



Second Quarter 2024 Financial Results & Corporate Update

August 7, 2024

# 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 financial and operating performance, including our future revenues and expenses; our expectations regarding the commercialization of CAPLYTA; our plans to expand our sales force, our plans to conduct clinical or non-clinical trials and the timing of developments with respect to those trials, including enrollment, initiation or completion of clinical conduct, or the availability or reporting of results; plans to make regulatory submissions to the U.S. Food and Drug Administration (FDA) and the timing of such submissions; whether clinical trial results will be predictive of future real-world results; whether CAPLYTA will serve an unmet need; the goals of our development programs; and our beliefs about the potential utility of our product candidates. 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; we may encounter issues, delays or other challenges in commercializing CAPLYTA; 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; challenges associated with supply and manufacturing activities, which in each case could limit our sales and the availability of our product; 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; there is no guarantee that a generic equivalent of CAPLYTA will not be approved and enter the market before the expiration of our patents; 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 FDA; our reliance on collaborative partners and other third parties for development of our product candidates; impacts on our business, including on the commercialization of CAPLYTA and our clinical trials, as a result of the COVID-19 pandemic, the conflicts in Ukraine, Russia and the Middle East, global economic uncertainty, inflation, higher interest rates or market disruptions; 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.

# Second Quarter 2024 Highlights

## CAPLYTA Performance

- Robust TRx Growth +36% in Q2'24 vs Q2'23
- Raising CAPLYTA '24 net sales guidance
- Expanding sales force

## Building for the Future

- Positive results in **TWO** lumateperone Phase 3 adjunctive MDD studies
  - sNDA submission on track for 2H'24
- Advancing pipeline

## Financial Position

- CAPLYTA revenue increased +46% in Q2'24 vs Q2'23
- Cash position ~\$1.025 Billion

# FINANCIAL & CAPLYTA PERFORMANCE

# Q2 2024 Financial Summary

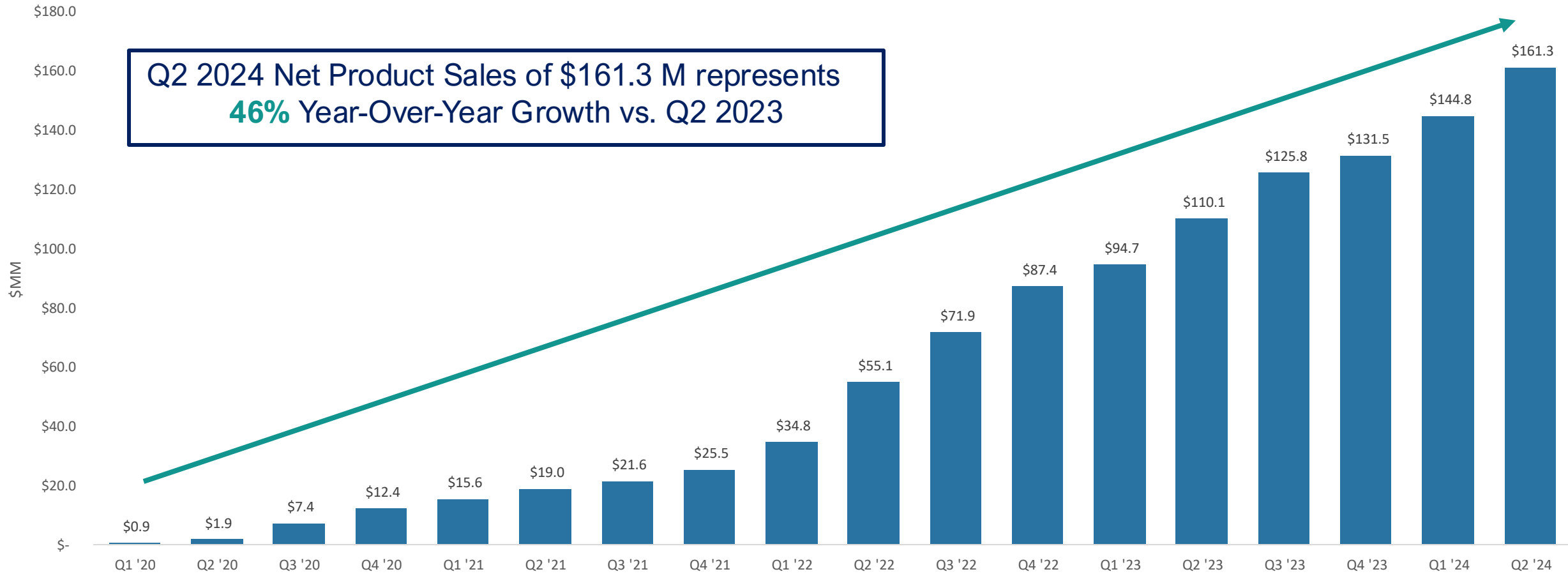
**\$ Millions, except for Net Loss per Share**

