



Q2 2024
Financial Results

## **Forward-Looking Statements**



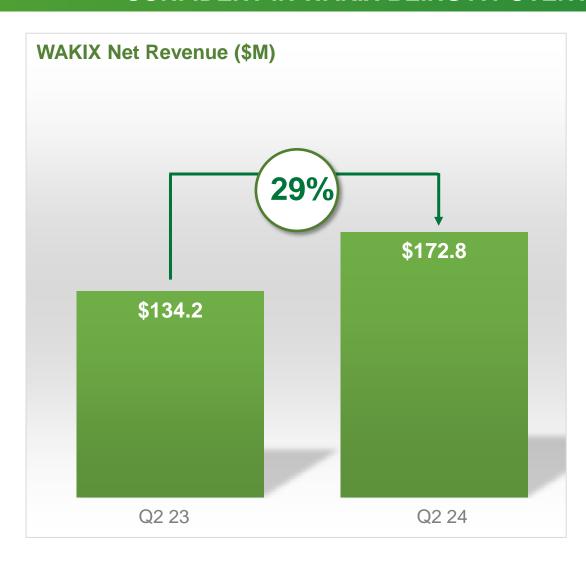
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## WAKIX® Net Revenue Performance



### **CONFIDENT IN WAKIX BEING A POTENTIAL \$1B+ OPPORTUNITY IN NARCOLEPSY ALONE**

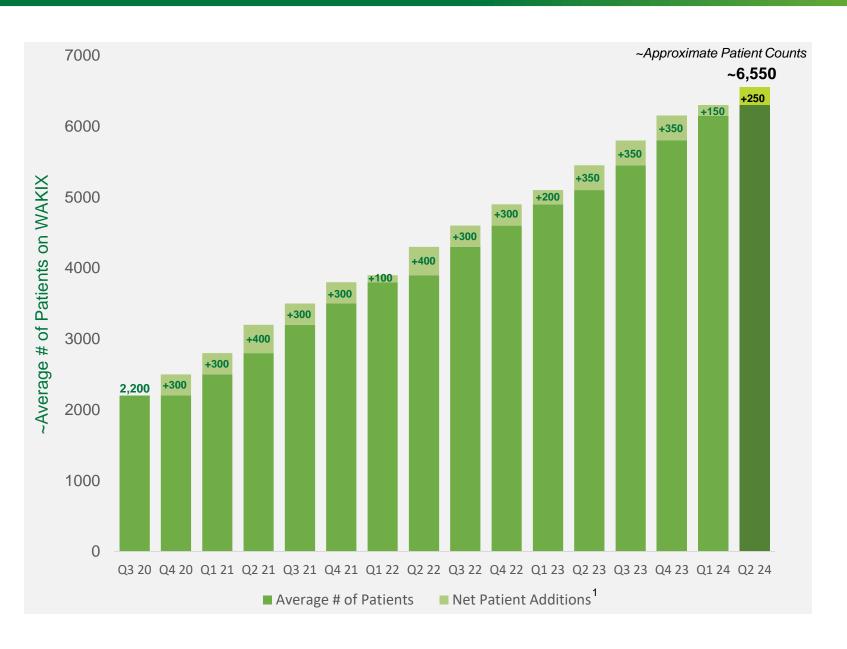


### **HIGHLIGHTS**

- Durable sales growth into year five on the market with 29% growth year-over-year
- Underlying demand drove continued revenue growth
  - Strong patient interest
  - Broad clinical utility
  - Continue to add new prescribers and grow WAKIX prescriber base

## **Solid Business Fundamentals Driving Growth**





## **Q2 24 Highlights**

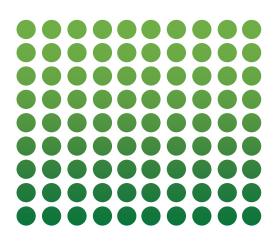


More unique prescribers of WAKIX® than sodium oxybate

Strong market access coverage (>80%) – even with the availability of generic and new oxybate options

