



Third Quarter 2024 Financial Results & Corporate Update

October 30, 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 and any product approvals; 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.

Third Quarter 2024 Highlights

CAPLYTA Performance

- Robust TRx Growth of 38% in Q3'24 vs Q3'23
- Raised CAPLYTA '24 net product sales guidance
 - Range: \$665-\$685 M
- Expanded sales force

Building for the Future

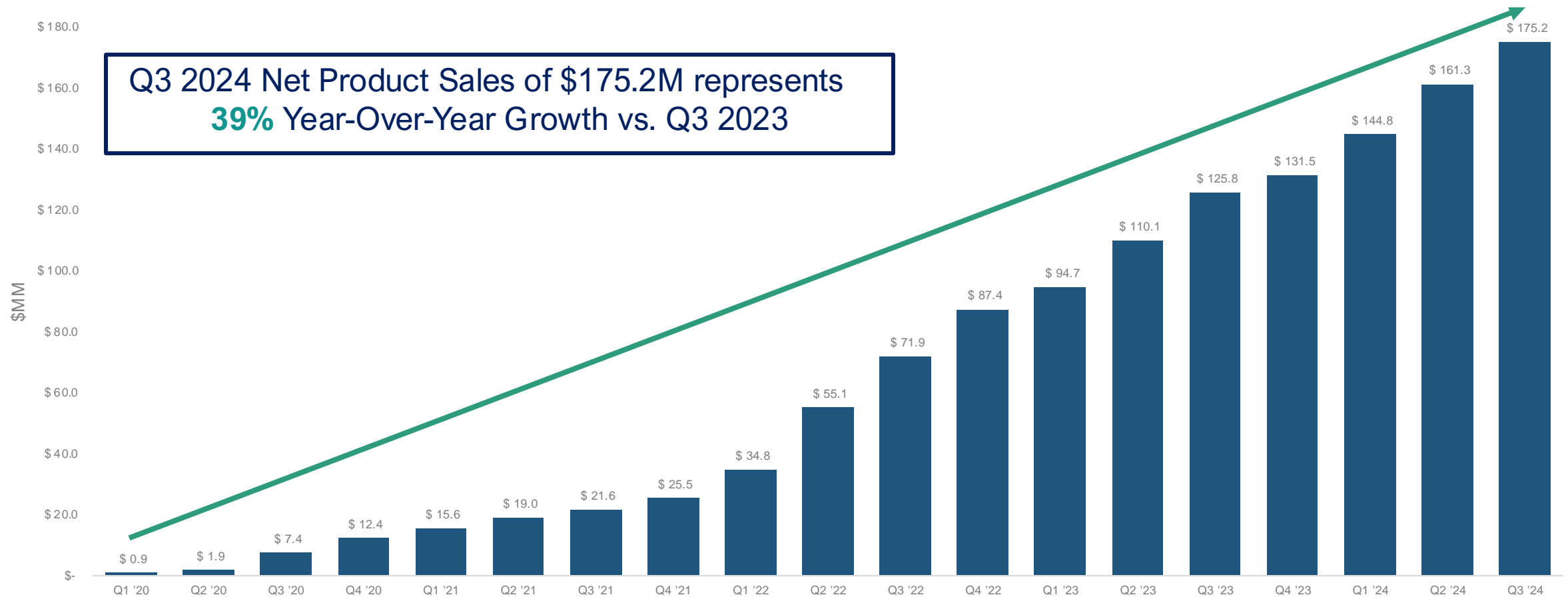
- Adj. MDD sNDA submission on track for Q4'24
 - MDD pre-launch preparations ongoing
- Advancing pipeline

Financial Position

- CAPLYTA revenue increased 39% in Q3'24 vs Q3'23
- Cash & Investments ~\$1.0 B

FINANCIAL & CAPLYTA PERFORMANCE

CAPLYTA Quarterly Net Sales Performance



FY 2024 CAPLYTA Net Product Sales Guidance

	2023 Net Product Sales (\$ Millions)	FY 2024 Updated Guidance (\$ Millions)
CAPLYTA Net Product Sales	\$462.2	\$665 - \$685

