

# Third Quarter 2023 Financial Results & Business Update

October 25, 2023



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# Forward-Looking Statements and Non-GAAP Financial Information

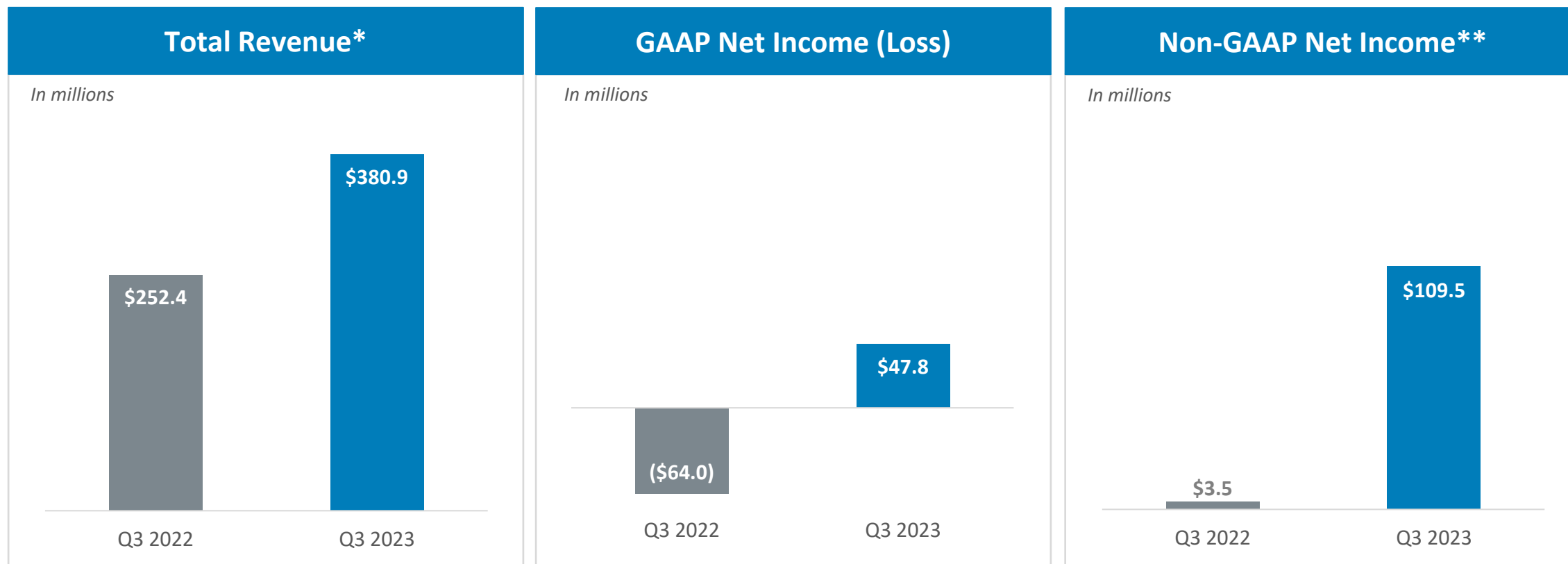
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# Q3 2023 Financial Performance

# Q3 2023 Financial Results Summary



\*Reflects reinstatement of certain U.S. royalties following the successful outcome of the Company's arbitration with Janssen Pharmaceutica N.V., a subsidiary of Johnson & Johnson ("Janssen"), announced in June 2023.

\*\*Reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure can be found in the Appendix of this presentation.

# Q3 2023 Revenue Summary

In millions, except %	Q3'23	Q3'22	Δ Q3'23 vs. Q3'22
Total Proprietary Net Sales	\$231.8	\$199.4	16%
VIVITROL®	\$99.3	\$96.5	3%
ARISTADA®*	\$81.8	\$75.7	8%
LYBALVI®†	\$50.7	\$27.1	87%
Manufacturing & Royalty Revenue**	\$149.1	\$52.9	182%
Research & Development Revenue	\$0.0	\$0.0	-
Total Revenue**	\$380.9	\$252.4	51%

Amounts in the table above may not sum due to rounding.

\*Inclusive of ARISTADA INITIO®

†LYBALVI was commercially launched in October 2021.

\*\*Reflects reinstatement of certain U.S. royalties following the successful outcome of the Company's arbitration with Janssen announced in June 2023.

# Alkermes: 2023 Financial Expectations<sup>1</sup>

(in millions, except per share amounts)	Financial Expectations for Year Ending Dec. 31, 2023
<b>Total Revenues</b>	<b>\$1,550 – \$1,680</b>
COGS	\$230 – \$250
R&D Expense	\$370 – \$400
SG&A Expense	\$695 – \$725
Amortization of Intangible Assets	~\$35
Interest Expense, net	\$5 – \$10
Income Tax Benefit	\$5 – \$10
<b>GAAP Net Income</b>	<b>\$225 – \$265</b>
<b>GAAP Earnings Per Share (Diluted)</b>	<b>\$1.31 – \$1.54</b>
<b>Non-GAAP Net Income<sup>‡</sup></b>	<b>\$230 – \$270</b>
<b>Non-GAAP Earnings Per Share (Diluted)<sup>‡</sup></b>	<b>\$1.34 – \$1.57</b>

## Total Revenues Breakdown:

- Expected net sales of proprietary products:
  - VIVITROL<sup>®</sup> net sales of \$380M – \$410M
  - ARISTADA<sup>®</sup> net sales of \$315M – \$345M
  - LYBALVI<sup>®</sup> net sales of \$180M – \$205M
- *Janssen royalty expectations:*
  - *Long-acting INVEGA<sup>®</sup> franchise back royalties and interest on late payments related to 2022: ~\$197M*
  - *INVEGA<sup>®</sup> franchise royalties related to 2023: \$265M – \$280M*

