



# Intra-Cellular THERAPIES

August, 2023

# Safe Harbor Statement

This presentation contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements.

Such forward-looking statements include statements regarding, among other things, our plans to commercialize CAPLYTA for bipolar depression and schizophrenia; our estimates of the size of the prescriber base; whether clinical trial results will be predictive of future real-world results; whether CAPLYTA will serve an unmet need; our beliefs about the potential utility of our product candidates; and our development efforts and plans. All such forward-looking statements are based on management’s present expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to, the following: there are no guarantees that CAPLYTA will be commercially successful; our financial and operating performance, including our future revenues, expenses, or profits; we may encounter issues, delays or other challenges in commercializing CAPLYTA; the COVID-19 pandemic may negatively impact our commercial plans and sales for CAPLYTA; the COVID-19 pandemic may negatively impact the conduct of, and the timing of enrollment, completion and reporting with respect to, our clinical trials; whether CAPLYTA receives adequate reimbursement from third-party payors; the degree to which CAPLYTA receives acceptance from patients and physicians for its approved indications; challenges associated with execution of our sales activities, which in each case could limit the potential of our product; results achieved in CAPLYTA in the treatment of schizophrenia and bipolar depression following commercial launch of the product may be different than observed in clinical trials, and may vary among patients; any other impacts on our business as a result of or related to the COVID-19 pandemic; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with CAPLYTA following commercial launch for the treatment of schizophrenia or bipolar depression or in ongoing or future trials and other development activities; our other product candidates may not be successful or may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety and/or efficacy in larger-scale or later clinical trials or in clinical trials for other indications; our proposals with respect to the regulatory path for our product candidates may not be acceptable to the U.S. Food and Drug Administration; our reliance on collaborative partners and other third parties for development of our product candidates; and the other risk factors detailed in our public filings with the Securities and Exchange Commission. All statements contained in this presentation are made only as of the date of this presentation, and the Company undertakes no duty to update this information unless required by law.

# Non-Promotional Presentation

This presentation is intended for the investor community only; materials are not intended to promote the products referenced herein or otherwise influence healthcare prescribing decisions.

# Intra-Cellular Therapies, Inc. (ITCI)

## A fully Integrated Biopharmaceutical Company

### Our Mission:

Deliver innovative treatments to improve the lives of individuals with neuropsychiatric, neurologic, and other disorders to reduce the burden on patients and their caregivers

**Successful Commercial  
Launch of CAPLYTA®  
(lumateperone)**

**Strongly Positioned for  
Future Growth**

**Robust  
Pipeline**

**Strong Financial  
Position**

# CAPLYTA is Approved for the Treatment of Schizophrenia and Bipolar I and II Depression in Adults



## Proven Efficacy

FDA approved for the treatment of schizophrenia and bipolar I and II depression in adults

## Favorable safety profile

Similar to placebo:

- Extrapyrimal symptoms (EPS) changes including akathisia
- Weight, fasting glucose, total cholesterol, and triglycerides
- Mean changes in prolactin

