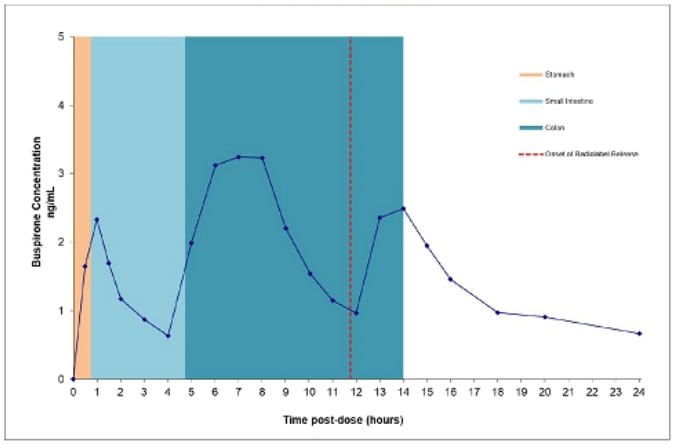
CTx-2103 – Buspirone HCl for the Treatment of Anxiety

Next-Generation Buspirone designed to Improve Patient Outcomes

Three Times a Day ***versus*** ***Once a Day***



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



CINGULATE®

Commercialization Strategy

Best in Class Market Preparation and Execution

CINGULATE® indegene®

CING-US-127-0724

Traditional Pharmaceutical Commercialization Is Increasingly Challenged

1 in 5

products reach peak U.S. sales of $1B[1]

62%

of products launched in the last 15 years have underperformed pre-launch forecasts[1]

50%

of products fail to reach peak U.S. sales of $250M[1]

Furthermore, a recent McKinsey study[2] indicated that…

50%

of Providers never plan to see a sales rep again

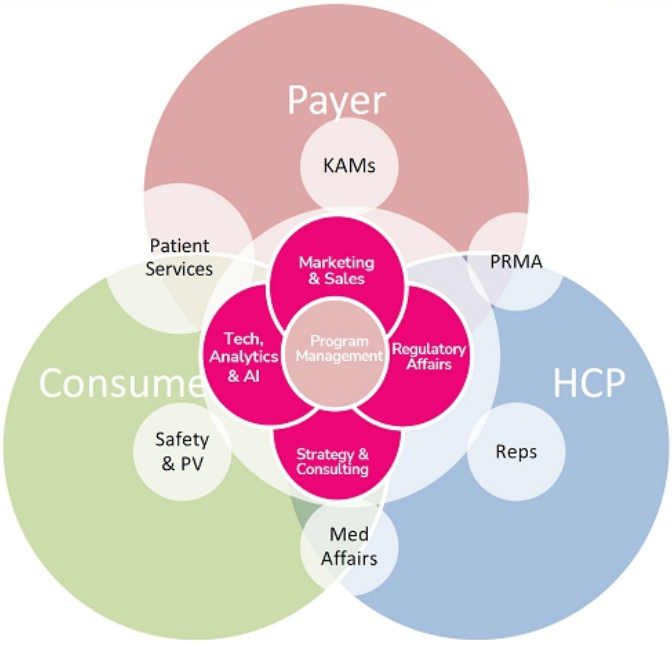
50%

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



*Consumer defined as Patient, Caregiver, Advocates

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)

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

CINGULATE®

Thank You