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):
April 20, 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.

Cingulate Inc. updated its investor presentation to be used at investor conferences and in investor meetings. A copy of the investor presentation is furnished as Exhibit 99.1 and incorporated by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	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: April 20, 2022

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

Exhibit 99.1


CINGULATE
Cingulate Therapeutics
Developing next-generation drug candidates where standard-of-care treatments result in suboptimal outcomes
April 2022
CING-US-106-0423

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, 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.

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

*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

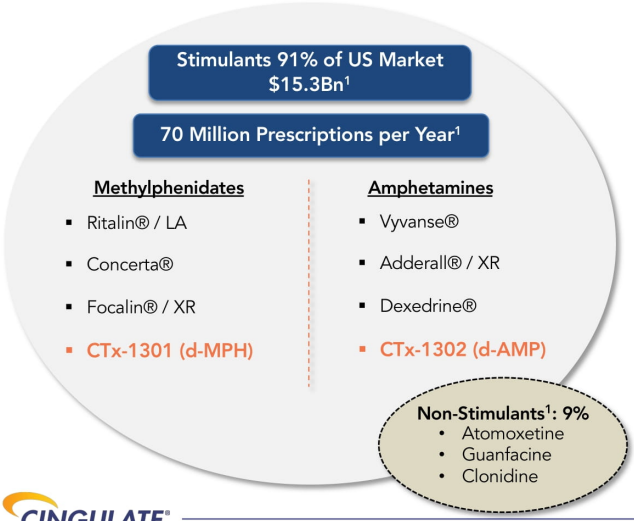
Children & Adolescents

- ~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!***

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

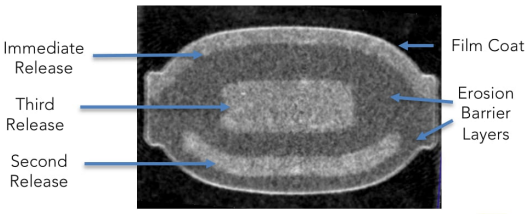
ACCOMPLISH® CTx-1302

CING-US-106-0423

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



See PTR in Action

Nine Significant Points of Differentiation

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 (d-MPH) and CTx-1302 (d-AMP)

Ideal Design Provides Exclusive Ability to Overcome Unmet Needs

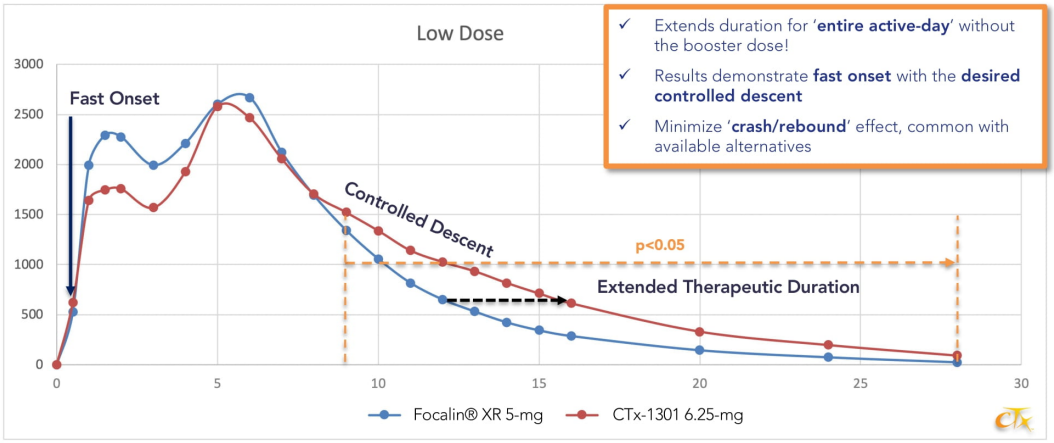
CINGULATE	TARGET ATTRIBUTES		RELEASE PROFILES		
	Onset	Duration	DOSE 1 / STYLE / TIME	DOSE 2 / STYLE / TIME	DOSE 3 / STYLE /TIME
CTx-1301 (d-MPH)	30 mins	Up to 16 hours	35% IMMEDIATE RELEASE	45% SUSTAINED RELEASE OVER 90 MINUTES AT HOUR 3	20% IMMEDIATE RELEASE AT HOUR 7
CTx-1302 (d-AMP)	30 mins	Up to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