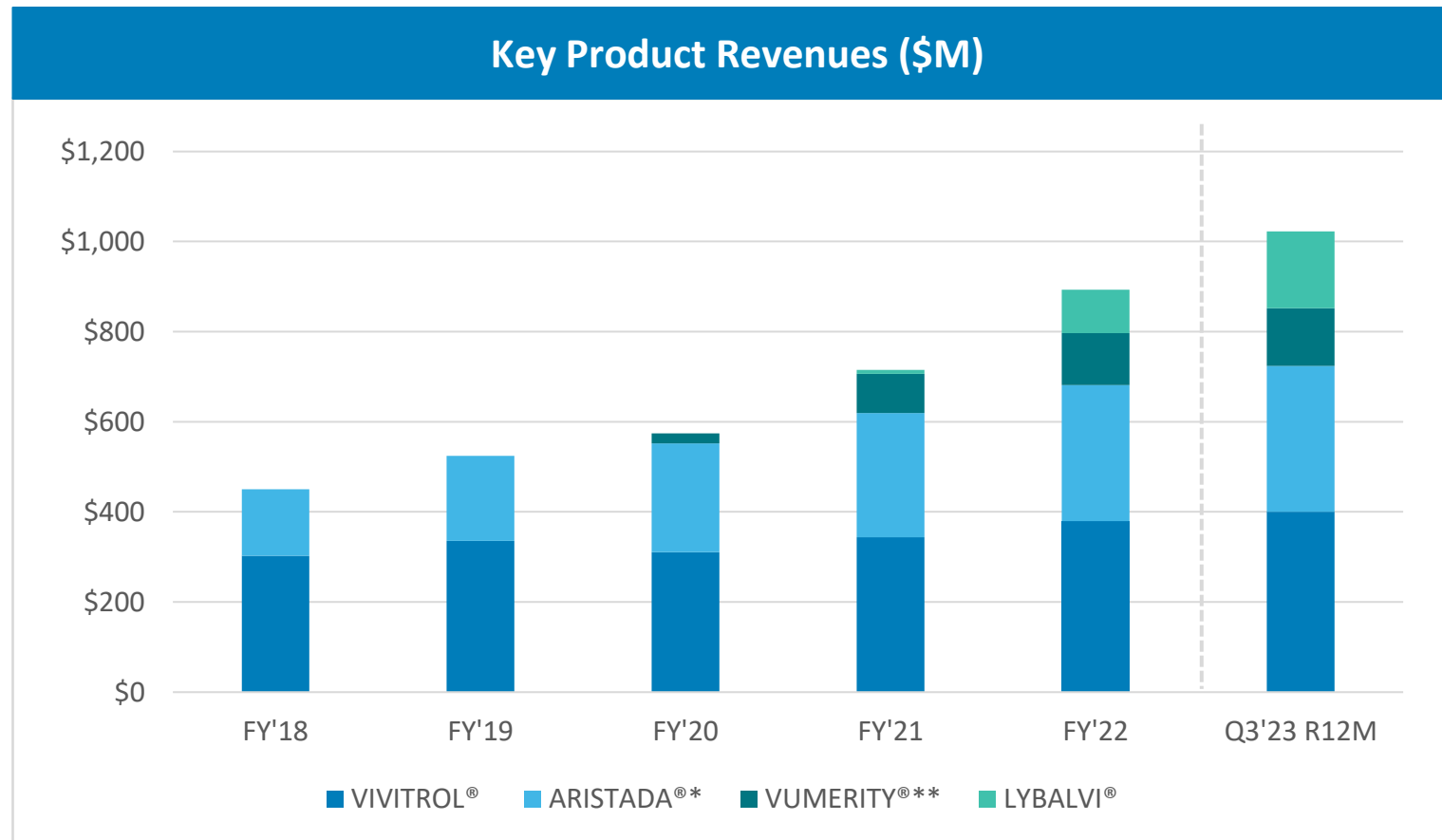
<sup>1</sup>“Financial Expectations for Year Ending Dec. 31, 2023” and “Janssen royalty expectations”, on the one hand, and “Expected net sales of proprietary products”, on the other hand, were initially provided by the Company on June 6, 2023 and Feb. 16, 2023, respectively. The Company reiterates these expectations as of Oct. 25, 2023, and such expectations are effective only as of this date. The Company expressly disclaims any obligation to update or reaffirm these expectations.

<sup>‡</sup>Reconciliation of these non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in the Appendix of this presentation.

The Company’s 2023 financial expectations continue to reflect Alkermes’ combined neuroscience and oncology business for the full year. The Company continues to work toward the planned separation of its oncology business, which it expects to complete in November 2023.