	Q2 2024	Q2 2023
Total Revenue	\$ 161.4	\$ 110.8
Product Sales, Net	\$ 161.3	\$ 110.1
SG&A Expense	\$ 121.6	\$ 101.0
R&D Expense	\$ 56.2	\$ 49.8
Net Loss	\$ (16.2)	\$ (42.8)
Net Loss per share	\$ (0.16)	\$ (0.45)
Cash & Investments (Period End)*	\$ 1,025	\$ 515

	FY 2024 Guidance (\$ Millions)
CAPLYTA Net Sales	\$650 - \$680
SG&A Expense	\$480 - \$510
R&D Expense	\$210 - \$230

\*Consists of cash and cash equivalents, investment securities and restricted cash as of the respective period end date.

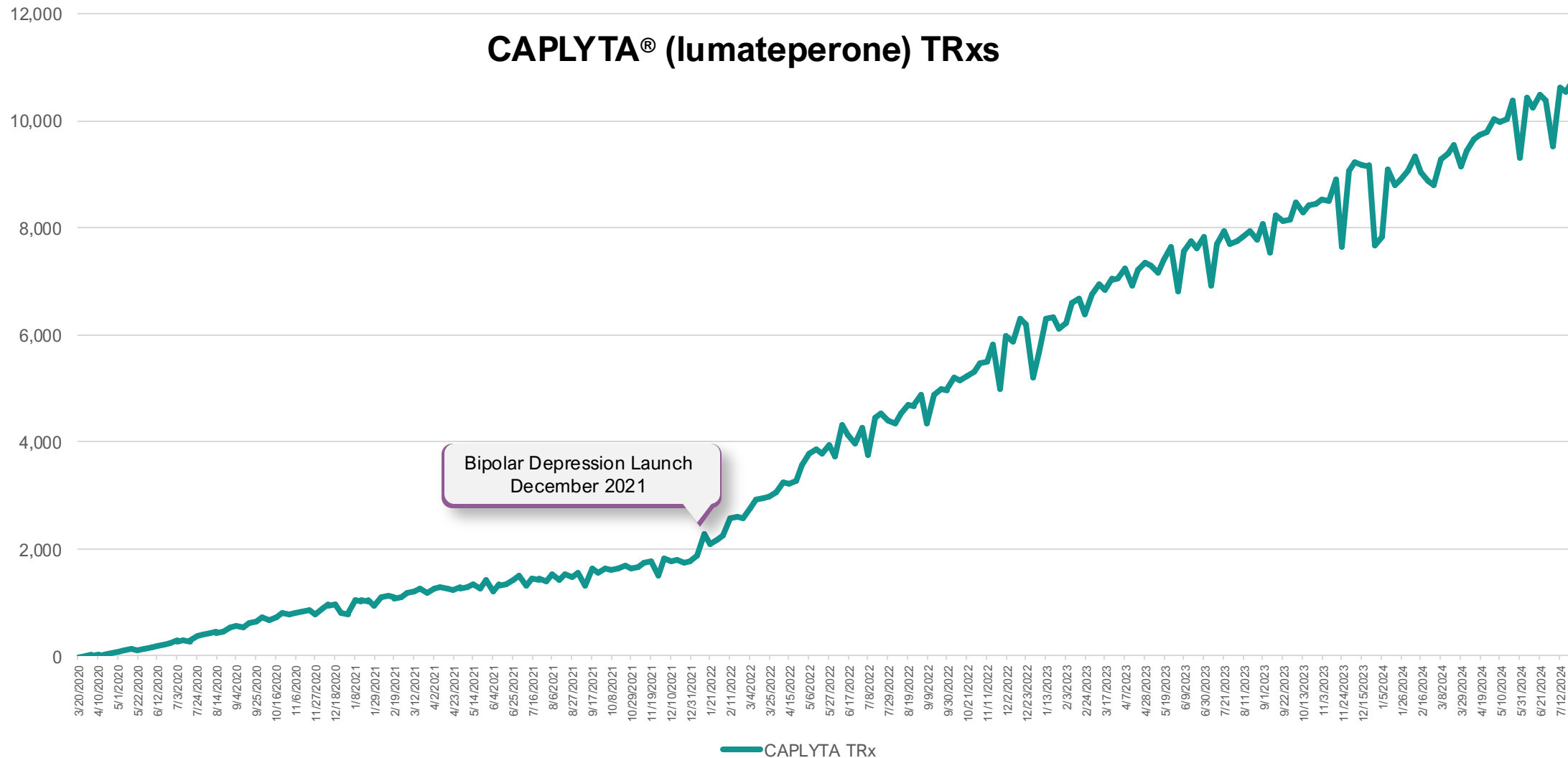
# CAPLYTA Quarterly Net Product Sales Performance