Q3 2024 Financial Summary

In \$ Millions

	Q3 2024	Q3 2023	% Change	YTD 2024	YTD 2023	% Change
Net Product Sales	\$ 175.2	\$ 125.8	39%	\$ 481.3	\$ 330.7	46%
SG&A Expense	132.1	105.2	26%	366.8	305.1	20%
R&D Expense	66.8	41.6	61%	165.8	129.4	28%

Cash and Investments

As of September 30, 2024

~\$1 Billion

- Net Product Sales increase was primarily driven by increased prescription demand
- SG&A expense increase was mainly a result of the recent sales force expansion, and increased marketing, advertising, and general administrative expenses to support the Company's growth
- R&D expense increased due to activities associated with lumateperone and other clinical programs

Revised Guidance Ranges

\$ Millions

	Updated Range	Previous Range
Net Product Sales	\$ 665 – 685	\$ 650 – 680
SG&A Expense	490 – 510	480 – 510
R&D Expense	220 – 230	210 – 230

- 2024 net product sales guidance range raised
- Strong momentum of prescription growth expected to continue
- Narrowed SG&A and R&D expense guidance ranges

EXPANDING CAPLYTA

Our Vision

Establish CAPLYTA as a First Choice Across Depressive Disorders

Bipolar I Depression



Approved

Bipolar II Depression



Approved

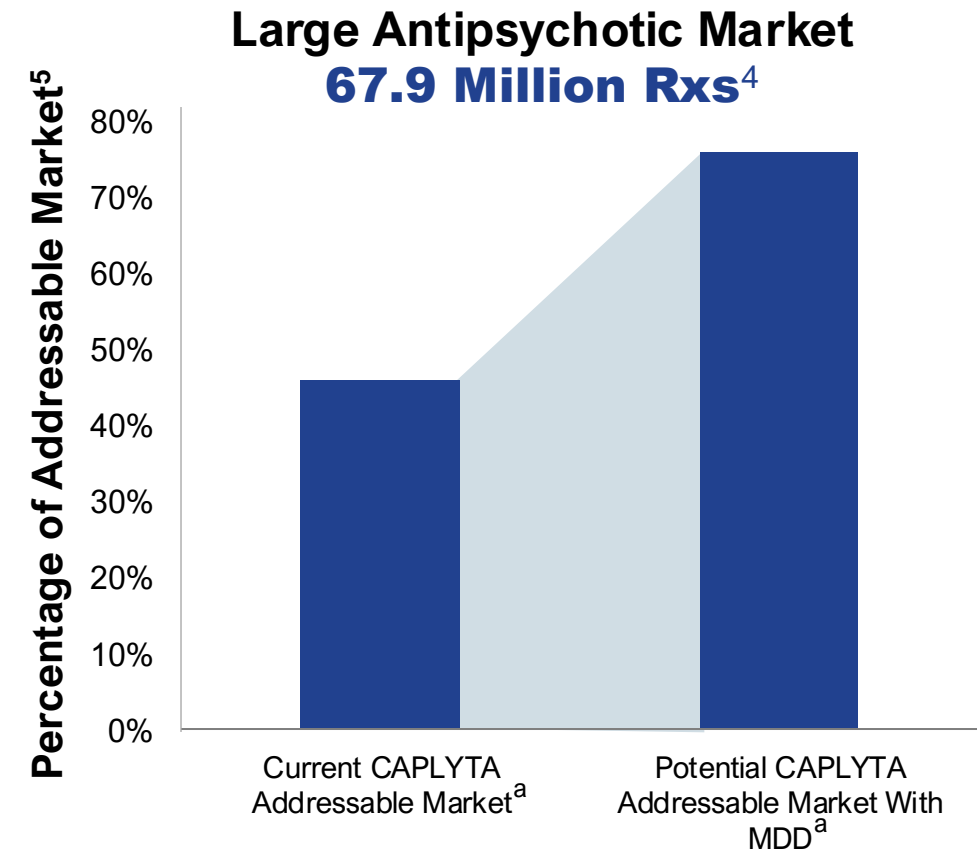
Major Depressive Disorder

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

sNDA submission
Expected **Q4 '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



^aCurrent CAPLYTA addressable market includes schizophrenia and bipolar disorder; potential CAPLYTA addressable market includes schizophrenia, bipolar disorder, and MDD.

