



First Quarter 2024 Financial Results  
& Corporate Update

May 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 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 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.

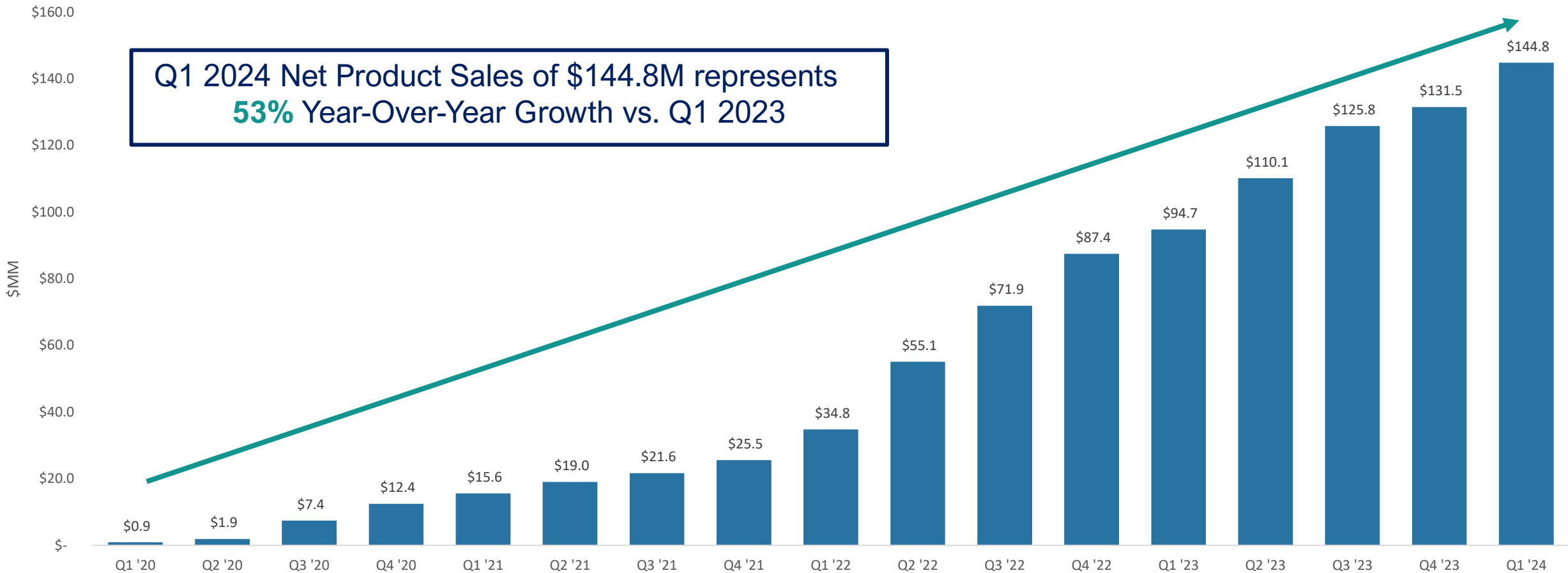
## Non-Promotional Presentation

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.