## FY 2024 CAPLYTA Net Product Sales Guidance

	2023 Net Product Sales (\$ Millions)	FY 2024 Net Product Sales Guidance (\$ Millions)
CAPLYTA Net Product Sales	\$462.2	\$650 - \$680

# Substantial Rx Trajectory



# EXPANDING CAPLYTA



# Our Vision

## Establish CAPLYTA as a First Choice Across Depressive Disorders

### Bipolar I Depression



Approved

### Bipolar II Depression



Approved

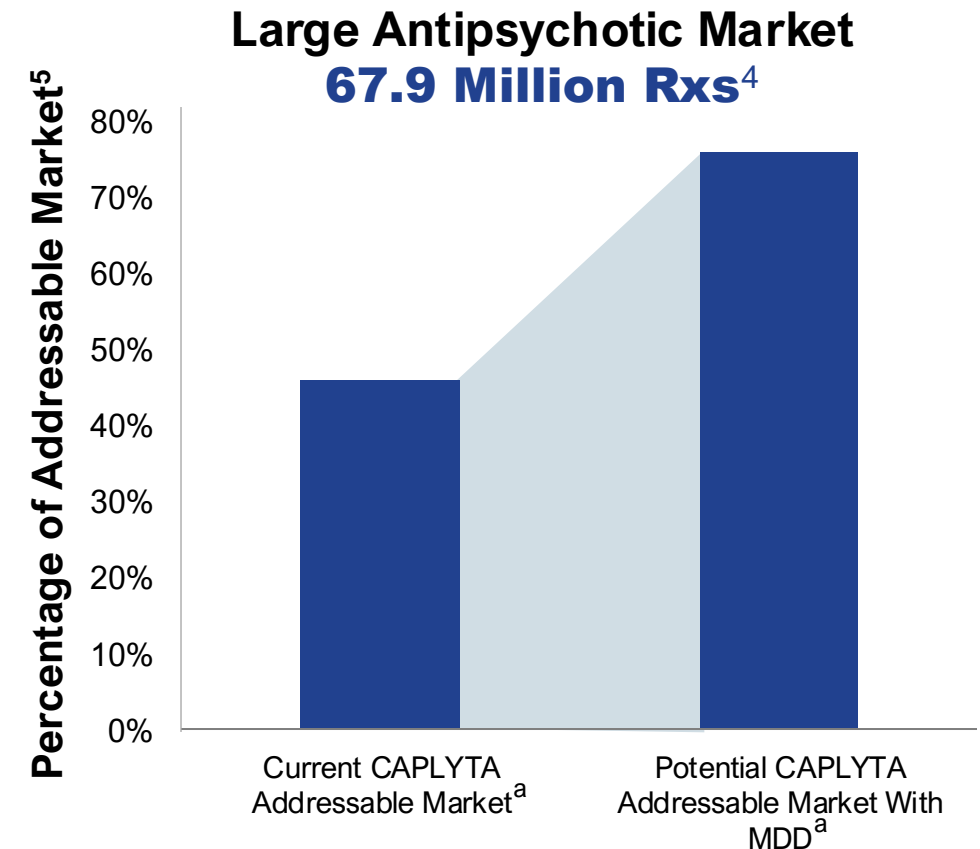
### Major Depressive Disorder

✓ **Positive Results** from  
Study 501 & 502

sNDA submission  
Expected **2H '24**

Robust efficacy, favorable safety/tolerability, and convenient dosing  
are preferred attributes in prescribing decisions

# These Disorders Are Highly Prevalent; Total Addressable Market Expands With MDD



<sup>a</sup>Current CAPLYTA addressable market includes schizophrenia and bipolar disorder; potential CAPLYTA addressable market includes schizophrenia, bipolar disorder, and MDD.

