



505(b)(2) CTx-2103 (buspirone HCl)

Joseph Corsetti
President – Global PharmaPartners, Inc.
Mobile: (201) 919-2047
Tel: (417) 885-7000
Email: jcorsetti@globalpharmapartners.com

Jonathan Camerer
Vice President – Global PharmaPartners, Inc.
Mobile: (417) 576-5082
Tel: (417) 885-7000
Email: jonathancamerer@globalpharmapartners.com

BRANDED PRODUCTS

BuSpar®: 505(b)(2) Registered Listed Drug
CTx-2103 (Brand Name TBD)

API NAME

Buspirone HCL (CTx-2103)

UNMET NEED

- Currently 2-3 daily doses
- Lack of efficacy when not taken as directed
- CTx-2103 solves both unmet needs

DOSAGE FORM & CHARACTERISTICS

- CTx-2103 (buspirone HCl) is a film-coated bimodal and/ or trimodal modified-release tablet based on a tablet-in-tablet technology.
- Release profile to be determined with partner per FDA guidance on bioavailability for 505(b)(2) candidate
- Max Dosage strengths (60mg per day)

INDICATION

Treatment of anxiety

MARKET DYNAMICS (US)

Total anxiety Market:\$5B. Generic buspirion 2023 sales 3.18B (Symphony Health Nov 2023)

In 2023 24% of adults were ever diagnosed with an anxiety disorder..

DRUG APPROVAL STATUS

Pre-IND meeting conducted. IND filing to be determined once final formulation determined.

PATENT EXPIRY DATE

BuSpar LOE: date 2001
CTx-2103 patents; earliest LOE is 2035

Timelines for Partnership for CTx-2103

- Non-Binding Term Sheet: **Q2 2024**
- Diligence conducted: **Q3 2024**
- Definitive agreement: **Q3-4 2024**
- Final formulation: **Q4 2024**
- IND filing: **Q2 2025**

Terms for US Partner

Remaining Development Costs Split:

50% Cingulate/50% US Partner (see details of estimated budget below)

Licensing fees: \$7.0M

- On signing of the contract: \$1.0M
- Successful IND submission: \$ 0.5M
- Completion of clinical studies: \$0.5M
- Conduct pre-NDA meeting: \$0.5 M
- 505(b)(2) NDA Filing: \$1.0M
- 505(b)(2) NDA approval: \$3.5M

Cost of Goods (estimated)

- Bi-release tablet: \$1.80/tab
- Tri-release tablet: \$1.45/tab

Net Profit Split:

50% Cingulate/50% US Partner

Sales Projection to US Partner

Sales Projections:

Year 1 Net Sales 100.0M
Year 2 Net Sales 150.0M
Year 3 Net Sales 300.0M
Year 4 Net Sales 500.5M
Year 5 Net Sales 750.0M

Development Budget for CTx-2103

CTx-2103

Action Item	Budget
Formulation and Human POC	\$ 800,000.00
Manufacturing and Analytics	\$ 1,900,000.00
Phase I/II	\$ 4,530,000.00
Phase III (not expected per 505(b)(2) path)	\$ 0.00
Regulatory (includes est'd filing fee of \$3.0M)	\$ 4,562,000.00
Grand Total:	\$ 11,792,000.00

About Cingulate and CTx-2103

Cingulate® (CTx®) is a Phase 3 clinical-stage biopharmaceutical company utilizing its proprietary Precision Timed Release™ (PTR™) drug delivery platform to build and advance a pipeline of branded next-generation pharmaceutical products. These will be 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) and Anxiety. Cingulate is identifying and evaluating additional therapeutic areas where PTR™ technology may be employed to develop future product candidates. (www.Cingulate.com)

About CTx-2103

Bupirone, an azapirone derivative and a 5-HT_{1A} partial agonist, is the #1 nonbenzodiazepine anxiolytic introduced for the treatment of anxiety disorder. Bupirone as it is not a scheduled agent, exhibits a decreased side-effect profile which includes withdrawal and dependency, as compared to other anxiolytic treatments.

In clinical practice bupirone is administered orally in two to three divided doses up to a maximum of 60mg per day. The usual therapeutic dose is 15 to 30mg daily. Cingulate is has investigated a triple pulse formulation of bupirone which would deliver the full total amount of daily bupirone in a single tablet. Based on FDA feedback (pre-IND communication) Cingulate believes the investigation of a bimodal release profil is also warrented.

About Anxiety

Anxiety disorders are the most common mental health concern in the United States. Over 40 million adults in the US (19.1%) have an anxiety disorder. Most people develop symptoms before age 21. Anxiety disorders can occur along with other mental health conditions, and they can often make the related condition worse (National Alliance on Mental Illness: NAMI). These may include:

- Depression
- Substance Use
- Attention Deficit /Hyperactivity Disorder (ADHD)
- Eating Disorders
- Trouble Sleeping