# Opening Remarks

**Sharon Mates, PhD,  
CEO & Chairman**

# 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 Sales	\$462.2	\$645 - \$675

# Q1 2024 Financial Summary

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

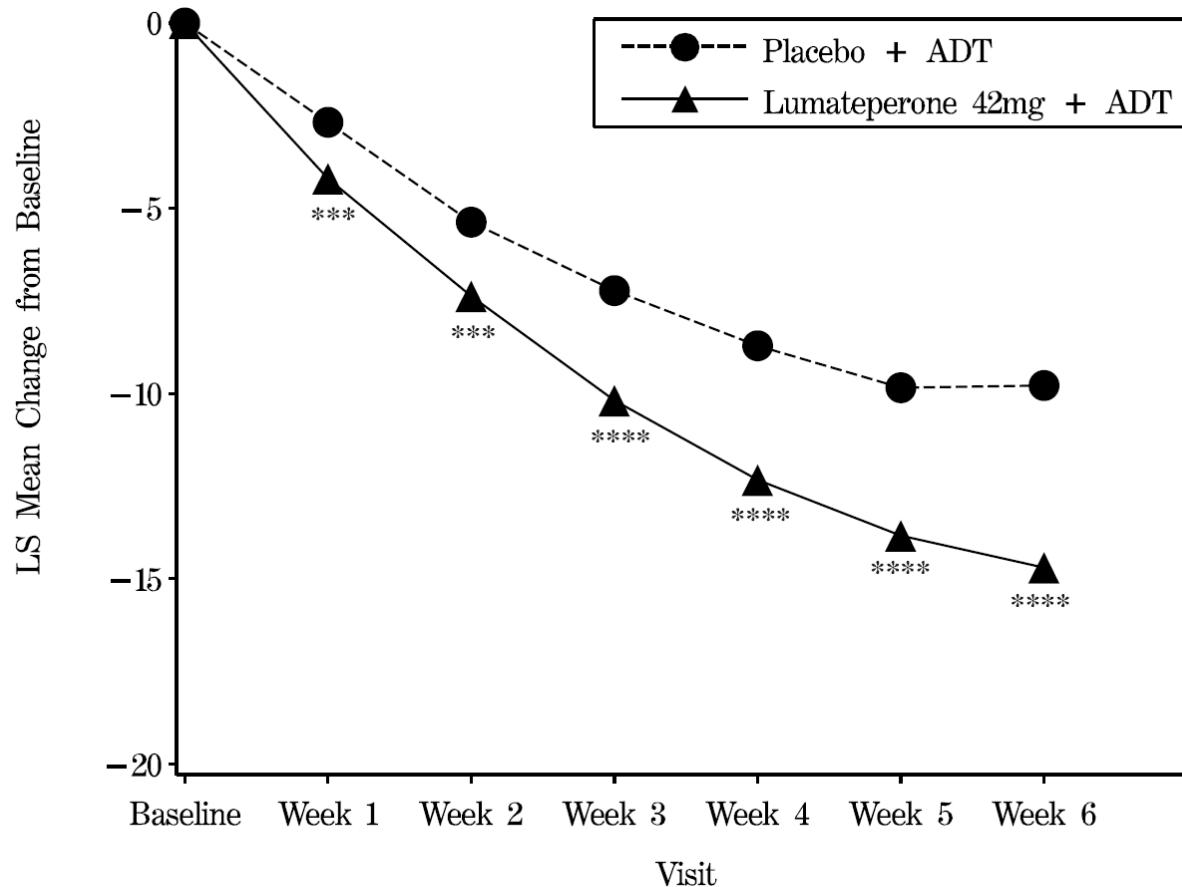
<b>Item</b>	<b>Q1 2024</b>	<b>Q1 2023</b>
<b>Total Revenue</b>	<b>\$ 144.9</b>	<b>\$ 95.3</b>
<b>Product Sales, Net</b>	<b>144.8</b>	<b>94.7</b>
<b>SG&amp;A Expense</b>	<b>\$ 113.1</b>	<b>\$ 98.9</b>
<b>R&amp;D Expense</b>	<b>\$ 42.8</b>	<b>\$ 38.0</b>
<b>Net Loss</b>	<b>\$ (15.2)</b>	<b>\$ (44.1)</b>
<b>Net Loss per share</b>	<b>\$ (0.16)</b>	<b>\$ (0.46)</b>

# **Study 501 Topline Results**

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

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

MADRS Total Score



LS mean difference vs placebo

**-4.9 points**

**p < 0.0001**

(actual p=0.0000000001413)