1. Johns Hopkins Medicine. Mental health disorder statistics. <https://www.hopkinsmedicine.org/health/wellness-and-prevention/mental-health-disorder-statistics>. Accessed Jan 3, 2024. 2. National Institute of Mental Health. Bipolar disorder. <https://www.nimh.nih.gov/health/statistics/bipolar-disorder>. Accessed Jan 3, 2024. 3. National Institute of Mental Health. Major depression. <https://www.nimh.nih.gov/health/statistics/major-depression.html>. Accessed Jan 3, 2024. 4. IQVIA NPA 2023. 5. Symphony YTD/Nov/23.

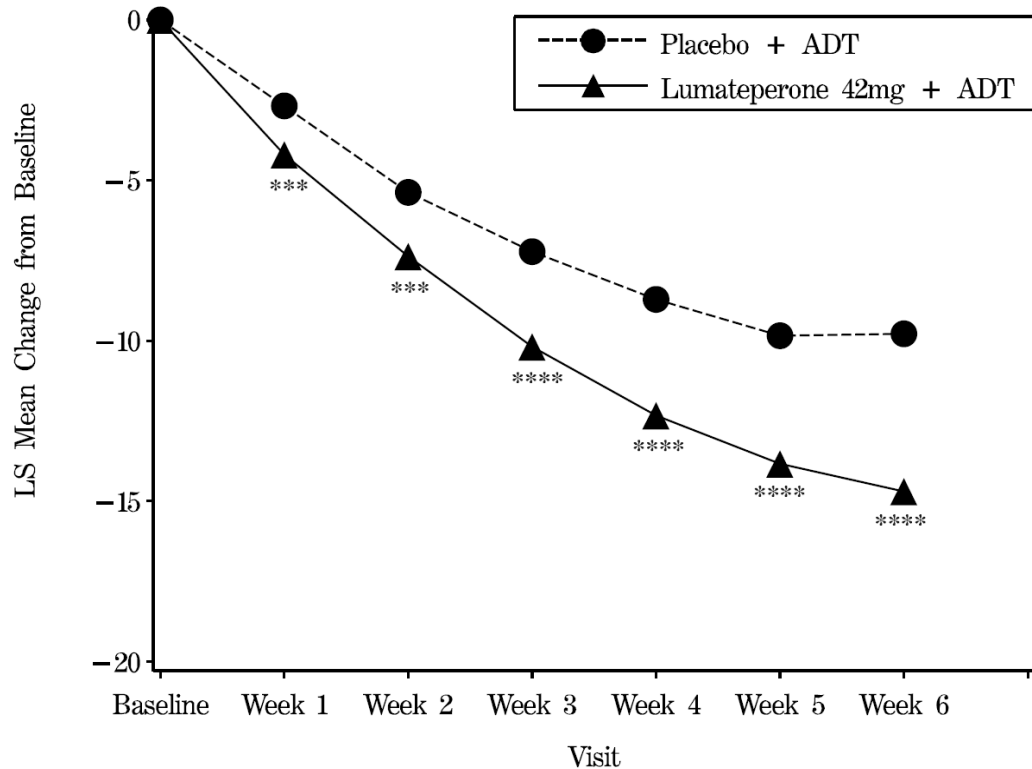
CAPLYTA® (lumateperone) is FDA-approved for the treatment of depressive episodes associated with bipolar I or bipolar II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate and for the treatment of schizophrenia in adults.