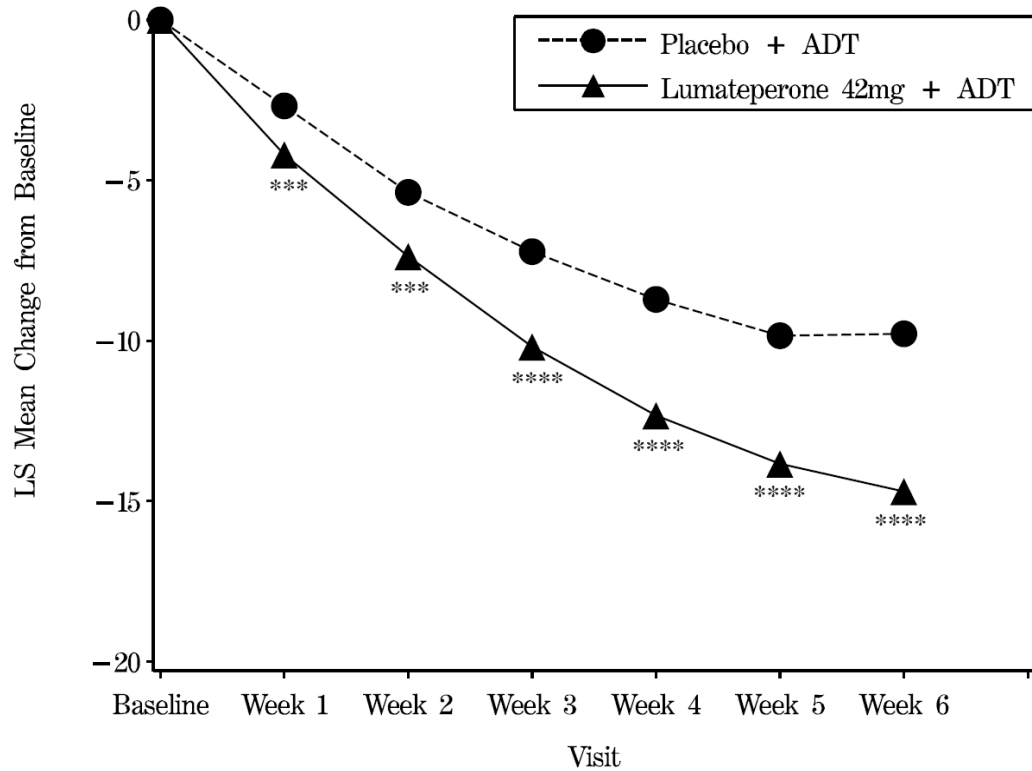
1. Johns Hopkins Medicine. Mental health disorder statistics. <https://www.hopkinsmedicine.org/health/wellness-and-prevention/mental-health-disorder-statistics>. Accessed Jan 3, 2024. 2. National Institute of Mental Health. Bipolar disorder. <https://www.nimh.nih.gov/health/statistics/bipolar-disorder>. 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.