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-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 Clinical Phase 2 Study Results

Plasma dexmethylphenidate (dMPH) Concentration vs Time

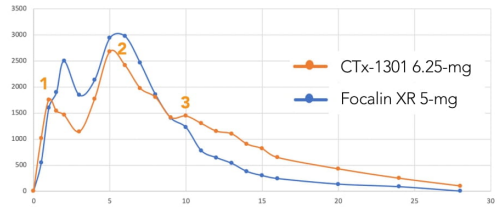


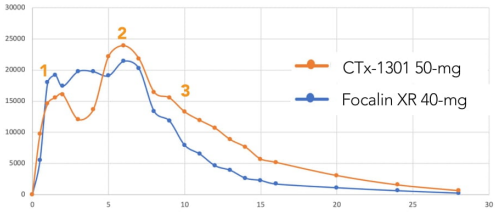
- ✓ Extends duration for '**entire active-day**' without the booster dose!
- ✓ Results demonstrate **fast onset** with the **desired controlled descent**
- ✓ Minimize '**crash/rebound**' effect, common with available alternatives

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





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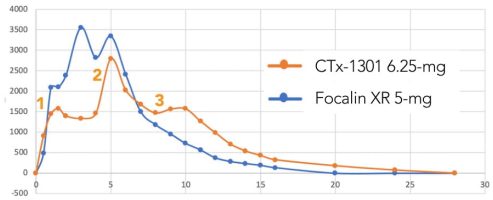
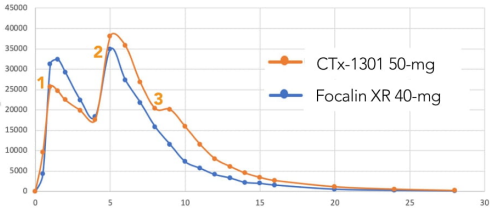




CTx-1301 Demonstrated Significantly Lower Adverse Events

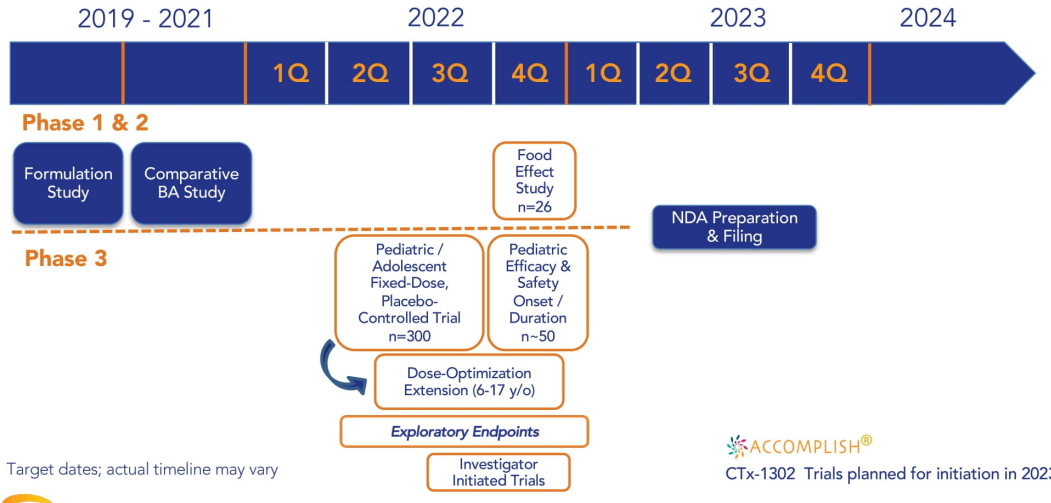
28.6% reduction in TEAE's related to CTx-1301 versus Focalin XR (14.3% difference)