# Q3 2023 Commercial Review

# Topline Growth and Diversification Reflect Evolving Business



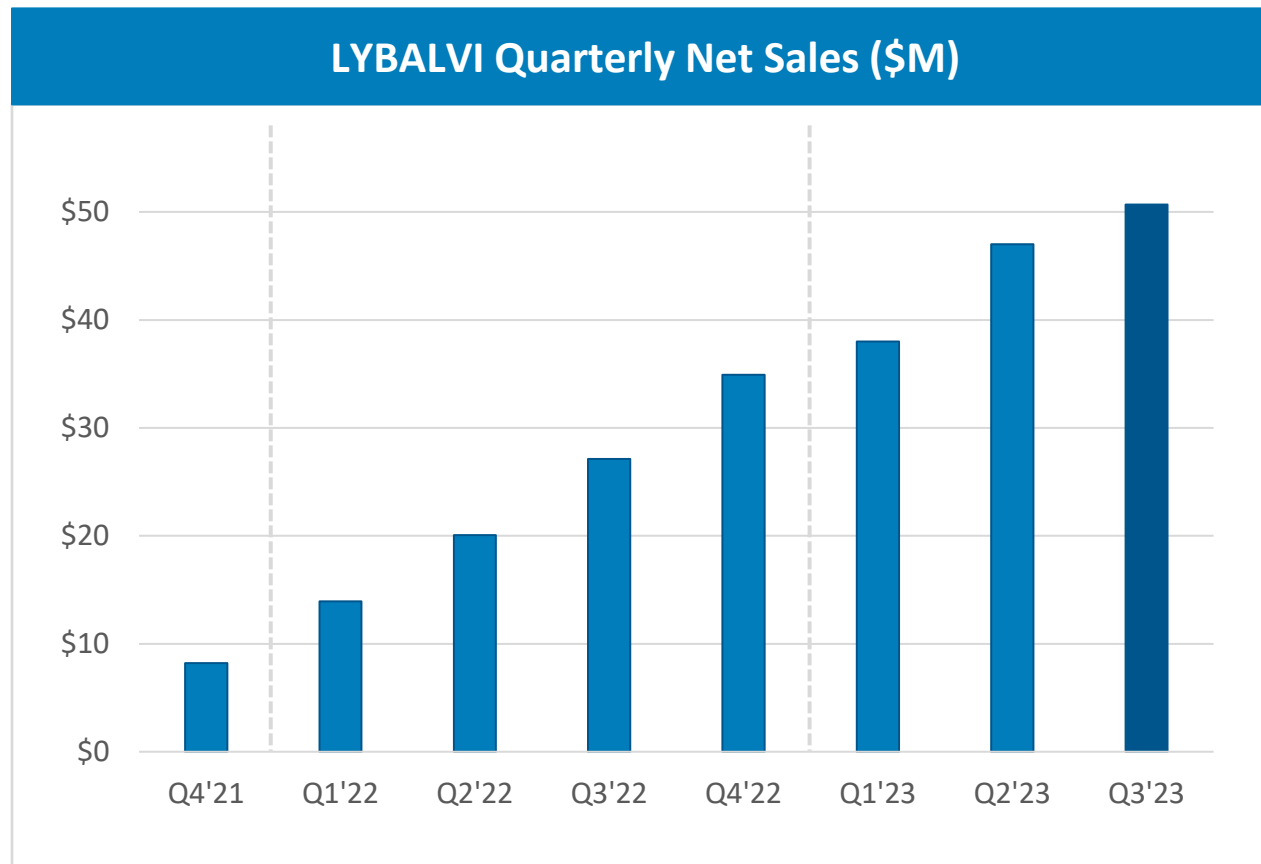
\*Inclusive of ARISTADA INITIO®

\*\*Licensed product (royalty & manufacturing revenue)

R12M = Rolling Twelve Months



# LYBALVI® Performance and Expectations



**Q3'23 net sales of \$50.7M reflect 8% sequential growth compared to Q2'23**

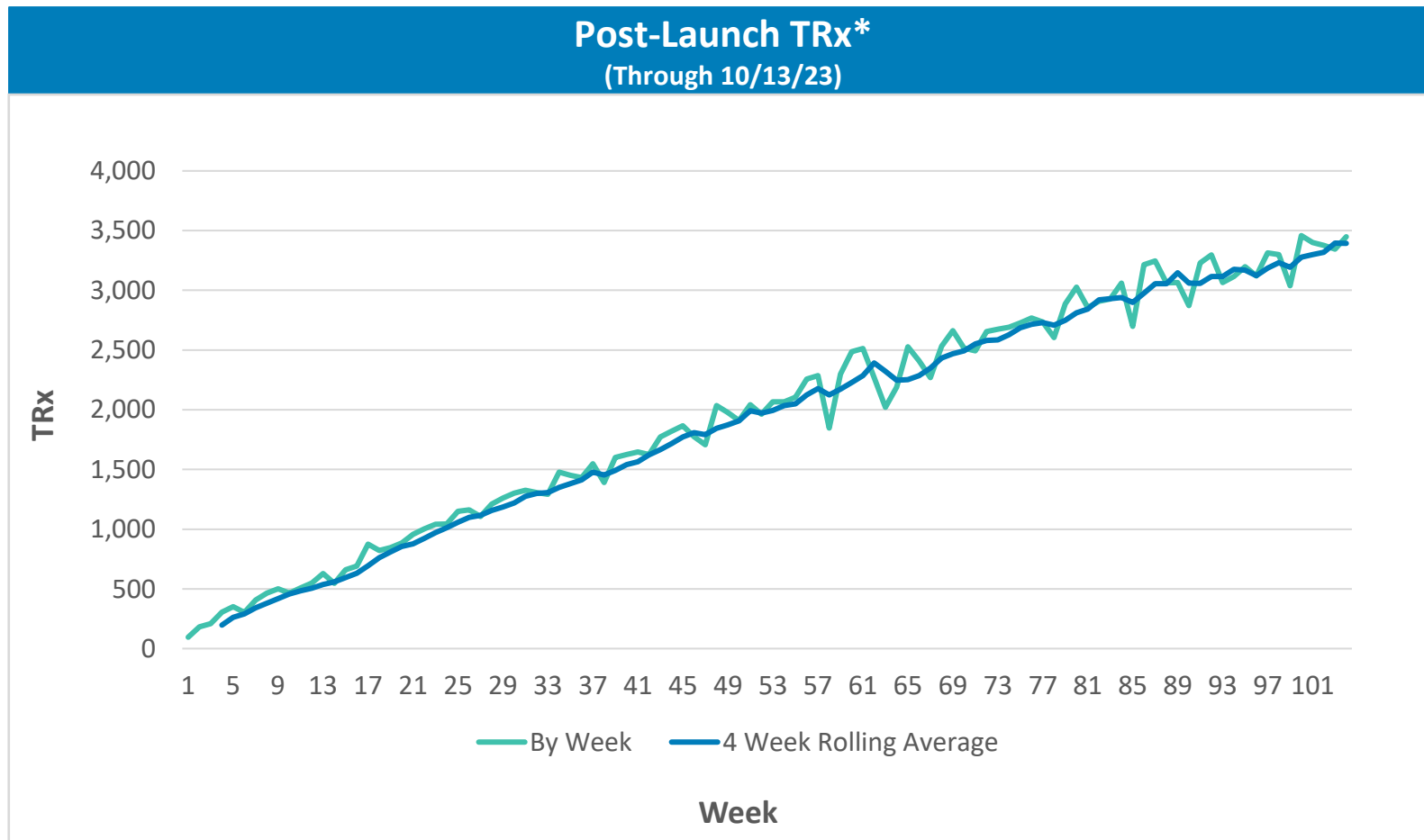
- Q3'23 gross-to-net deductions: ~25%

**Outlook:**

- FY'23 net sales expected to range from \$180M – \$205M\*

\*These expectations were initially provided by the Company on Feb. 16, 2023. The Company reiterates these expectations as of Oct. 25, 2023 and such expectations are effective only as of this date. The Company expressly disclaims any obligation to update or reaffirm these expectations.