## Convenient dosing

Once daily, with or without food

Start and stay, with no titration required

## Most common adverse reactions\*

Somnolence/sedation, dizziness, nausea, and dry mouth

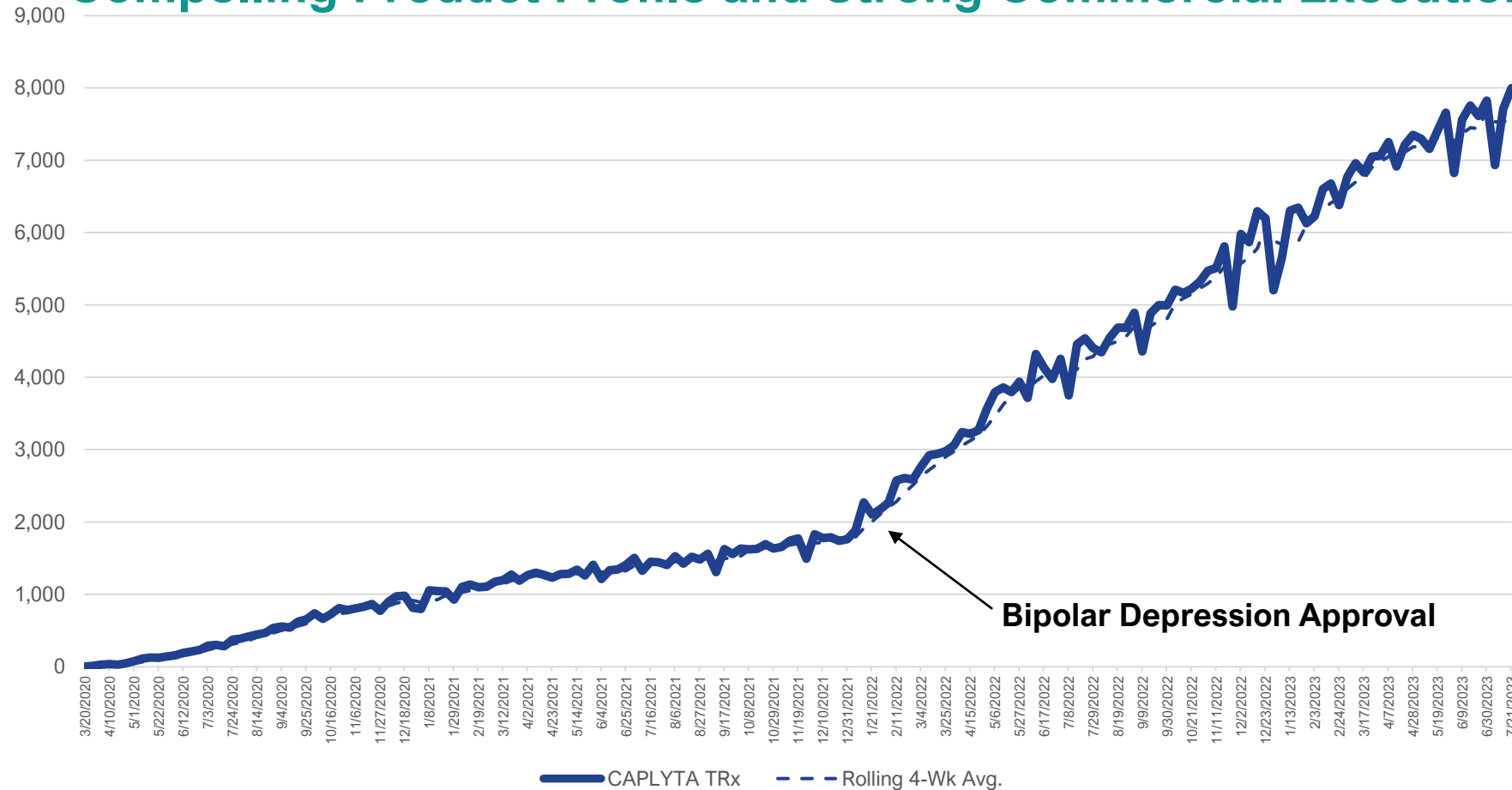
CAPLYTA (lumateperone) is FDA-approved for the treatment of depressive episodes associated with bipolar I or bipolar II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate and for the treatment of schizophrenia in adults.

Please see full Prescribing Information including **BOXED Warnings** at [https://www.intracellulartherapies.com/docs/caplyta\\_pi.pdf](https://www.intracellulartherapies.com/docs/caplyta_pi.pdf)

\*≥5% and twice the rate of placebo

# CAPLYTA has Achieved Commercial Success

## Compelling Product Profile and Strong Commercial Execution



- Substantial Rx inflection following bipolar depression approval<sup>1</sup>
- 5x to 6x increase in weekly new patient starts vs. prior to bipolar depression
- Rx volume tripled in 2022 vs 2021

# Bipolar Disorder Is a Chronic Disease With a Substantial Burden and Unmet Need



Approximately 11 million adults affected by bipolar disorder in the U.S.<sup>1</sup>



Depressive episodes are longer and recur more often than manic/hypomanic episodes and can be severely debilitating<sup>2,3</sup>