# **Lumateperone as Adjunctive Therapy in Patients with Major Depressive Disorder**

## **Study 501 & 502 Results**

# Lumateperone Demonstrated a Statistically Significant Reduction on the MADRS Total Score Compared to Placebo at Week 6

Study 501 (MADRS)



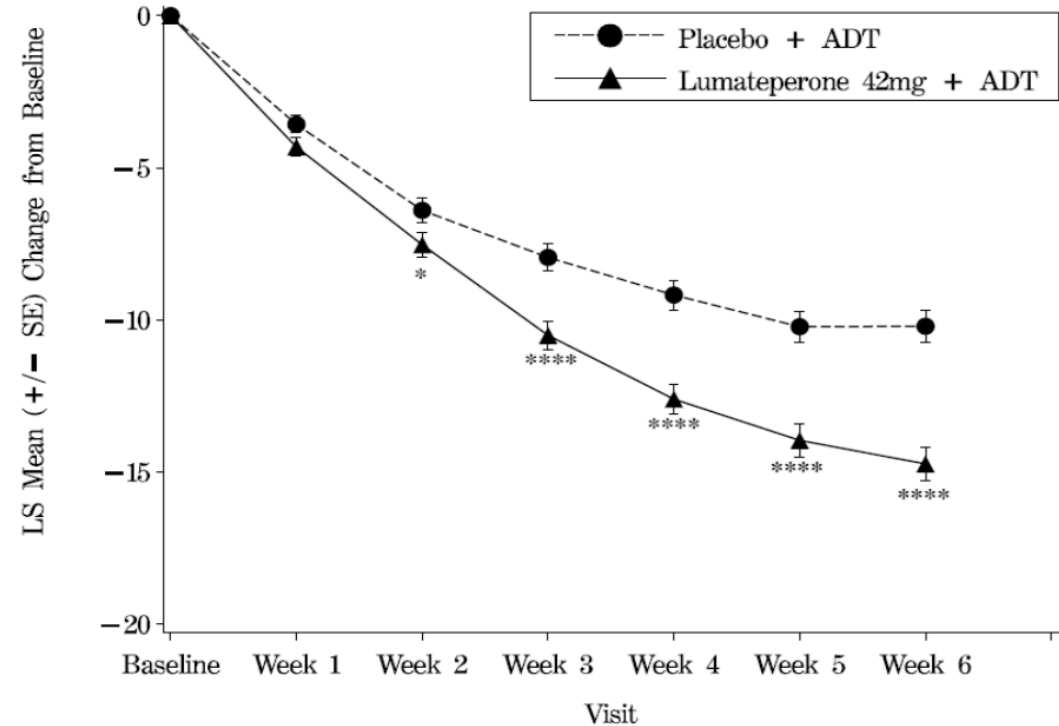
LS mean difference vs placebo: **-4.9 points**

**p < 0.0001**

Cohen's d effect size: **0.61**

mITT population: Lumateperone N=239, Placebo N=242: \*\*\*p<0.001 \*\*\*\*p<0.0001

Study 502 (MADRS)



