CINGULATE®

IPhO Industry Pharmacists Organization

# IPhO Post-Doctoral Fellowships:

- Marketing & Medical Affairs
- Clinical Operations & Regulatory Affairs

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VP, Medical Affairs and Market Access

# Cingulate Therapeutics

## Company Overview

- Location: Westwood, KS (Kansas City Metropolitan Area)
- Founded: 2012
- Founder(s): Shane J Schaffer, Pharm.D., Raul Silva, MD, Matthew Brams, MD
- Cingulate® (CTx®) is a clinical stage biopharmaceutical company:
  - Utilizes its proprietary Precision Timed Release™ (PTR™) drug delivery platform
  - 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 Attention Deficit/Hyperactivity Disorder (ADHD).
  - Cingulate is identifying and evaluating additional therapeutic areas where PTR™ technology may be employed to develop future product candidates.
- Information on PTR ™ Delivery Platform: Click Here

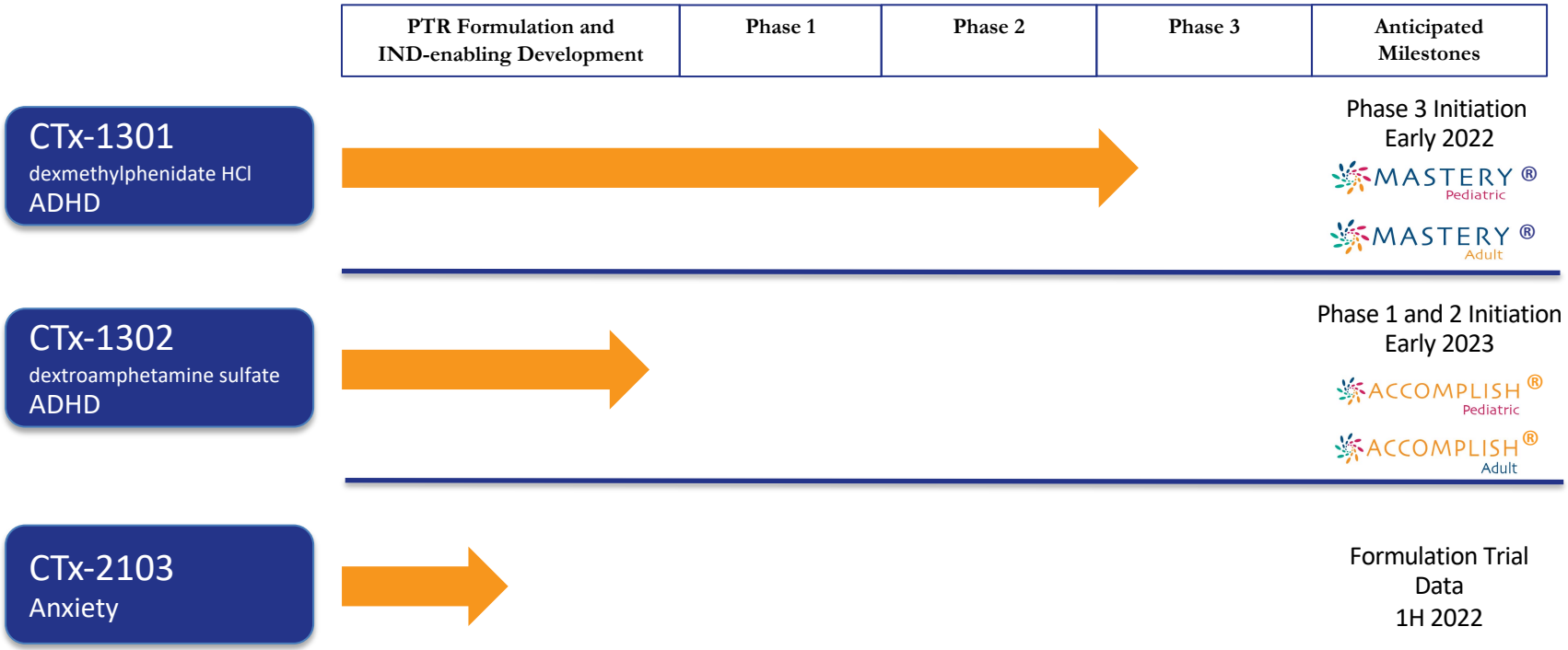
# Cingulate At A Glance

- ✓ Next-generation drug candidate pipeline for frequently diagnosed conditions in large markets currently underserved by standard-of-care treatments and resulting suboptimal treatment outcomes