The top 2 reported reasons for why patients wanted to change their treatment were side effects and feeling that the treatment wasn't working sufficiently<sup>4</sup>



Few drugs approved for bipolar I depression, and CAPLYTA is one of only two drugs approved for bipolar II depression

# Bipolar II Depression Is Under-Diagnosed and has Greater Symptom Burden than Bipolar I

## Patients with bipolar II<sup>1,2</sup>



Experience a **higher frequency of depressive episodes** that last longer

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Are more likely to have **comorbid psychiatric disorders**

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Have a **higher risk of death by suicide**

***Bipolar I and Bipolar II disorder patient populations are of similar size<sup>3</sup>***

# CAPLYTA is Approved for a Broad Range of Adult Patients with Bipolar Depression

## The FIRST AND ONLY treatment

indicated for depressive episodes associated with bipolar I and II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate

Clinical studies evaluating adults with a depressive episode associated with bipolar disorder (bipolar depression)	Monotherapy		Adjunctive (with lithium or valproate)	
	Bipolar I	Bipolar II	Bipolar I	Bipolar II
<b>CAPLYTA</b>	✓	✓	✓	✓
Quetiapine/Quetiapine XR	✓	✓		
Olanzapine/Fluoxetine	✓			
Lurasidone	✓		✓	
Cariprazine	✓			

There are no head-to-head studies comparing the safety and efficacy of these products. This chart is descriptive of the FDA-approved indications in adults with bipolar depression and does not represent all approved indications for each product.

CAPLYTA (lumateperone) is FDA-approved for the treatment of depressive episodes associated with bipolar I or bipolar II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate and for the treatment of schizophrenia in adults.

Please see full Prescribing Information including **BOXED Warnings** at [https://www.intracellulartherapies.com/docs/caplyta\\_pi.pdf](https://www.intracellulartherapies.com/docs/caplyta_pi.pdf)



# ITCI Long-term Growth Strategy Anchored in Three Strategic Pillars

**1**

**Maximize**  
CAPLYTA  
performance

**2**

**Develop** CAPLYTA  
in additional  
mood disorders

**3**

**Advance**  
Pipeline

# Driving Continuous Growth with Robust Prescriber and Consumer Promotion

## Prescriber Promotion

**Educating 43,000+ prescribers\***  
including psychiatrists, NP/PAs and primary care

- Experienced sales specialists
- Peer to peer medical education programs (in-person and on-demand)
- Robust digital promotion



## Consumer Promotion

**Broad national advertising**  
through television and social media  
platforms to enhance awareness  
for the 11MM adults with bipolar  
disorder

\*Accounting for ~80% of branded schizophrenia and bipolar prescriptions

# Strong Market Access Position

**>98%** of **Medicare / Medicaid lives**


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**~90%** of **Commercial lives**

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**LYTAlink™** **Effective patient support program**