# Prescriber Dynamics Support Continued WAKIX® Growth in Narcolepsy: Broad Clinical Utility

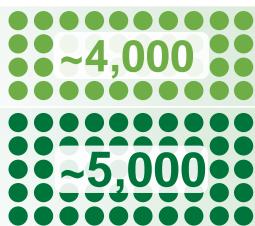




~9,000
Narcolepsy
Treating HCPs

Harmony Field Sales Team covers narcolepsy treating HCP universe

Access to ~100% of diagnosed patient opportunity



HCPs enrolled in oxybate REMS



Depth of prescribing in oxybate REMS enrolled HCPs



HCPs not enrolled in oxybates REMS





Breadth of prescribing in HCPs not enrolled in oxybate REMS



98% of HCPs surveyed with WAKIX experience stated they would write the same/increase Rx in next 6 months.<sup>1</sup>



**50%** of HCPs surveyed who had not prescribed WAKIX to date indicated intent to **Rx in next 6 months**.<sup>1</sup>



Unique feature as non-scheduled treatment is the highest performing driver and differentiator for WAKIX.<sup>1</sup>

<sup>1.</sup> Harmony Market Research, May 2024

# Robust Late-Stage Pipeline



	Product / Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Regulatory Filing	Marketed Product	Milestone
	WAKIX <sup>®</sup>							
	EDS in Narcolepsy (Adults)							
	Cataplexy in Narcolepsy (Adults)							
	EDS in Narcolepsy (Pediatric)							Approved June 21, 2024
	Pitolisant							
Sleep/Wake	Idiopathic Hypersomnia (IH)							Submit sNDA 4Q2024
	Prader-Willi Syndrome (PWS)							Initiated Ph3 Trial 1Q2024
	Myotonic Dystrophy (DM1)							Positive Topline Data 4Q2023
	Pitolisant Gastro-Resistant (GR)							Dosing Optimization Study 4Q2024 BE Study 1Q2025
	Pitolisant High-Dose (HD)							Pilot PK Data 2Q2024
	TPM-1116 (Orexin-2 Receptor Agonist)							
	Sleep/Wake Disorders							IND Filing Mid-2025
	HBS-102							
	PWS							POC Data 2H2024
	ZYN002 (Cannabidiol Gel)							
Neurobehavioral	Fragile X Syndrome (FXS)							Topline Data Mid-2025
	22q11.2 Deletion Syndrome (22q)							Ph 3 Prep Ongoing
Rare Epilepsy	EPX-100 (Clemizole Hydrochloride)							
	Dravet Syndrome (DS)							Topline Data 2026
	Lenox-Gastaut Syndrome (LGS)							Initiate Ph3 Trial 2H2024
	EPX-200 (Lorcaserin)							
	Developmental and Epileptic Encephalopathies (DEE)							E
								6

## Strengthening Our Leadership Position in Sleep/Wake: Pitolisant LCM Addressing Unmet Medical Needs With Meaningfully Differentiated **Product Profiles**