LS mean difference vs placebo: **-4.5 points**

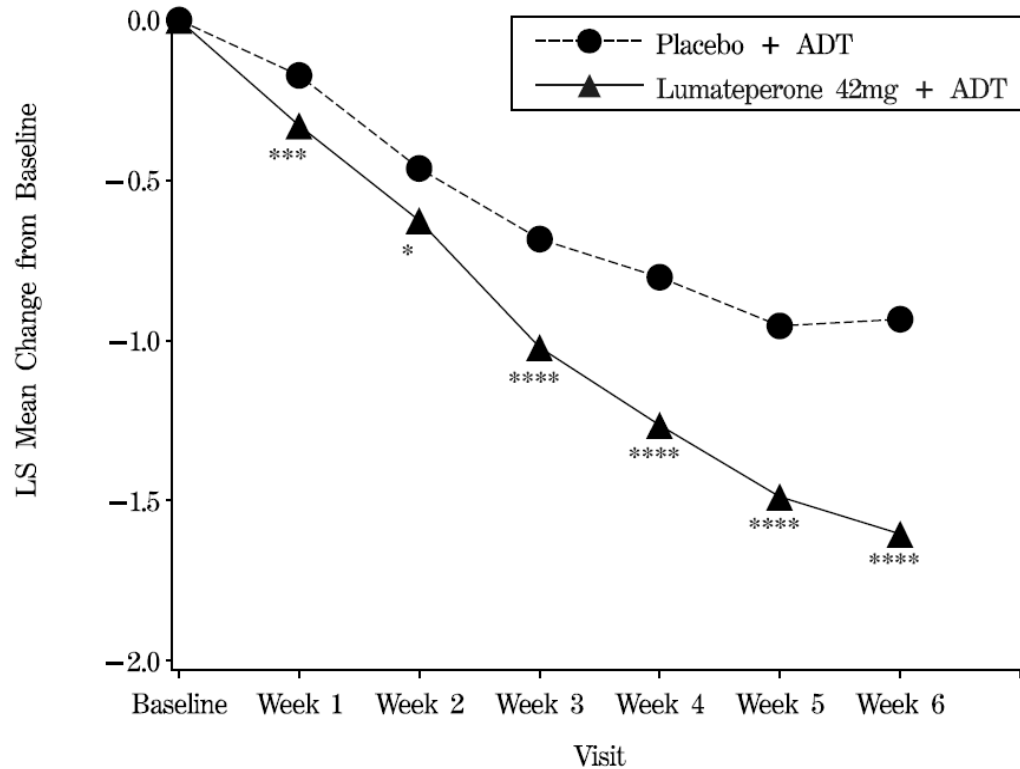
**p < 0.0001**

Cohen's d effect size: **0.56**

mITT population: Lumateperone N=232, Placebo N=237: \*p<0.05 \*\*\*\*p<0.0001

# Lumateperone Demonstrated a Statistically Significant Reduction on the CGI-S Score Compared to Placebo at Week 6

Study 501 (CGI-S)

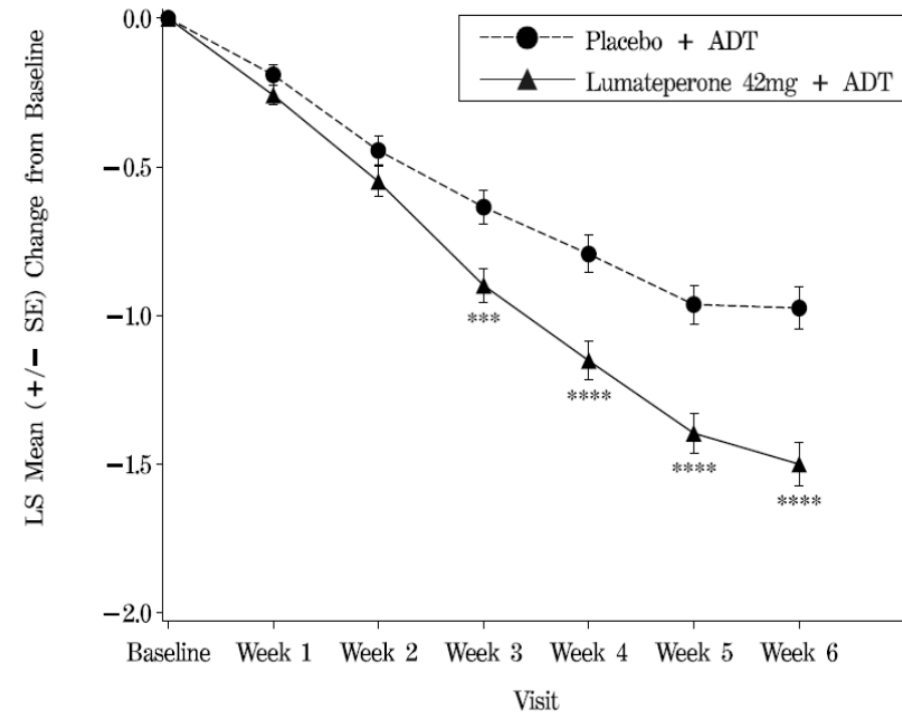


**p < 0.0001**

Cohen's d effect size: **0.67**

mITT population: Lumateperone N=239, Placebo N=242: \*p<0.05 \*\*\*p<0.001 \*\*\*\*p<0.0001

Study 502 (CGI-S)



**p < 0.0001**

Cohen's d effect size: **0.51**

mITT population: Lumateperone N=232, Placebo N=237: \*\*\*p<0.001 \*\*\*\*p<0.0001