# Lumateperone Programs Extend Across Multiple Major Neuropsychiatric Conditions

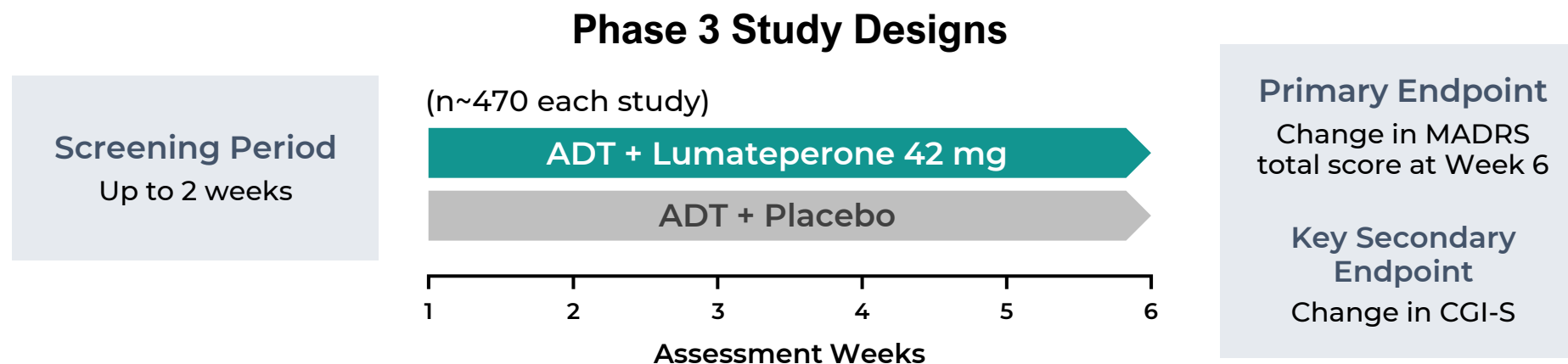
 <p>APPROVED INDICATIONS</p>	Schizophrenia	~2.4 M Patients <sup>1</sup>
	Bipolar I or II depression as monotherapy and as adjunctive treatment with lithium or valproate	~ 11 M patients <sup>2</sup>
DEVELOPMENT PROGRAMS	Adjunctive treatment of MDD	21 M patients <sup>3</sup>
	MDD or Bipolar Depression w/ Mixed Features	~1/3 of patients with MDD and bipolar depression <sup>4, 5</sup>
LONG-ACTING INJECTABLE	Schizophrenia	~2.4 M patients <sup>1</sup>

Oral lumateperone is FDA-approved for the treatment of depressive episodes associated with bipolar I or bipolar II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate and for the treatment of schizophrenia in adults. The safety and efficacy has not been established for other formulations or uses.

1. NIH. <https://archives.nih.gov/asites/report/09-09-2019/report.nih.gov/nihfactsheets/ViewFactSheet76f.html?csid=67&key=S#S>. Accessed Dec 23, 2022. 2. National Institute of Mental Health. Bipolar Disorder. <https://www.nimh.nih.gov/health/statistics/bipolar-disorder>. Accessed Dec 23, 2022. 3. National Institute of Mental Health, Major Depression. <https://www.nimh.nih.gov/health/statistics/major-depression.shtml>. Accessed Dec 23, 2022. 4. Perugi G, Angst J, Azorin JM, et al: Mixed features in patients with a major depressive episode: the BRIDGE-II-MIX study. J Clin Psychiatry 2015; 76:e351–e358. 5. McIntyre RS, Soczynska JK, Cha DS, et al. The prevalence and illness characteristics of DSM-5-defined "mixed feature specifier" in adults with major depressive disorder and bipolar disorder. Journal of Affective Disorders 172 (2015) 259-264

# Adjunctive Treatment of MDD

- Three Phase 3 adjunctive treatment of MDD studies
  - Study 501, Study 502 and Study 505 are global 6-week, randomized, double-blind, placebo-controlled, multicenter, clinical trials in adult patients with MDD who are having inadequate response to antidepressant monotherapy (ADT)

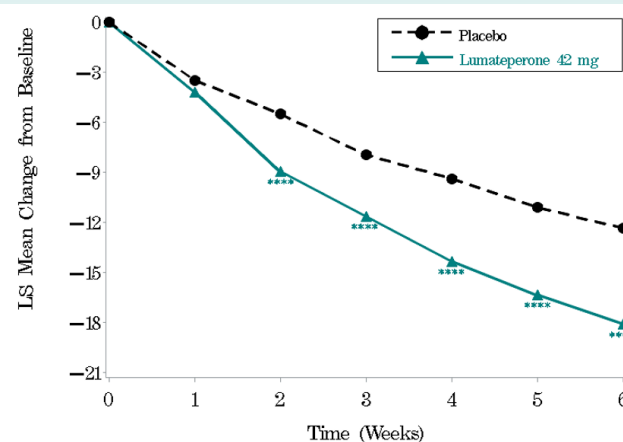


Study 503 is an open label roll-over study to assess safety for 6 months

# Study 403: Positive Results Evaluating Lumateperone as Monotherapy in Patients with MDD with Mixed Features and Bipolar Depression with Mixed Features