# LYBALVI® Prescription Growth Trends

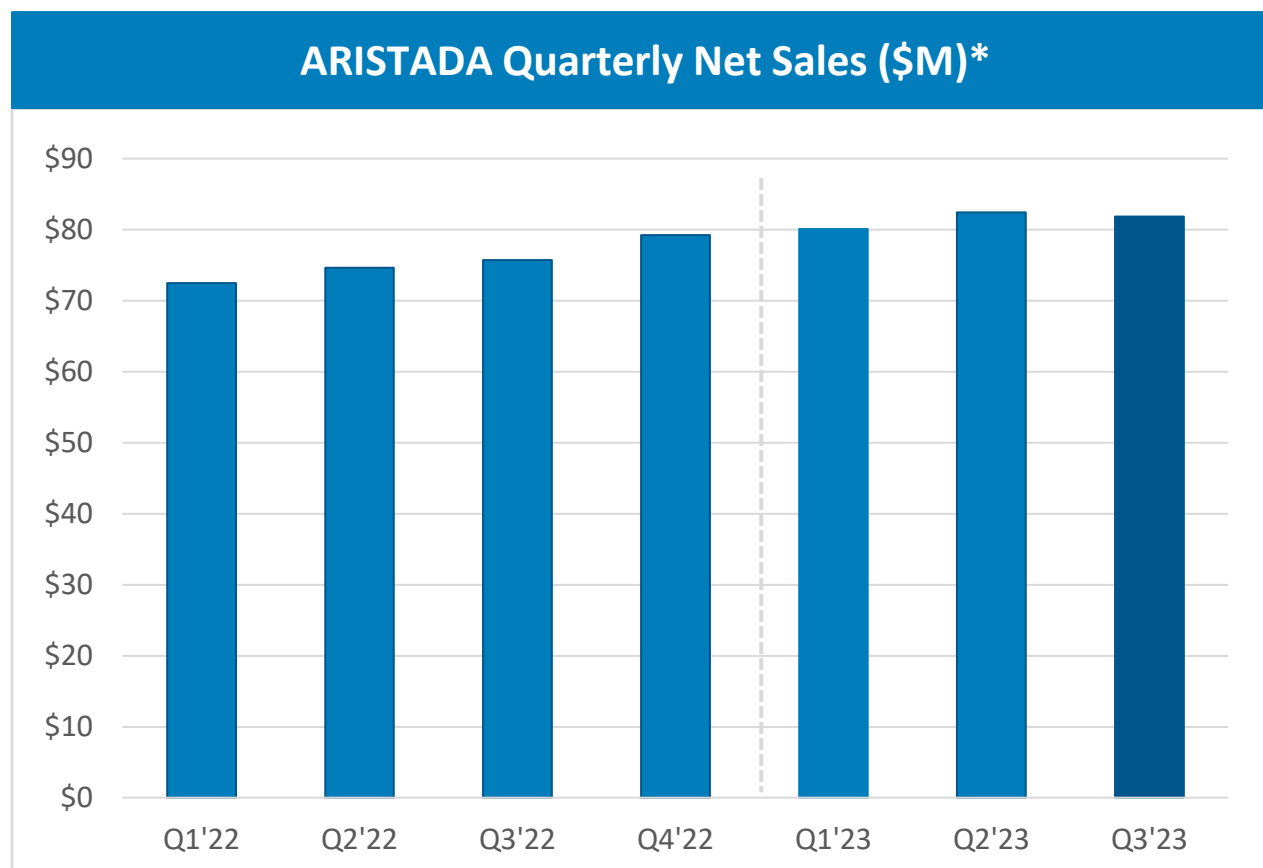


## Q3'23 total TRx:

- ~41,800 reflecting 10% sequential growth compared to Q2'23

\*Source: IQVIA NPA Weekly

# ARISTADA® Performance and Expectations



**Q3'23 year-over-year net sales increased 8% to \$81.8M**

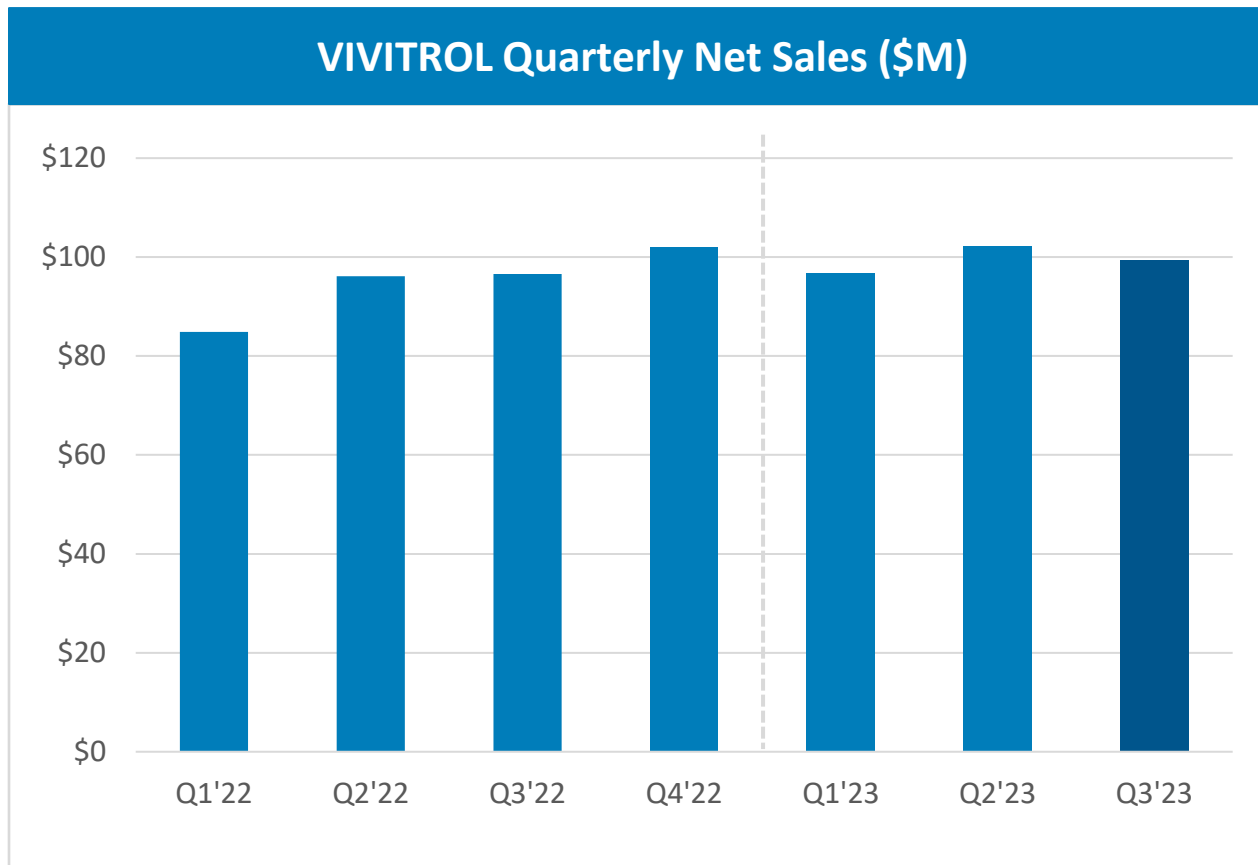
**Outlook:**

- FY'23 net sales expected to range from \$315M – \$345M<sup>†\*</sup>

\*Inclusive of ARISTADA INITIO®

<sup>†</sup> These expectations were initially provided by the Company on Feb. 16, 2023. The Company reiterates these expectations as of Oct. 25, 2023 and such expectations are effective only as of this date. The Company expressly disclaims any obligation to update or reaffirm these expectations.

# VIVITROL® Performance and Expectations



**Q3'23 year-over-year net sales increased 3% to \$99.3M**

**Outlook:**

- FY'23 net sales expected to range from \$380M – \$410M\*

\*These expectations were initially provided by the Company on Feb. 16, 2023. The Company reiterates these expectations as of Oct. 25, 2023 and such expectations are effective only as of this date. The Company expressly disclaims any obligation to update or reaffirm these expectations.