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)



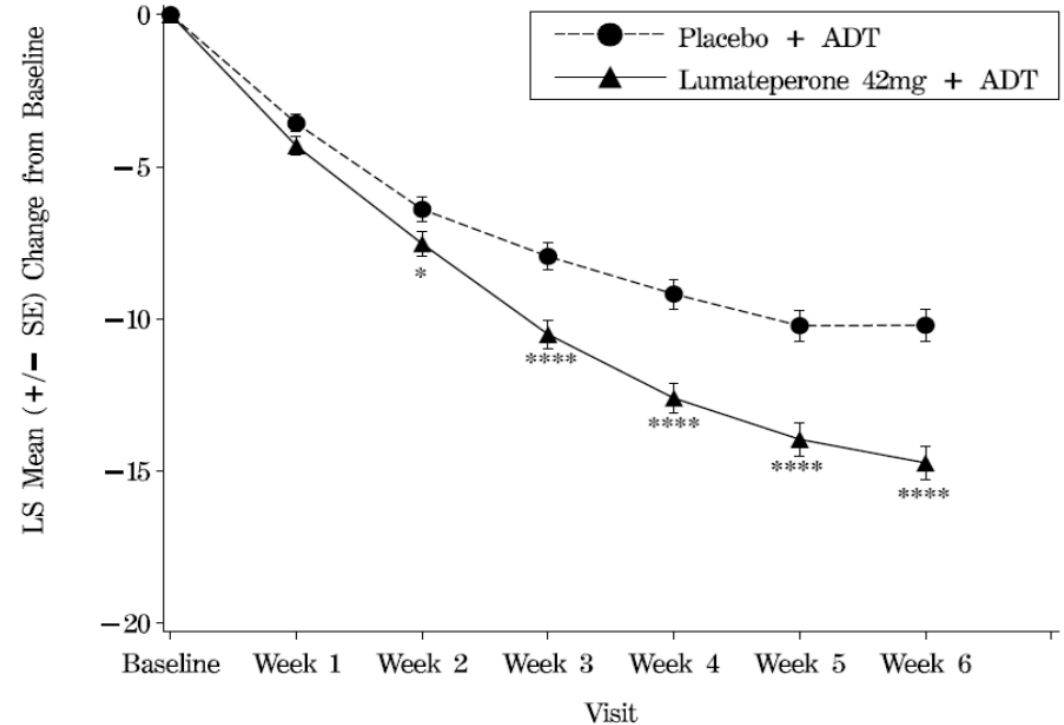
LS mean difference vs placebo: **-4.9 points**