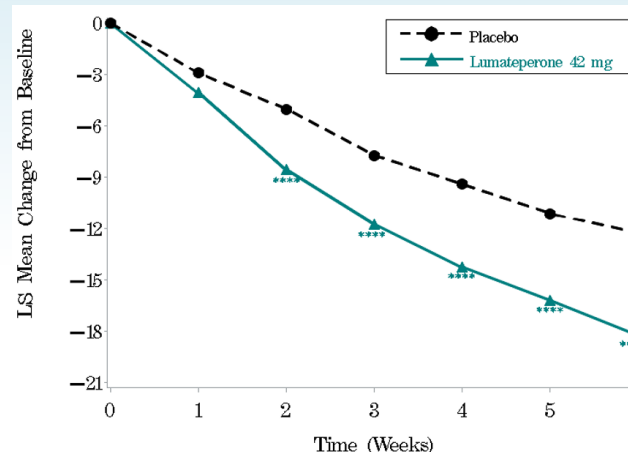
## Combined population: MDD+MF & Bipolar Depression+MF

Lumateperone 42 mg  
**Met the primary endpoint:** MADRS total score  
( $p < 0.0001$ ; Cohen's d effect size = 0.64)



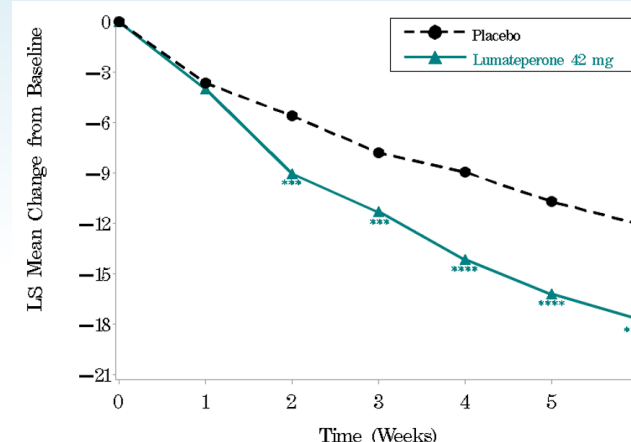
## Individual Populations MDD+MF

Lumateperone 42 mg  
**Met the primary endpoint:** MADRS total score  
( $p < 0.0001$ ; Cohen's d effect size = 0.67)



## Individual Populations Bipolar Depression+MF

Lumateperone 42 mg  
**Met the primary endpoint:** MADRS total score  
( $p < 0.0001$ ; Cohen's d effect size = 0.64)



- Key secondary endpoint:** Lumateperone demonstrated a statistically significant reduction in the CGI-S score compared to placebo at Week 6 in the **combined** patient population ( $p < 0.0001$ ; ES= 0.59), patients with **MDD** with mixed features ( $p = 0.0003$ ; ES= 0.57), and patients with **bipolar depression** with mixed features ( $p < 0.0001$ ; ES=0.61).
- Lumateperone was generally safe and well tolerated, with a side effect profile consistent with prior lumateperone trials.

\* $p < 0.05$  \*\* $p < 0.01$  \*\*\* $p < 0.001$  \*\*\*\* $p < 0.0001$

# Advancing our Pipeline

## ITI-1284-ODT-SL

**ITI-1284 ODT-SL** is a deuterated form of lumateperone, a NME formulated as an oral disintegrating tablet for sublingual administration

Phase 2 programs in **generalized anxiety disorder, in psychosis in patients with Alzheimer's disease (AD),** and in **agitation in patients with AD** to begin in 2023

## PDE 1 Inhibitors

Our portfolio of **PDE1 inhibitors** are being developed to treat diseases in which PDE1 activity is highly active