# Preliminary Results from a Phase 1 Study of ALKS 2680, an Orexin 2 Receptor Agonist, in Healthy Participants and Patients with Narcolepsy or Idiopathic Hypersomnia

# ALKS 2680 Is an Investigational Oral Orexin 2 Receptor Agonist for the Treatment of Narcolepsy

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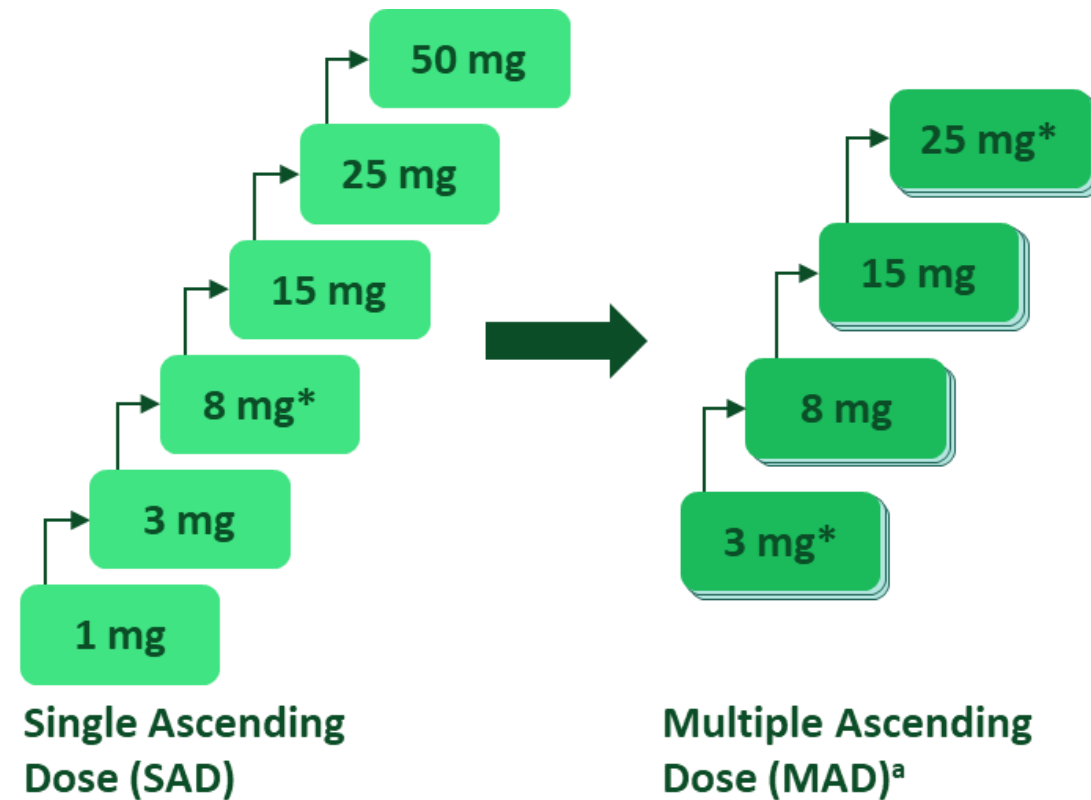
- ALKS 2680 is a highly potent, orally bioavailable, selective OX2R agonist
  - $\geq 10$  fold more potent than orexin A<sup>a</sup>
  - >5,000-fold selectivity relative to OX1R<sup>a</sup>
- Designed to address underlying pathology of narcolepsy and achieve:
  - Improved wakefulness duration and quality, with a PK/PD profile that mirrors natural sleep/wake cycle
  - Cataplexy control
  - Low therapeutic dose with once-daily oral dosing
  - Acceptable safety profile with wide therapeutic window
- ALKS 2680 demonstrated dose-dependent improvements in wake duration and cataplexy control in a mouse model of narcolepsy<sup>b</sup>
- Initial data from the ongoing Phase 1 study, which includes innovative translational approaches, has shown:
  - ALKS 2680 is generally well tolerated
  - Proof of concept in patients with narcolepsy type 1

<sup>a</sup>Data from preclinical studies using CHO cells. <sup>b</sup>Orexin DTA mice

CHO: Chinese Hamster Ovary; DTA: diphtheria toxin subunit A; OX1R: orexin receptor type 1; OX2R: orexin receptor type 2; PD: pharmacodynamic; PK: pharmacokinetic