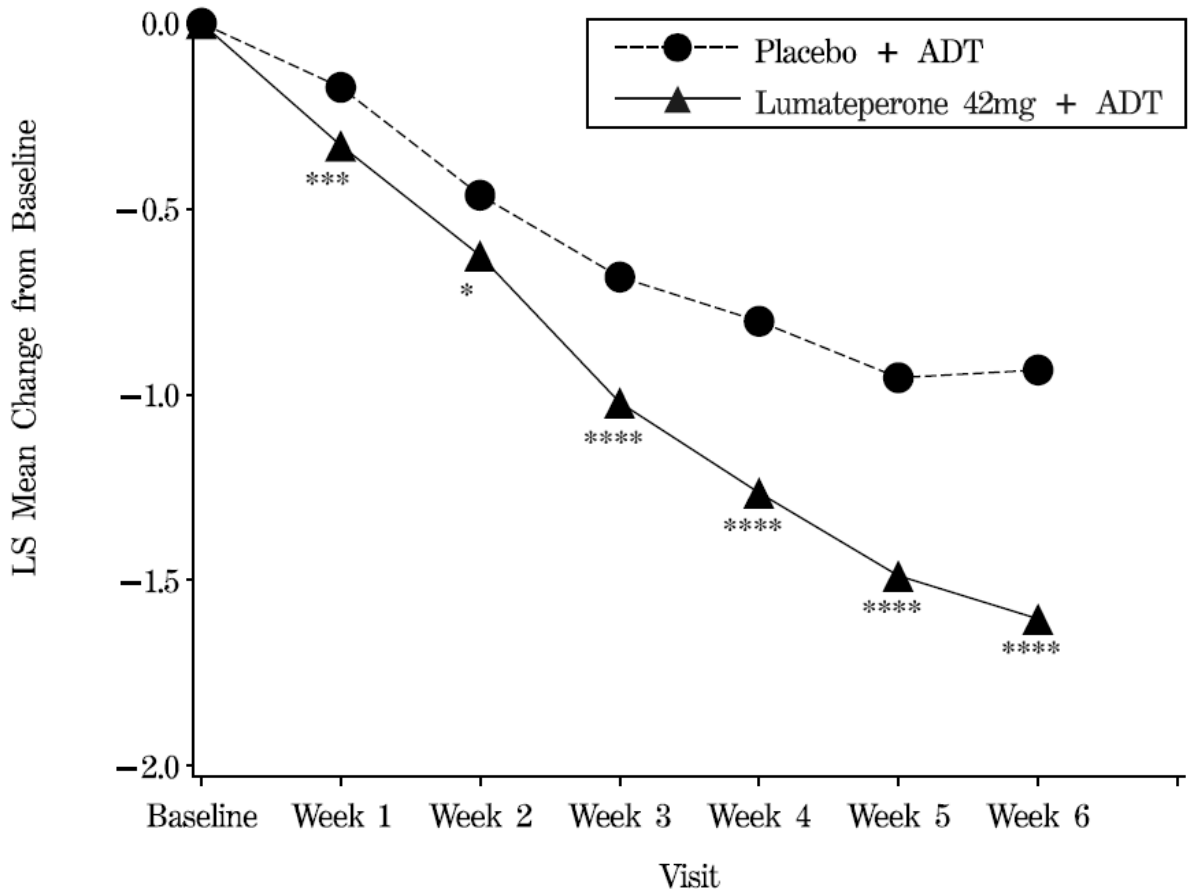
Cohen's d effect size:

**0.61**

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

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

CGI-S Score



**p < 0.0001**  
*(actual p=0.0000000000046)*

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

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

Measurement Statistics	Lumateperone 42 mg + ADT (N=241)	Placebo + ADT (N=243)
Baseline, Mean (SD)	18.1 (2.31)	17.6 (2.28)
Change from Baseline to Day 43		
n	236	238
LS Mean (SE)	-8.0 (0.33)	-5.6 (0.33)
LSMD vs Placebo (SE)	-2.4 (0.44)	—
95% CI	(-3.23, -1.51)	—
P-Value	<0.0001 (actual p=0.0000000987146)	—

# Favorable Safety and Tolerability Profile

- Adverse events similar to prior studies of lumateperone
  - Most common adverse events ( $\geq 5\%$  lumateperone group and twice placebo): dry mouth (10.8%), fatigue (9.5%), and tremor (5.0%). Adverse events were mostly mild to moderate and resolved within a short period of time
- 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