**Lenrispodun (ITI-214)** is in Phase 2 development for **Parkinson's disease**

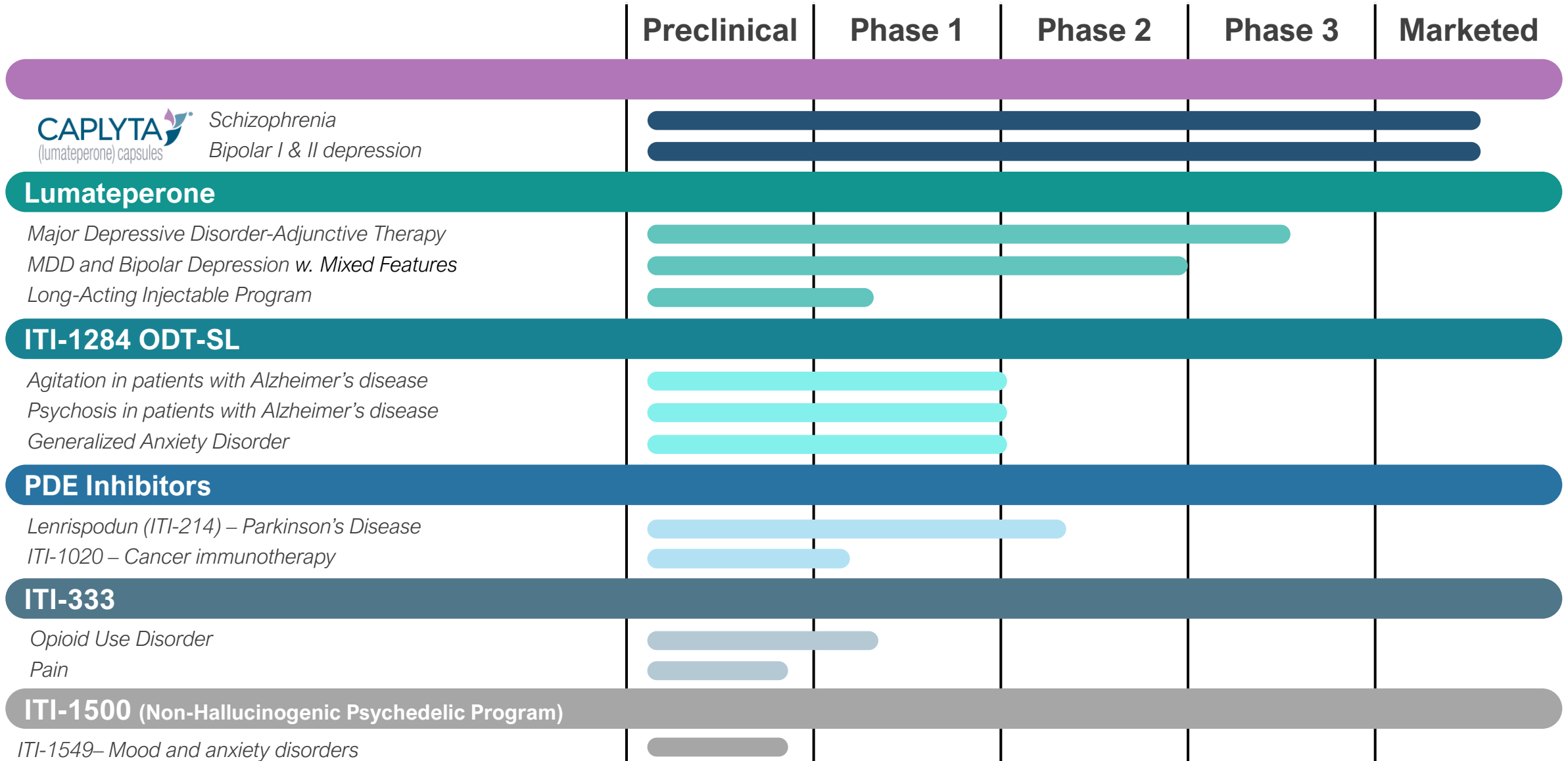
**ITI-1020 cancer immunotherapy program**; Phase 1 SAD study ongoing

## ITI-333

Our 5-HT<sub>2A</sub> antagonist and  $\mu$ -opioid receptor partial agonist provides potential utility in the treatment of **opioid use disorder** and **pain**

A multiple ascending dose study and a positron emission tomography (PET) study are ongoing