**Pitolisant-HD PDUFA 2028** 

EDS & Cataplexy

EDS &

Cataplexy

Well tolerated: safety profile

Non-scheduled

Gastro-Resistant coating

No titration

Higher Dose, Enhanced Efficacy

**Fatique** Indication

**Pitolisant-GR PDUFA 2026** 

Well tolerated: safety profile

Non-scheduled

Gastro-Resistant coating

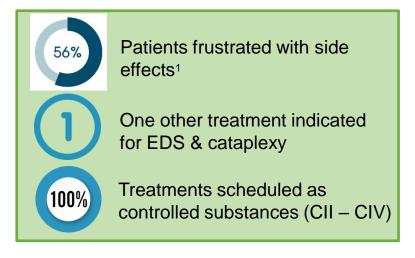
No titration

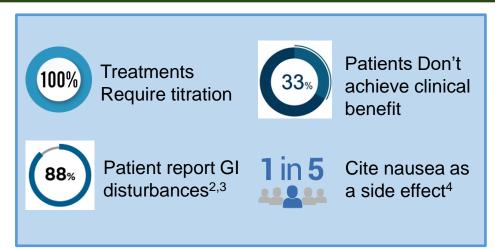
**WAKIX FDA Approval 2019** 

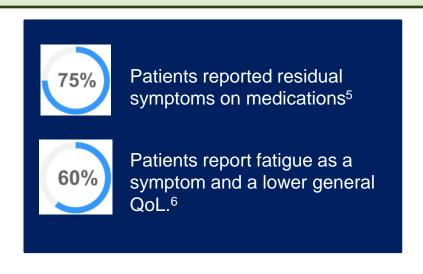
EDS & Cataplexy Well tolerated: safety profile

Non-scheduled

#### PATIENT AND HCP UNMET NEEDS

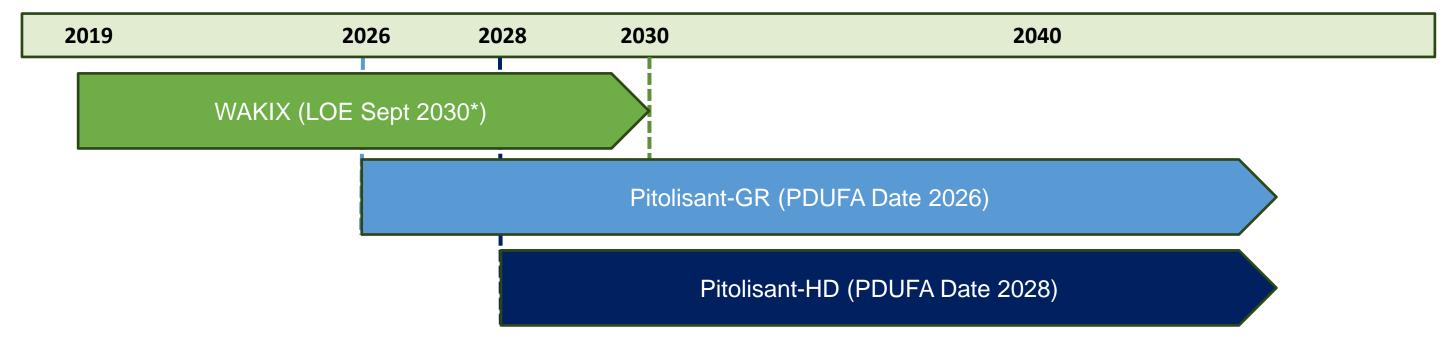






# Strengthening Our Leadership Position in Sleep/Wake: Extending The Pitolisant Franchise To the Mid 2040s





- Two meaningfully differentiated product profiles building off WAKIX with PDUFAs prior to LOE
  - Pitolisant GR PDUFA date in 2026; supports expanding pitolisant patient base
  - Pitolisant HD PDUFA date in 2028; designed to deliver meaningful differentiation, clinically superior product profile
    - Provides an opportunity to introduce a differentiated product 18-24 months prior to WAKIX LOE
    - Harmony Commercial Model uniquely suited to maximize this opportunity
- Provisional patents filed out to 2044 to extend durable patient and net revenue growth for the pitolisant franchise to the mid 2040's