# Lumateperone Robustly Improved Depressive Symptoms as Reported by Patients

## Change From Baseline to Day 43 in QIDS-SR-16 Total Score

	Study 501		Study 502	
	Lumateperone 42mg + ADT	Placebo + ADT	Lumateperone 42mg + ADT	Placebo + ADT
Baseline, Mean (SD)	18.1 (2.31)	17.6 (2.28)	17.9 (2.56)	18.0 (2.48)
<b>Change from Baseline to Day 43</b>				
LS Mean (SE)	-8.0 (0.33)	-5.6 (0.33)	-7.9 (0.35)	-5.7 (0.35)
LSMD vs Placebo (SE)	-2.4 (0.44)	—	-2.2 (0.46)	—
P-Value	<0.0001	—	<0.0001	—

## Favorable Safety and Tolerability Profile

- Lumateperone 42 mg plus antidepressant was generally safe and well tolerated in patients with MDD
- Adverse events were generally similar to prior studies of lumateperone
  - In the pooled safety data of Studies 501 and 502, the most common adverse events ( $\geq 5\%$  and greater than twice placebo) with lumateperone versus placebo were: dizziness, dry mouth, somnolence, nausea and fatigue
  - Mean changes in metabolic parameters were similar between lumateperone and placebo
    - Glucose, insulin, triglycerides, and cholesterol (total, LDL, HDL)
  - Mean changes in weight were also similar to placebo

A large, semi-transparent teal graphic consisting of two concentric circular arcs and a solid teal circle on the right side, resembling a stylized 'C' or a partial circle with a dot.

# **ADVANCING PIPELINE**



# Other Lumateperone Development Programs

- **Pediatric Program**

- An open-label safety study in schizophrenia and bipolar disorder: ongoing
- A double-blind, placebo-controlled study in bipolar depression: ongoing
- Two double-blind, placebo-controlled studies in irritability associated with autism spectrum disorder: patient enrollment expected to begin 2H 2024

- **Bipolar Mania Program**

- Two Phase 3 double-blind, placebo-controlled studies in adults with bipolar mania: ongoing

- **Long-Acting Injectable (LAI) Program**

- Initial LAI formulation: pre-clinical development and Phase 1 single ascending dose study completed
- Initiation of clinical conduct of Phase 1 study with additional LAI formulations: 2H 2024

# Other Pipeline Programs

## ITI-1284

Initiated patient enrollment in Phase 2 study in **generalized anxiety disorder** and in Phase 2 study in **psychosis in patients with Alzheimer's disease (AD)**. Patient enrollment in Phase 2 Study **in agitation in patients with AD** expected to start in 2H 2024

## PDE 1 Inhibitors

Our portfolio of **PDE 1 inhibitors** are being developed to treat diseases in which PDE 1 activity is highly active.

- **Lenrispodun (ITI-214)** is in Phase 2 development for **Parkinson's disease**
- **ITI-1020 oncology** program; Phase 1 single ascending dose 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

## ITI-1500

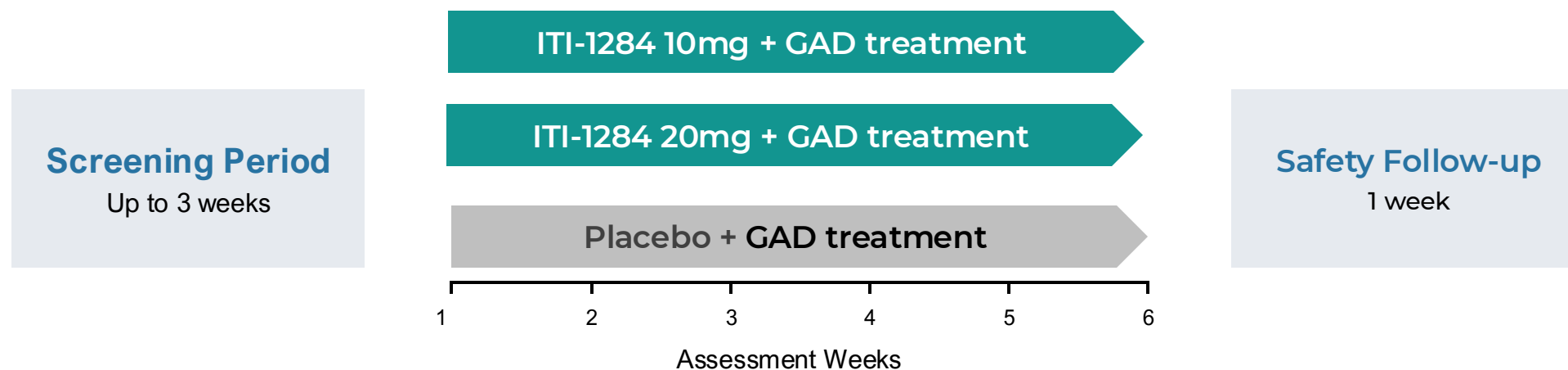
Portfolio of **non-hallucinogenic neuroplastogens** with potential to treat mood, anxiety and other neuropsychiatric disorders **without the liabilities** of hallucinations and cardiovascular effects of psychedelics.