# Ongoing Randomized, Double-Blind, Placebo-Controlled First-in-Human Study of ALKS 2680: SAD and MAD

- Each dose cohort in both SAD and MAD included 8 new participants
  - 6 on ALKS 2680, 2 on placebo
- Objectives:
  - Safety and tolerability
  - Pharmacokinetics (PK) and pharmacodynamics (PD)



\*Denotes dynamic decision points for triggering subsequent cohorts

<sup>a</sup>In MAD, participants were dosed for 10 days once daily

# ALKS 2680 Was Generally Well Tolerated in Healthy Volunteers in Both SAD and MAD

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- Maximum tolerated dose not reached
- Most AEs were mild and observed at doses  $\geq 15$  mg (SAD) and  $\geq 8$  mg (MAD)
  - No severe AEs or serious adverse events (SAEs) were reported
  - Most AEs were transient and resolved without intervention or treatment interruption
  - AEs observed in  $>1$  participant ( $>5\%$ ) and deemed related to study drug were:
    - SAD: dizziness, pollakiuria, nausea, and blurred vision
    - MAD: insomnia, dizziness, pollakiuria, and visual disturbance (described as blurred or distorted vision, increased light sensitivity)
- No safety signal identified in vital signs, laboratory parameters, or ECGs
- One participant in MAD discontinued after taking a single 25 mg dose due to transient, non-serious, non-severe AEs that resolved without treatment

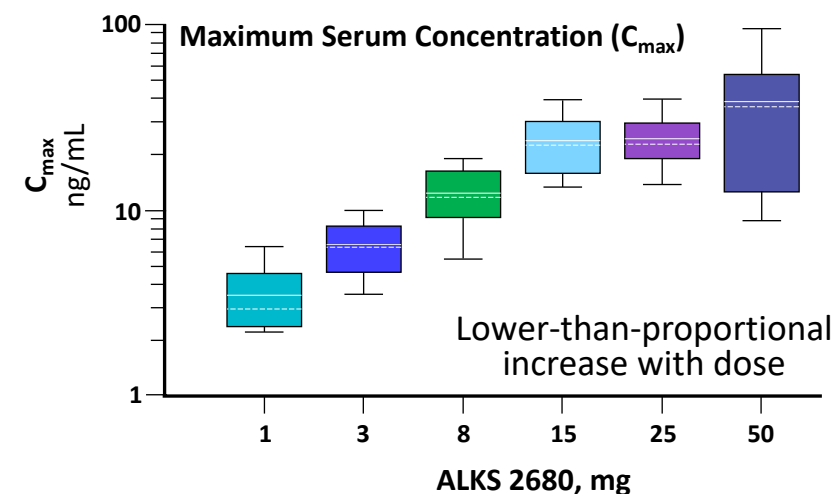
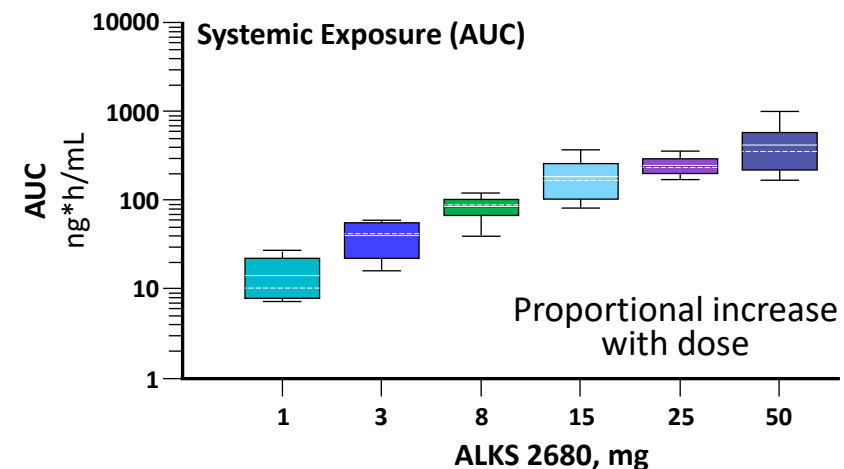
AE: adverse event; ECG: electrocardiogram; MAD: multiple ascending dose; SAD: single ascending dose



# ALKS 2680 Achieved Desired Pharmacokinetic Profile With Once-Daily Dosing

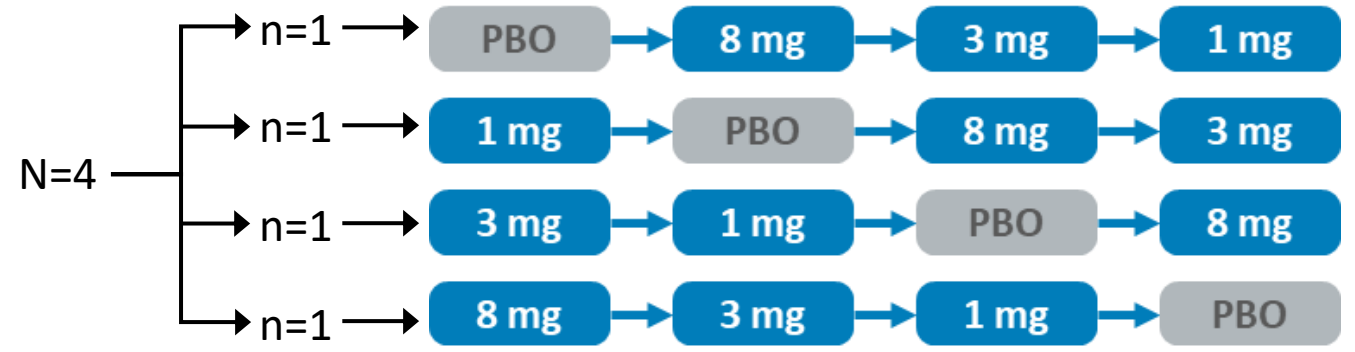
- Overall PK profile supports once-daily dosing
  - Mimics natural sleep/wake cycle
  - Half life = 8-10 hours
- Wide safety margin
  - ~100-fold safety multiples for planned therapeutic doses relative to toxicology studies<sup>a</sup>
- 2 metabolites measured
  - Consistent with preclinical studies
  - Neither contribute to pharmacologic activity
  - No reactive metabolites have been identified