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**

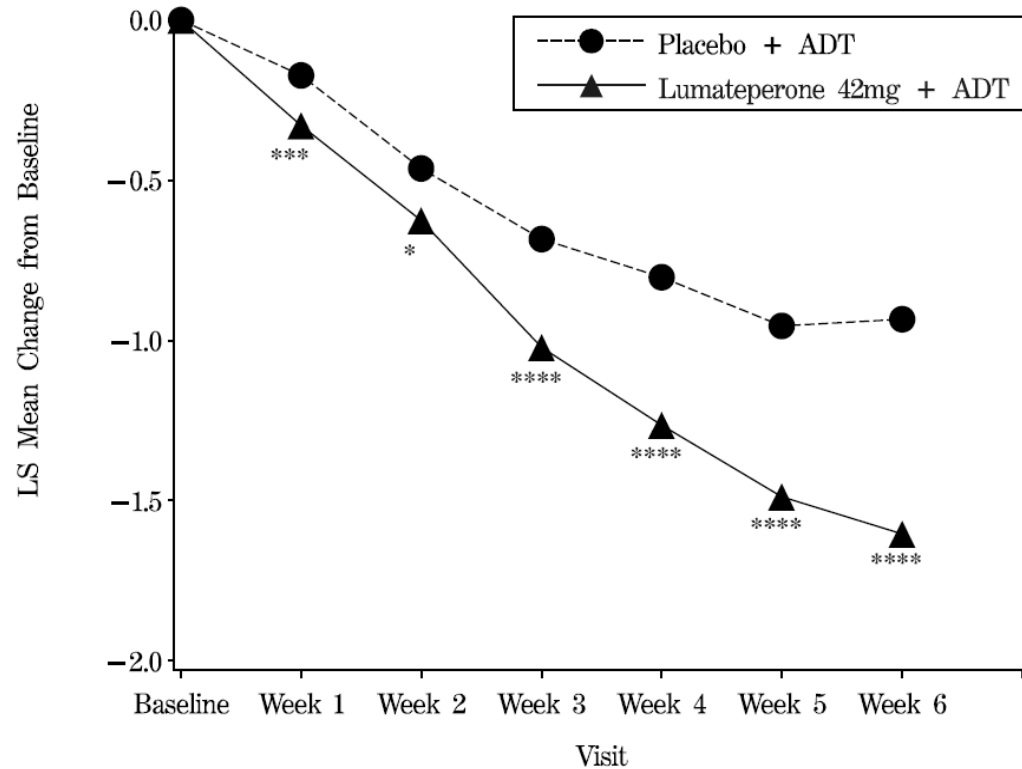
p < 0.0001

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)

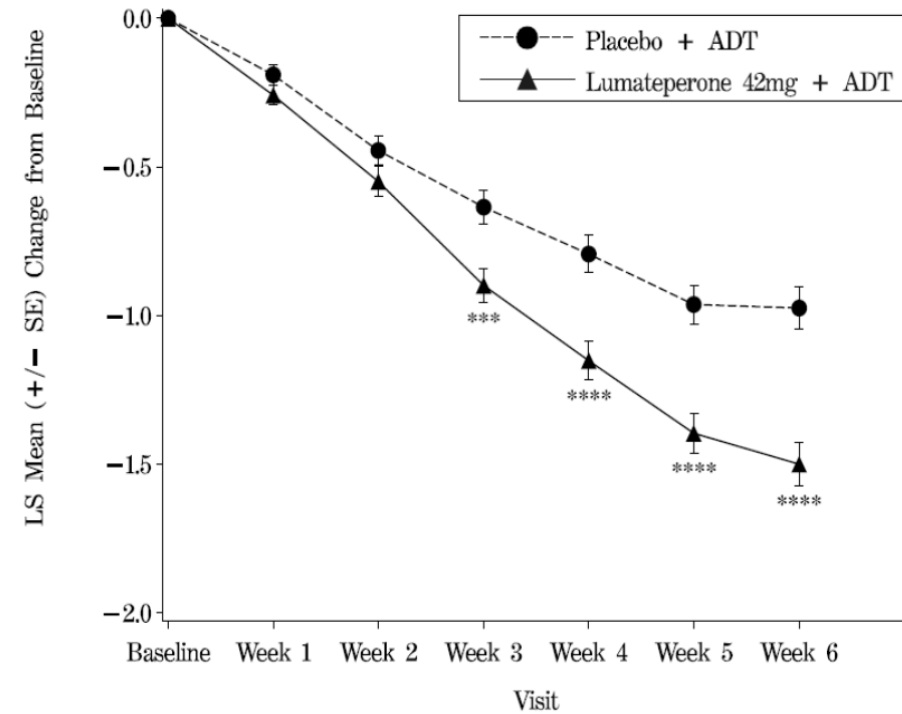


p < 0.0001

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)
Change from Baseline to Day 43				
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	—