	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

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

- Efficacy, tolerability, 1 vs 2 Rx's, Abuse/Diversion
- *REBATES*
- 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 ~ Clinicians, Patients, & 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

*Symphony Data. 12-months rolling through Feb 2022

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

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

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

CINGULATE®

Appendix

Senior Management Team

Proven, Experienced Pharmaceutical Industry Team

Leadership team brings extensive expertise in ADHD, clinical trials, pharmaceutical development, manufacturing, commercialization, market access, and patient care. Team has led 200+ clinical trials, 300+ publications, 30+ FDA drug approvals and the management of several billion-dollar brands.

Shane J Schaffer, PharmD
Chairman & Chief Executive Officer

Pfizer · Novartis · Sanofi

Matthew N Brams, MD
Chief Medical Officer

Baylor College of Medicine · Bayou City Research

Laurie A Myers, PhD MBA
Chief Operating Officer

Pfizer · Novartis · DuPont · Sanofi

Louis G Van Horn, MBA
Chief Financial Officer

EHL · Kimball Electronics · pwc

Raul R Silva, MD
Chief Science Officer

NYU Child Study Center

Craig S Gilgallon, Esq
General Counsel

Davis Polk · PGR

Board of Directors

Experienced and Accomplished Directors

Shane J Schaffer, PharmD

Chairman & Chief Executive Officer

Pfizer · NOVARTIS · SANOFI

Gregg Givens

DST MASTER COMPLEXITY™ · pwc

Jeff Hargroves

PROPHARMA GROUP®

Peter J Werth

CHEMWERTH

Jeff Conroy

EMBODY

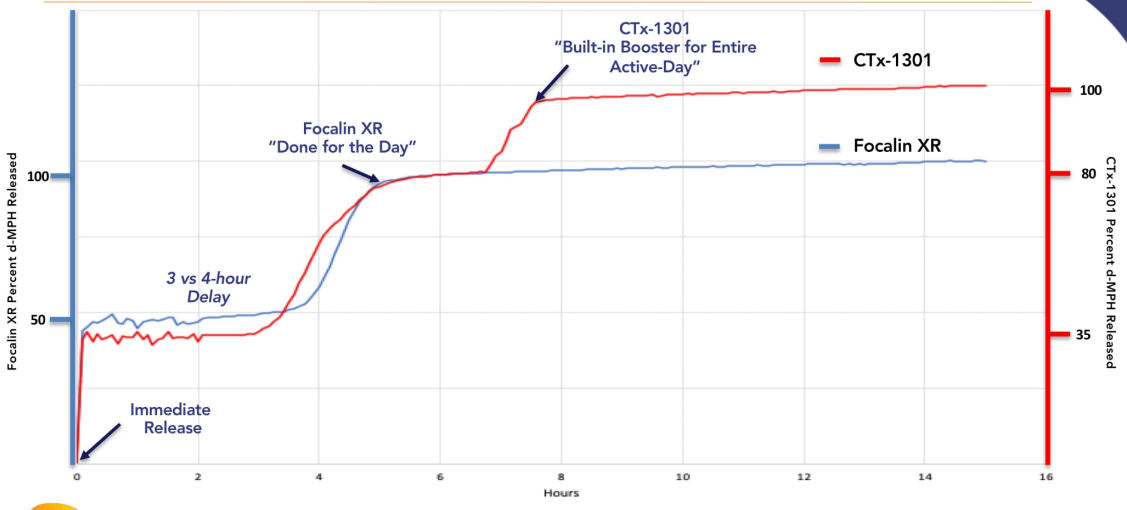
Patrick Gallagher, MBA CFA

LAIDLAW & COMPANY

Curt Medeiros, MBA ChemE

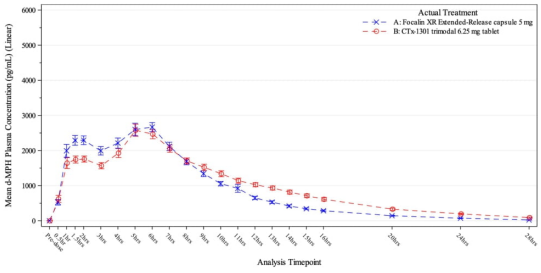
OPTUM® · ontrak better, together

In-Vitro Comparison: CTx-1301 (25-mg) and Focalin XR (20-mg)

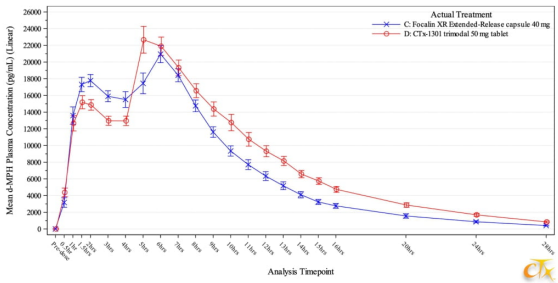