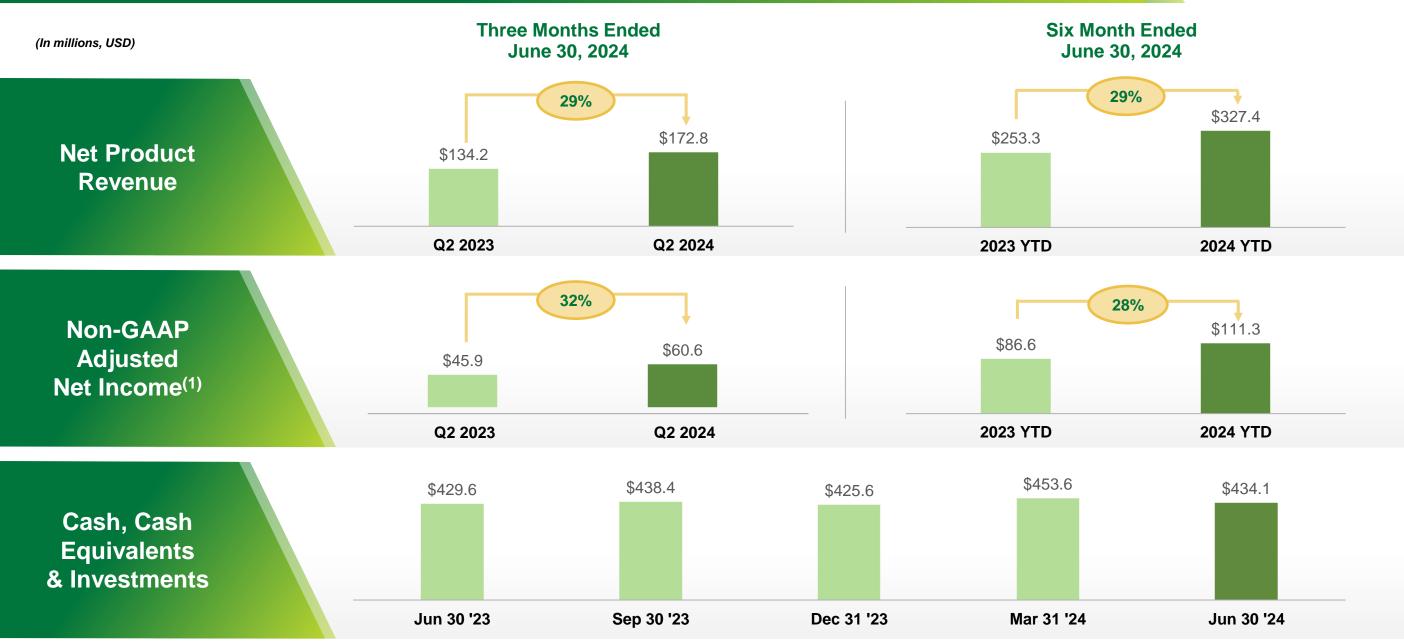
# Pitolisant High-Dose (HD) Formulation: Differentiated Product Profile



Attributes	Development Plan	Potential differentiated features	
Higher dose	Up to 2x compared to current highest WAKIX labeled dose	Better efficacy in EDS/cataplexy; Higher POS for fatigue in narcolepsy	<b>✓</b>
Optimized PK profile	Pilot PK study	Higher relative bioavailability for the same dose compared to WAKIX; decreased variability	<b>✓</b>
Gastro-resistant coating	Confirmed with dissolution assays	Designed to address GI issues in patients with narcolepsy; start at the therapeutic dose range	
Differentiated Indications	Fatigue in Narcolepsy Sleep inertia in IH EDS and Fatigue in Myotonic Dystrophy	First product indication for these symptoms; Differentiated label compared to WAKIX	
IP	Provisional patent filed	Potential IP until 2044	

## **Financial Highlights**





## **Financial Summary**



(In millions, USD)	Three Months Ended June 30,		% Change	Six Months Ended June 30,		% Change
Totals may not foot due to rounding	2024	2023		2024 2023		
Net Product Revenue	\$172.8	\$134.2	29%	\$327.4	\$253.3	29%
Cost of Product Sold	32.1	25.0	28%	59.6	45.8	30%
Total Operating Expenses	\$119.3	\$62.3	92%	\$194.4	\$120.2	62%
R&D Expense (1)	63.6	15.0	NM	85.8	28.3	NM
S&M Expense	28.5	24.5	16%	55.7	47.1	18%
G&A Expense	27.2	22.8	19%	52.9	44.9	18%
Net Income	\$11.6	\$34.3	(66%)	\$49.9	\$63.8	(22%)
Cash, cash equivalents & investments	\$434.1					