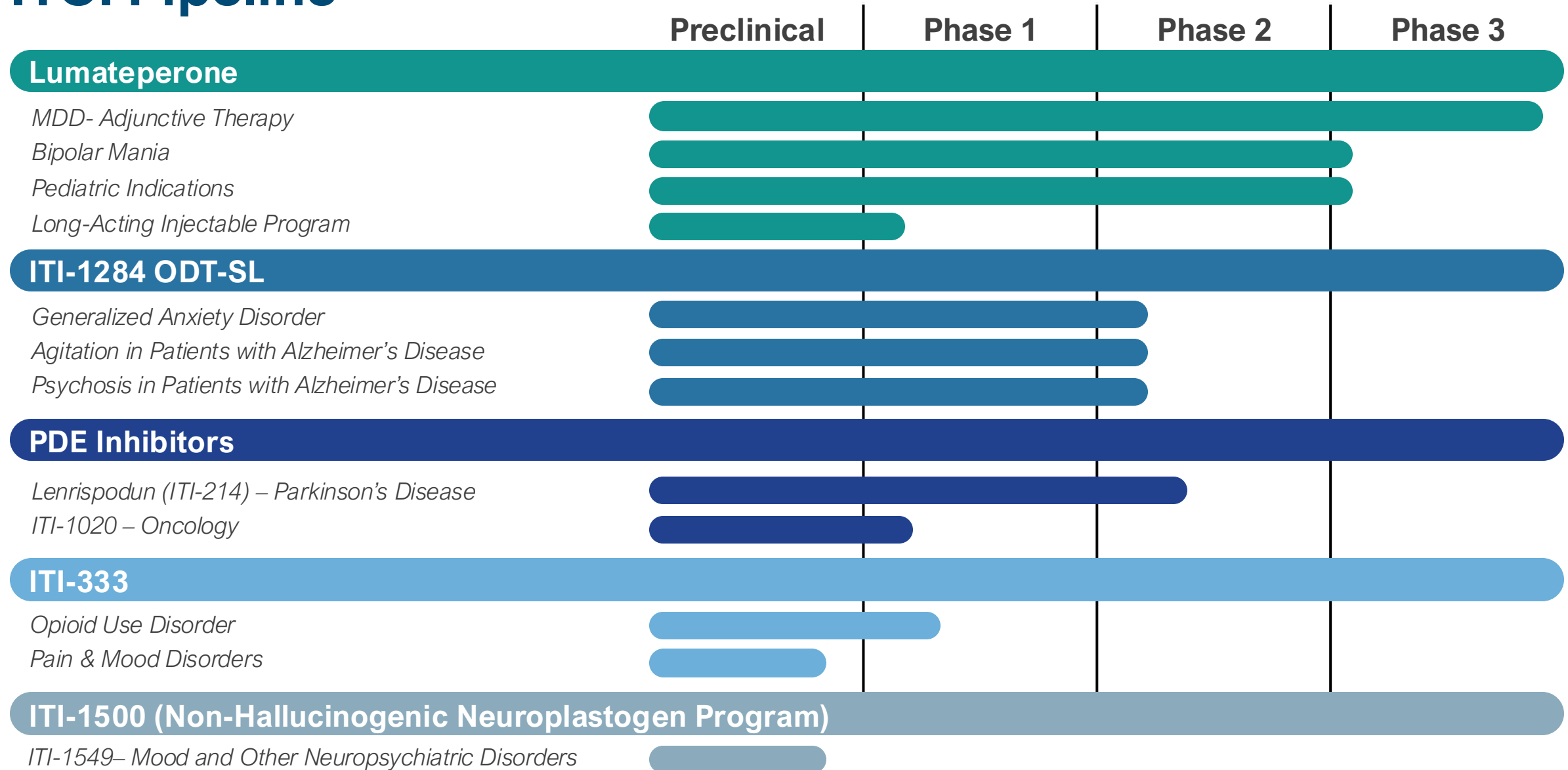
Favorable Safety and Tolerability Profile

- 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 to the right, resembling a stylized 'C' or a partial 'E'.

ADVANCING PIPELINE

ITCI 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 Q4 2024

- **Bipolar Mania Program**

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

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

- Phase 1 single ascending dose study with several formulations: ongoing

Other Pipeline Programs

- **ITI-1284 (deuterated lumateperone)**
 - Phase 2 adjunctive study in generalized anxiety disorder (GAD): ongoing
 - Phase 2 monotherapy GAD study expected to initiate patient enrollment in Q4 2024
 - Phase 2 clinical study in patients with psychosis associated with Alzheimer's disease: ongoing
 - Phase 2 clinical study in patients with agitation associated with Alzheimer's disease: ongoing
- **PDE1 Inhibitors**
 - Lenrispodun (ITI-214) Phase 2 development for Parkinson's disease: ongoing
 - ITI-1020 oncology program; Phase 1 single ascending dose study: ongoing
- **Non-Hallucinogenic Neuroplastogens**
 - ITI-1549 continues to advance through IND enabling studies and is expected to enter human testing in 2025



Thank you