CTx-1301 Clinical Phase 2 Study Results

PTR™ Technology Delivers Minimal Intersubject Variability



- ✓ Despite expected intersubject variability with all methylphenidates, illustrated by the error bars, **all the benefits of PTR™ are maintained**
- ✓ **39 ADHD Subjects, very tight standard error especially in late day**
- ✓ Provides **ideal entire active day concentration with ability to minimize "crash"**



100% of Stimulants Have Been Approved

30 stimulant product approvals in ADHD over last 50+ years

Methylphenidates	Status	Approval Date
Azstarys*	APPROVED	March 2021
Adhansia XR*	APPROVED	February 2019
Jornay PM*	APPROVED	August 2018
Cotempla XR ODT*	APPROVED	June 2017
Quillichew ER*	APPROVED	December 2015
Quillivant XR*	APPROVED	September 2012
Aptensio XR*	APPROVED	April 2015
Daytrana*	APPROVED	April 2006
Focalin XR	APPROVED	May 2005
Methylin Chewable Tablets*	APPROVED	April 2003
Ritalin LA	APPROVED	June 2002
Focalin	APPROVED	November 2001
Metadate CD*	APPROVED	April 2001
Concerta	APPROVED	August 2000
Metadate ER*	APPROVED	June 1988
Desoxyn	APPROVED	Pre-1984
Ritalin	APPROVED	Pre-1984

Amphetamines	Status	Approval Date
Evekeo ODT*	APPROVED	January 2019
Evekeo	APPROVED	August 2018
Adzenys ER*	APPROVED	September 2017
Mydayis	APPROVED	June 2017
Adzenys XR/ODT*	APPROVED	January 2016
Dyanavel XR	APPROVED	October 2015
Zenzedi	APPROVED	May 2013
Procentra	APPROVED	January 2008
Vyvanse	APPROVED	February 2007
Adderall XR	APPROVED	October 2001
Adderall	APPROVED	February 1996
Dextrostat	APPROVED	Pre-1984
Dexedrine Spansule	APPROVED	Pre-1984
TRN-110 (Tris Pharma)	Phase 3 (Oct. 2019)	Projected 2021
Amphetamine Transdermal System (Noven)	Phase 2 (March 2013)	Projected 2022
ADAIR (Abuse Deterrent Amphetamine IR - Vallon)*	Phase 2 (June 2017)	Projected 2023

References: ClinicalTrials.gov, FDA Summary of Approvals, Noven Pharmaceuticals, Tris Pharma, and Vallon Pharmaceuticals

Note: Asterisks indicate stimulants used / plan to use the 505(b)2 regulatory pathway for approval