NM denotes not meaningful % change

<sup>(1)</sup> Includes upfront licensing fee of \$25.5M related to the 2024 Bioprojet Sublicense Agreement and IPR&D charge of \$17.1M related to the acquisition of Epygenix for the three months and six month ended June 30, 2024

## **GAAP vs NON-GAAP Reconciliation**



(In millions, USD)	Three Mont June		Six Months Ended June 30,	
Totals may not foot due to rounding	2024	2023	2024	2023
GAAP net income	\$11.6	\$34.3	\$49.9	\$63.8
Non-cash interest expense <sup>(1)</sup>	0.2	0.4	0.4	0.8
Depreciation	0.1	0.1	0.3	0.2
Amortization <sup>(2)</sup>	6.0	6.0	11.9	11.9
Stock-based compensation expense	11.0	7.8	21.4	14.4
Licensing fee and milestone payments <sup>(3)</sup>	25.5	-	25.5	0.8
Transaction related costs <sup>(4)</sup>	17.1	-	17.1	-
Income tax effect related to Non-GAAP adjustments(5)	(10.8)	(2.7)	(15.1)	(5.3)
Non-GAAP adjusted net income	\$60.6	\$45.9	\$111.3	\$86.6
GAAP net income per diluted share	\$0.20	\$0.56	\$0.87	\$1.05
Non-GAAP adjusted net income per diluted share	\$1.05	\$0.76	\$1.93	\$1.42
Weighted average number of shares of common stock used in non-GAAP diluted per share	57,541,696	60,743,953	57,571,570	60,997,410

<sup>(1)</sup> Includes amortization of deferred finance charges.

<sup>(2)</sup> Includes amortization of intangible asset related to WAKIX.

<sup>(3)</sup> Amount represents upfront licensing fee incurred upon closing the 2024 Bioprojet Sublicense Agreement and milestone payment related to HBS102 in March 2023.

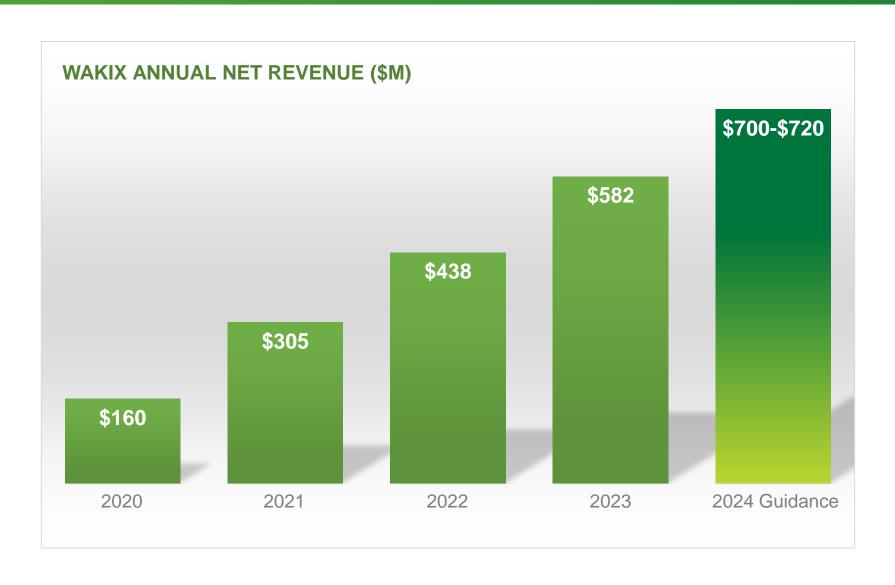
<sup>(4)</sup> Includes IPR&D charge related to the acquisition of Epygenix.

<sup>(5)</sup> Calculated using the reported effective tax rate for the periods presented less impact of discrete items.

## Reiterates 2024 Net Revenue Guidance



### **CONFIDENT IN WAKIX BEING A POTENTIAL \$1B+ OPPORTUNITY IN NARCOLEPSY ALONE**



Reiterates
2024 Guidance

\$700-\$720M



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