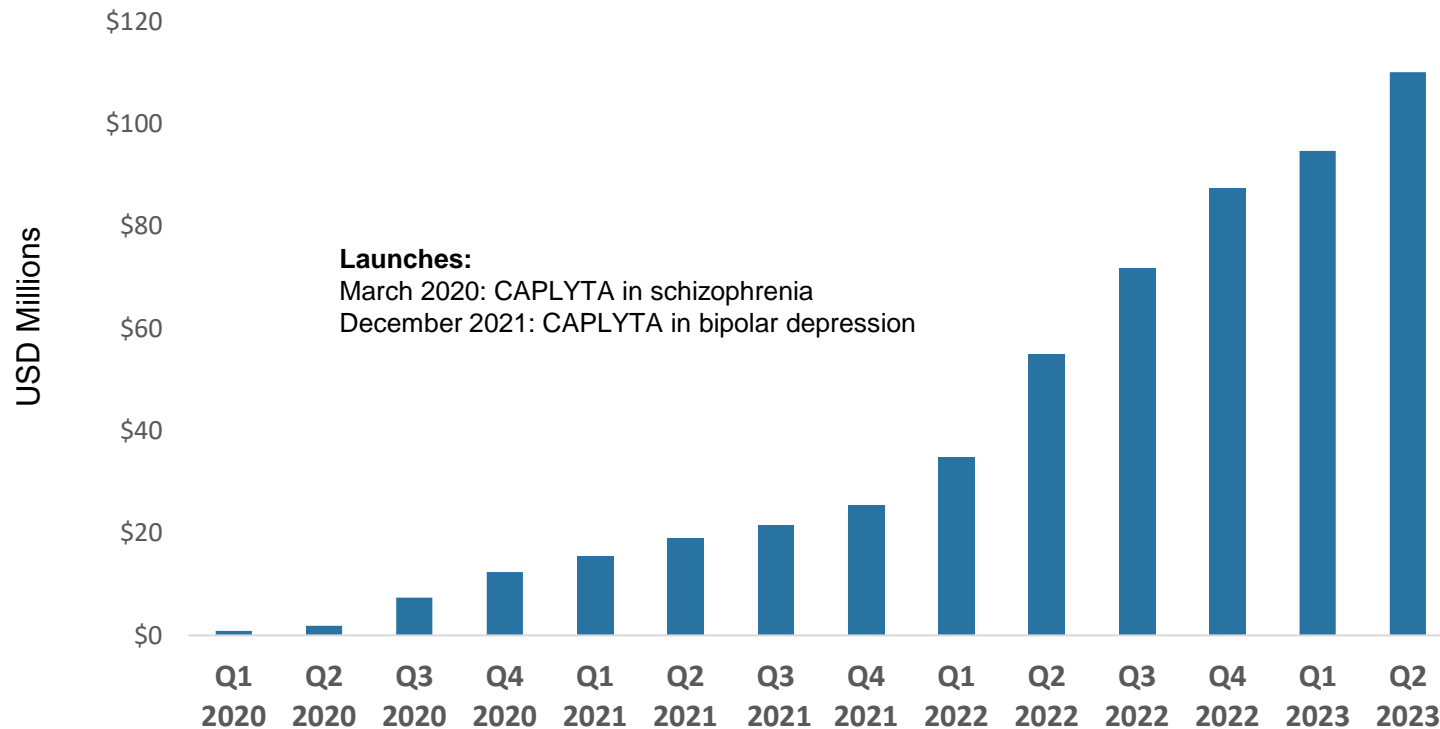
# Portfolio





# Financials

## CAPLYTA (lumateperone) Net Sales



**CAPLYTA FY '23 Net Sales Guidance: \$445 - \$465 million**

### CAPLYTA

Q2 2023 Net Sales Growth

**+100%** vs Q2 2022

FY2022 Net Sales Growth

**+243%** vs FY 2021

As of June 30, 2023 (unaudited)

**~\$514.6 Million** cash,  
cash equivalents and investments

**No Debt**

A large, stylized circular graphic composed of several concentric, semi-transparent teal rings. The rings are of varying shades of teal, creating a layered effect. The text "Thank you" is centered within this graphic.

**Thank you**