<sup>a</sup>Toxicology studies in mice up to 28 days of dosing completed  
AUC: area under the curve; PK: pharmacokinetics



# Ongoing Randomized, Double-Blind, Placebo-Controlled First-in-Human Study of ALKS 2680 in Patients With NT1

- 1:1:1:1 randomization in a 4-way cross-over design
- Up to 8 patients per cohort
  - First 4 patients in the NT1 cohort completed
- Objectives:
  - Safety and tolerability
  - Sleep latency (MWT) at each cross-over



→ = 48-hour washout between doses

NT2 and IH patient cohorts are currently being evaluated at higher doses

IH: idiopathic hypersomnia; NT1: narcolepsy type 1; NT2: narcolepsy type 2; PBO: placebo; MWT: Maintenance of Wakefulness Test

# Demographics and Baseline Characteristics

Demographic Characteristic	Total (N=4)
<b>Age</b> , years, mean (SD)	23.5 (6.40)
<b>Female</b> , n (%)	1 (25)
<b>White Race</b> , n (%)	4 (100)
<b>Body Mass Index</b> , kg/m <sup>2</sup> , mean (SD)	30.5 (5.45)

Baseline Disease Severity	Total (N=4)
<b>Narcolepsy Severity Scale</b> , mean (SD) Severe 29-42, very severe 43-54	39.8 (3.50)
<b>Epworth Sleepiness Scale</b> , mean (SD) Score >10 suggests excessive daytime sleepiness	16.0 (2.83)
<b>Weekly Cataplexy Rate</b> , mean (SD)	9.0 (10.61)

# Single Doses of ALKS 2680 Were Generally Well Tolerated

	Placebo	ALKS 2680		
	n=4	1 mg n=4	3 mg n=4	8 mg n=4
<b>Adverse events (AEs) reported as related to study drug, n (%)</b>	0	0	0	4 (100)
Insomnia	0	0	0	3 (75)
Pollakiuria	0	0	0	2 (50)
Salivary hypersecretion	0	0	0	2 (50)
Blood pressure increased	0	0	0	1 (25)
Bruxism	0	0	0	1 (25)
Dizziness	0	0	0	1 (25)
Hyperhidrosis	0	0	0	1 (25)

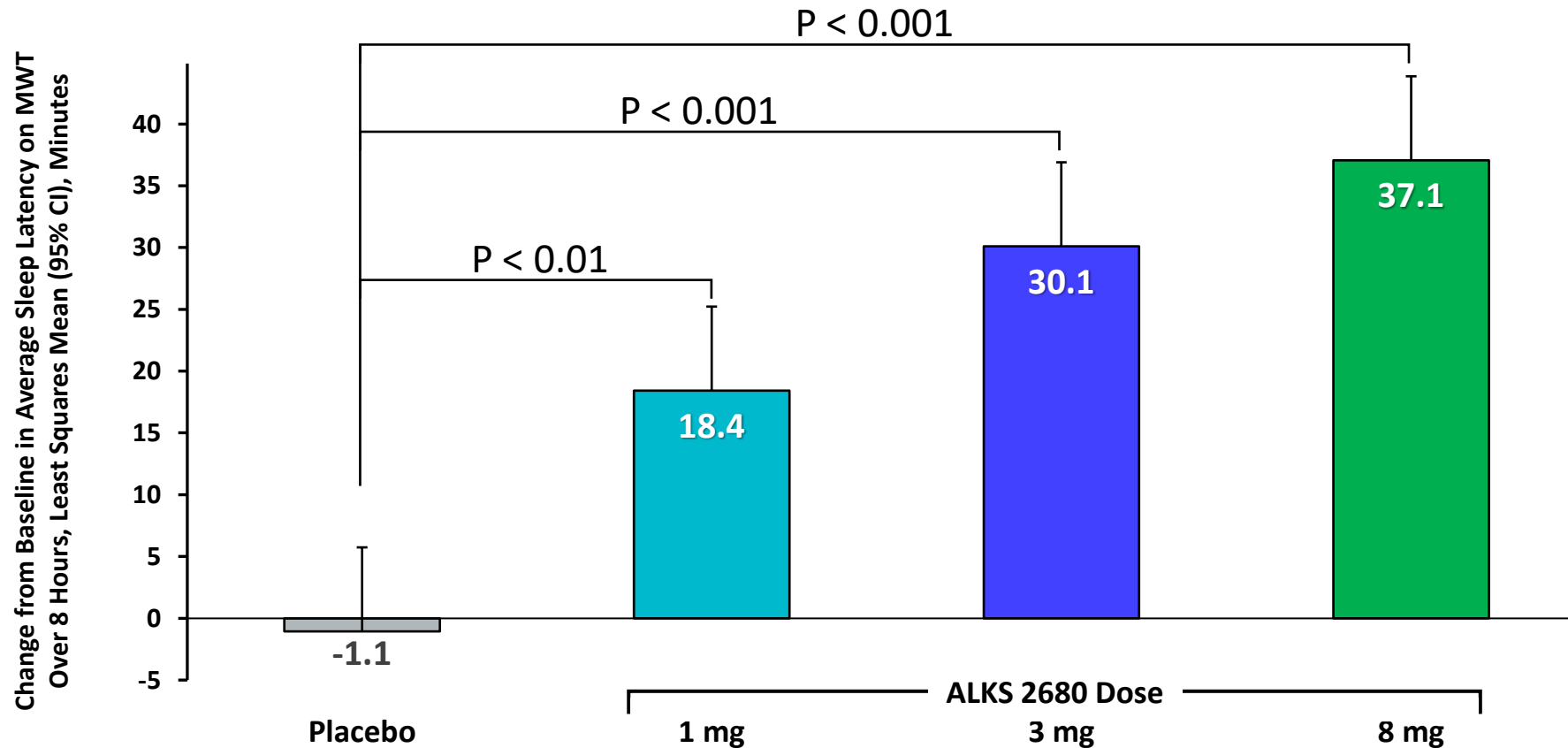
- All AEs were mild in severity; no serious AEs or AEs leading to discontinuation were reported
- No treatment-emergent, clinically meaningful changes in laboratory parameters or ECGs at any dose