- ✓ Proprietary Precision Timed Release (PTR™) platform technology underpinned by built-in Erosion Barrier Layer unlocking 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
- ✓ Positive Phase 1/2 bioavailability data for lead candidate, CTx-1301, successfully establishing target product profile and clear validation of PTR platform
  - ✓ Phase 3 trial initiation in 1Q22 with 2023 NDA filing for CTx-1301 *(via 505(b)(2) development pathway)*
- ✓ Additional early-stage PTR™ pipeline anxiety disorder candidate with plans to leverage technology in multitude of other $1Bn+ potential indications
- ✓ Positioned for Regulatory Approval and Successful Commercial Rollout along with robust IP estate



*Symphony Data. 12-months rolling through Feb 2021

# Our Proprietary Development Pipeline

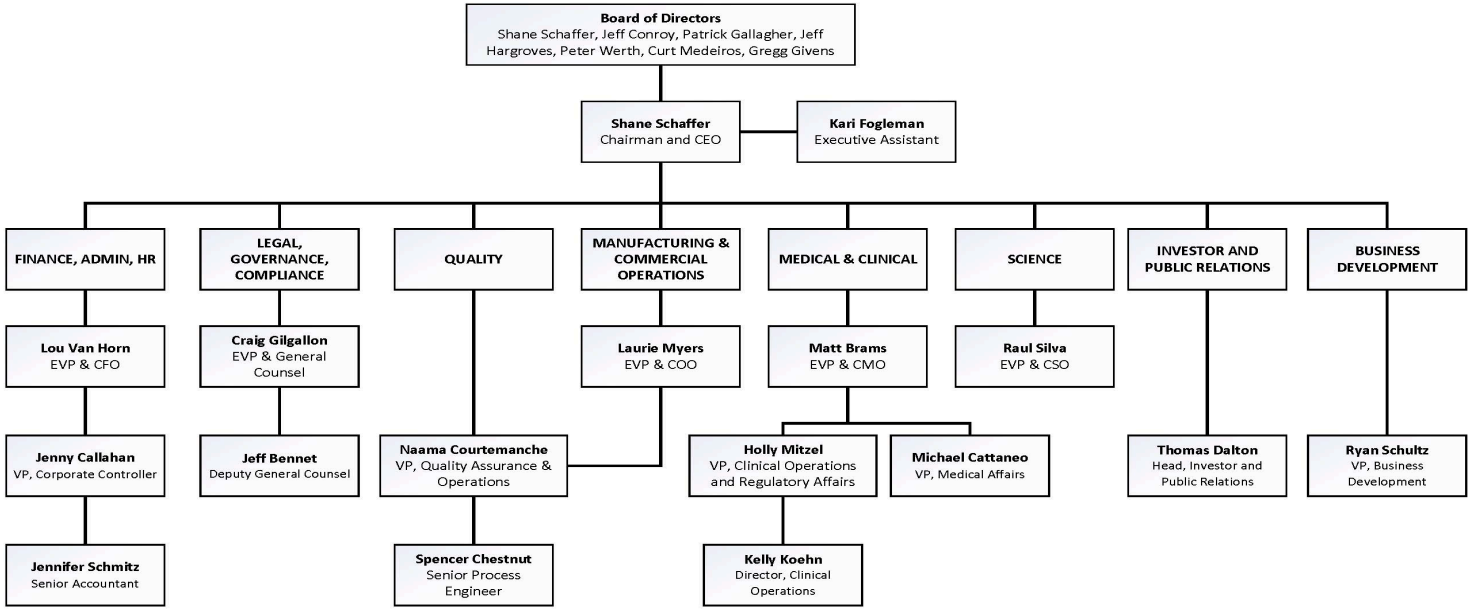



MASTERY and ACCOMPLISH are branded references to the Phase 3 clinical programs for CTx-1301 and CTx-1302, respectively

# Cingulate Company Organization

## Cingulate Organizational Chart

As of 1Q 2022



# Post-Doctoral Fellowships Overview

The 2 Fellowships will be a 2 years in length with an emphasis on the following guiding principles:

- Year 1 Fellowship
  - Engagement with departments company wide:
  - Focus: Clinical Operations/Regulatory, Medical Affairs, Market Access, Executive Team: Market Prep/Pricing
  - Other experiences: Manufacturing, Investor/Public Relations, Business Development, Finance, Legal
- Year 2 Fellowship Marketing/Medical Affairs/Market Access
  - Engage and Lead coordination of Market Access, Medical Affairs, Sales
    - Mastery of Market Dynamic and Pipeline Strategy
  - Oversight of Brand management
  - Launch preparation
  - Commercial value and execution
  - Fellow project and deliverable in Management
  - Publication strategy,
- Year 2 Fellowship Clinical Operations/Regulatory Affairs
  - Master 505b2 Process for inline and pipeline Cingulate assets.
  - Mastery of Clinical Trial Plan, strategy, execution
  - Cross company partnership with Market/Med Aff/Mark Acc Fellow on Pipeline Strategy and Tactics
  - Update the company on current cGMP with Manufacturing.
  - Fellow project and deliverable in Clinical Operations/Regulatory Affairs

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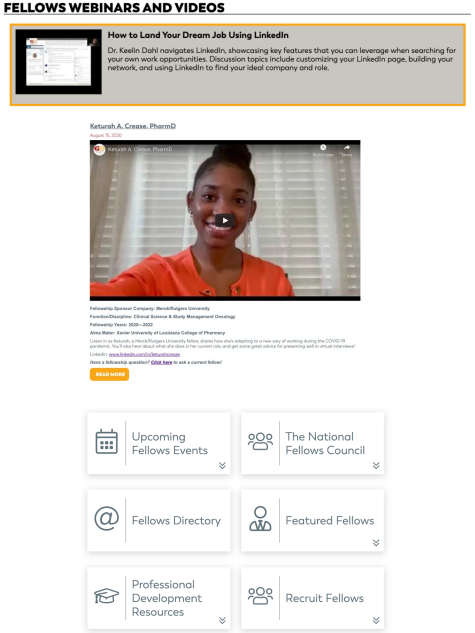
## Networking

## Professional Development





## Scholarly Activity

### An Analysis of 2021-2022 PharmD Industry Fellowships

James G. Alexander, PharmD[1], Preston Skersick, PharmD[2], Vineet Pradhan, PharmD[3], My Tran, PharmD[4], Austin Mullins, PharmD[5], Pranita Chilakamarri, PharmD[6]

National Fellows Council Chiefs

**Nicolas James, PharmD, MBA**
Fellowship Affiliation: IPhO Fellowship Company: UCB Global Regulatory Affairs Fellow Albany College of Pharmacy & Health Sciences

**Karmen Wong**
Fellowship Affiliation: Rutgers Fellowship Company: Bayer Pharmaceuticals Global Innovation and Product Development Fellow University of Hawaii at Hilo

**Muaz Sadeia**
Fellowship Affiliation: University of the Pacific (UoP) Fellowship Company: Genentech Clinical Scientist Fellow St. John's University

# Marketing & Med Affairs (MMAF) Overview

- OVERVIEW
  - At Cingulate®, Marketing serves a central role in understanding marketplace needs, unmet needs and lead in solution-focused strategy and brand creation. The Marketing Fellow will be provided with marketing and Medical affairs deep dive training to help further develop the following competencies of a successful product manager according to the marketing and medical affairs models.
- GOAL
  - The primary focus of this fellowship is Market Development, commercialization of the life cycle management plan, as well as the process of creating brand awareness and integrated communications strategies, which may encompass the functions of advertising and promotion, public and professional relations, and patient education.

# Clinical Operations/Regulatory Affairs (CORAF)

- OVERVIEW
  - At Cingulate®, Clinical Operations & Regulatory Affairs serves a central role in understanding FDA approval 505b2 needs, cGMP, Trial Master Planning and execution. The Clin Op/Reg Affairs Fellow will understand the Cingulate approach to Clinical Trails and Regulatory, along with a mastery of timing and budgetary goals to attain FDA approval as soon as possible, minimizing costs, while ensure cGMP and safety. CORAF will complete their fellowship with broad company-wide knowledge and deep understanding how to bring a compound to FDA approval.
- Goal
  - CORAF will master understanding of the all needs, assets, time, processes to ensure timely, cGMP clinical trial plan and FDA approval.