# Our Vision

**Establish CAPLYTA as First Choice Across Depressive Disorders**

**Bipolar I Depression**



**Bipolar II Depression**

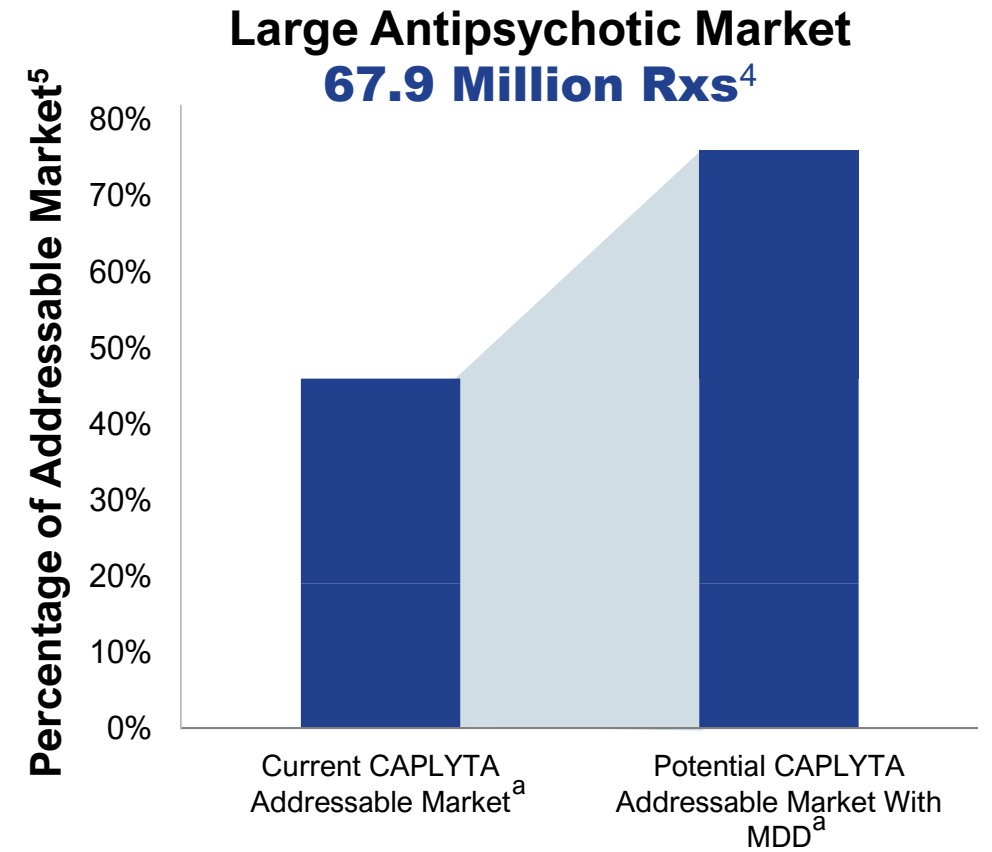


**Major Depressive Disorder**

✓ **Positive Results** from Study 501

Study 502 Topline Data  
Expected **Q2 '24**

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



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

# Other Lumatepetone 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 to begin Q3 '24**
- Long-Acting Injectable (LAI) Program
  - Initial LAI formulation: pre-clinical development and Phase 1 single ascending dose study **completed**
  - Initiation of Phase 1 study with additional LAI formulations: **2H 2024**

# Other Pipeline Programs

## ITI-1284

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

## ITI-1500

Portfolio of **non-hallucinogenic psychedelics** with potential to treat mood and other neuropsychiatric disorders **without the liabilities** of hallucinations and cardiac valvular pathologies of known psychedelics.

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

# Commercial Update

**Mark Neumann,  
Executive Vice President & Chief Commercial Officer**

# Financial Results

**Larry Hine,  
Senior Vice President & Chief Financial Officer**



**Thank you**