AE: adverse event; ECG: electrocardiogram

# ALKS 2680 Significantly Improved Sleep Latency With a Clear Dose Response

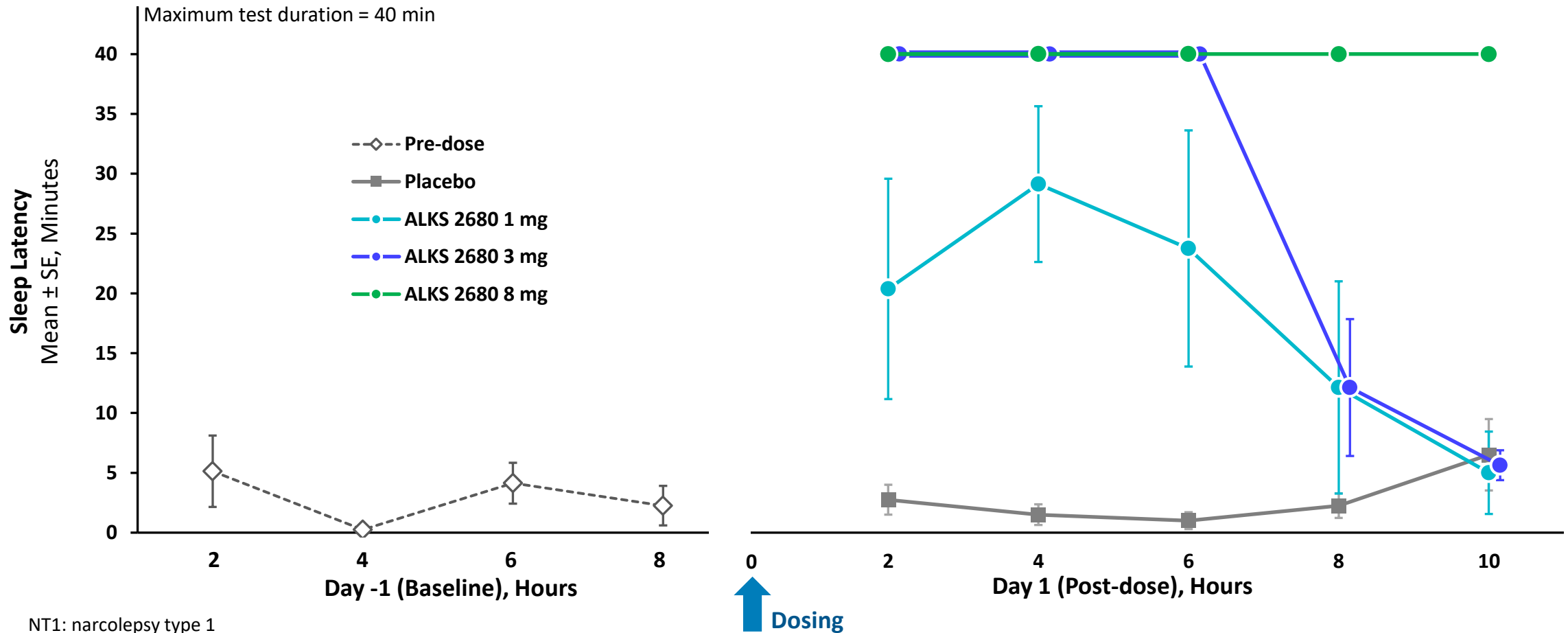
## Average Sleep Latency on the Maintenance of Wakefulness Test (MWT)

(N = 4 per dose)



# ALKS 2680 Single Dose Time Course Suggests a Therapeutic Dose Between 3 mg and 8 mg in NT1

Maintenance of Wakefulness Test (MWT)



NT1: narcolepsy type 1

# Conclusions

Initial benefit/risk profile supports continued clinical evaluation of ALKS 2680

ALKS 2680 in  
Healthy Volunteers  
(N = 80)

Generally well tolerated up to doses of 50 mg  
Increased objective and subjective measures of alertness  
PK/PD profile supports once-daily oral dosing

ALKS 2680 in  
NT1 Patients  
(N = 4)

Generally well tolerated at all doses tested; drug-related adverse events only observed at highest dose (8 mg)  
Statistically significant, clinically meaningful, and durable improvement of sleep latency  
Profile supportive of once-daily administration  
Improvement in sleep latency observed at a low therapeutic dose targeted between 3 and 8 mg in narcolepsy type 1

# Appendix



# Appendix: Financial Results GAAP to Non-GAAP Adjustments

<i>(In millions)</i>	<b>Three Months Ended September 30, 2023</b>
<b>Net Income — GAAP</b>	<b>\$ 47.8</b>
Adjustments:	
Share-based compensation expense	23.9
Depreciation expense	9.7
Amortization expense	9.0
Separation expense	9.6
Restructuring expense	5.9
Income tax effect related to reconciling items	3.5
Non-cash net interest expense	0.1
<b>Non-GAAP Net Income</b>	<b>\$ 109.5</b>

# Appendix: 2023 Guidance GAAP to Non-GAAP Adjustments

<i>(In millions, except per share data)</i>	<b>Year Ending December 31, 2023</b>	<b>Shares<sup>+</sup></b>	<b>Earnings Per Share</b>
<b>Projected Net Income — GAAP</b>	<b>\$ 245.0</b>	<b>171.5</b>	<b>\$ 1.43</b>
Adjustments:			
Share-based compensation expense	97.5		
Depreciation expense	42.5		
Amortization expense	35.0		
Separation expense	21.0		
Income tax effect related to reconciling items	3.5		
Non-cash net interest expense	0.5		
Final award in the Janssen arbitration (2022 back royalties and interest on late payments)*	(195.0)		
<b>Projected Net Income — Non-GAAP</b>	<b>\$ 250.0</b>	<b>171.5</b>	<b>\$ 1.46</b>

Projected GAAP and non-GAAP measures reflect the mid-points within the Company's financial expectations ranges.

<sup>+</sup>2023 per share expectations are calculated based on a weighted average diluted share count of approximately 171.5 million shares outstanding.

\*Back royalties and interest on late payments related to 2022 pursuant to final award related to arbitration proceedings with Janssen.

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