- ITI-1549 continues to advance through IND enabling studies and is expected to enter human testing in 2025

# ITI-1284 GAD Study

**Objective:** To evaluate ITI-1284 as adjunctive treatment in adult patients with generalized anxiety disorder (GAD) who are having inadequate response to GAD treatment

Global, multicenter, randomized, double-blind, placebo-controlled clinical trial (n=705)



## Primary Endpoint

- Mean change in Hamilton Anxiety Rating Scale (HAM-A) at Week 6

## Key Secondary Endpoint

- Mean change in CGI-S at Week 6

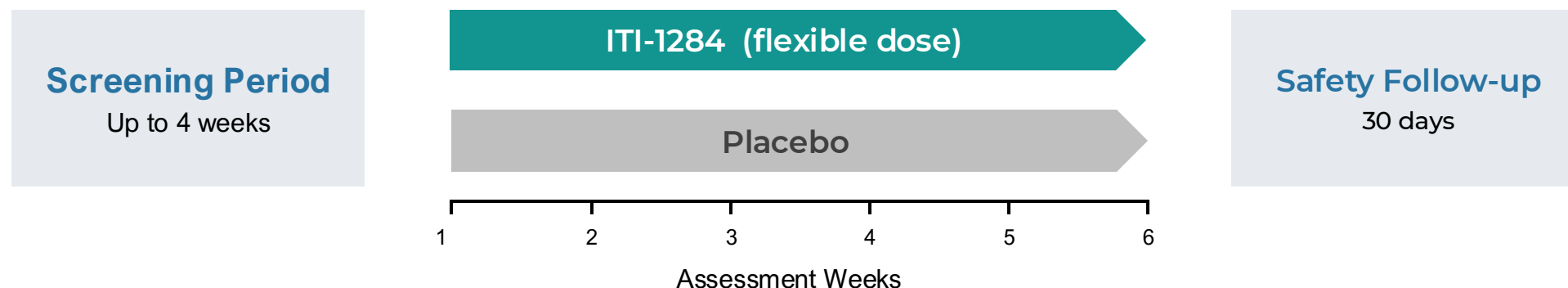
## Key inclusion criteria

- > 18 years of age
- Meet DSM-5 criteria for moderate or severe GAD
- History of inadequate response (<50% improvement in anxiety symptoms) to at least 1 GAD approved treatment (paroxetine, venlafaxine XR, duloxetine, escitalopram, or buspirone) taken at sufficient dose and duration
- Currently having inadequate response to a different approved GAD treatment (paroxetine, venlafaxine XR, duloxetine, escitalopram, or buspirone) taken at sufficient dose and duration

# ITI-1284 Psychosis in Alzheimer's Disease Study

**Objective:** To evaluate ITI-1284 in adult patients with Alzheimer's Disease (AD) who are experiencing psychosis

Global, multicenter, randomized, double-blind, placebo-controlled clinical trial (n=370)



## Primary Endpoint

- Mean change in Behavioral Pathology in Alzheimer's Disease Rating Scale (BEHAVE-AD) psychosis subscale score at Week 6

## Key Secondary Endpoint

- Mean change in CGI-S at Week 6

## Key inclusion criteria

- $\geq 55$  years of age
- Meets clinical criteria for AD based on 2011 NIA-AA dementia criteria and biomarker criteria
- Meets criteria for psychosis in accordance with the International Psychogeriatric Association (IPA) provisional consensus definition at Screening and Baseline
- Scoring  $\geq 2$  on any item of the BEHAVE-AD Part A. Paranoid and Delusional Ideation item and/or Part B. Hallucinations item (i.e., psychosis subscale) at Screening and Baseline
- Lives at home or in an assisted living/long-term care facility



**Thank you**