



# Q3 2023 Financial and Business Update

October 31, 2023



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# Strongest Revenue Quarter in Harmony's History; Advancement and Expansion of the Pipeline

## Continued Strong Growth For WAKIX® in Adult Narcolepsy

- Q3 23: WAKIX Net Revenue of \$160.3M **+37% Year-over-Year Growth**
- Q3 23: **~5,800** average number of patients on WAKIX
- **Continued strong growth** in average number of patients & WAKIX prescriber base

## Advancing the Pipeline

- Reported topline results from Phase 3 INTUNE study; **remain committed to IH patient community and actively pursuing IH indication**; next step is to meet with the FDA informed by review of the full data set
- Received FDA feedback on study protocol for Phase 3 TEMPO study in patients with PWS; **expect to initiate the study in Q1 24**
- **On track** for topline data from DM1 Phase 2 POC study in Q4 23
- **On track** for submission of sNDA for pediatric narcolepsy indication in Q4 23
- **Advancing new pitolisant based** formulations into the clinic in Q4 23
- **Expanded and diversified the pipeline** with acquisition of Zynerba Pharmaceuticals; Zysel in Phase 3 pivotal trial for Fragile X syndrome

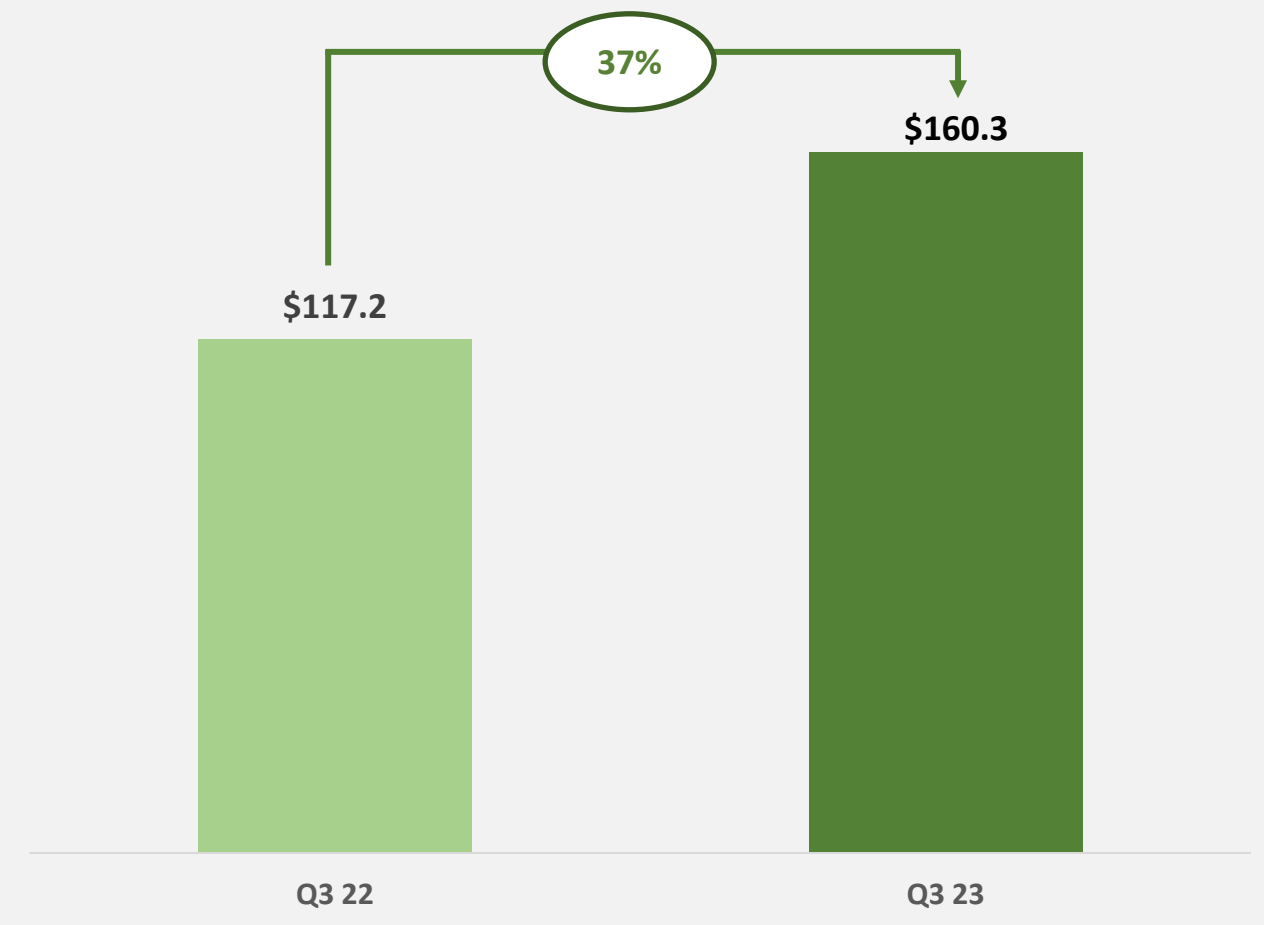
## Strong Financial Position to Maximize Shareholder Value

- **Profitable, cash generating** with **\$438.4M** on the balance sheet
- **Share repurchase program**: Repurchased ~1.4M shares of common stock at an aggregate cost of \$50M during Q3 23. Board of Directors authorized new \$200M share repurchase program.
- **Well positioned** to execute on business development to build out robust pipeline

# WAKIX<sup>®</sup> Net Revenue Performance

CONFIDENT IN WAKIX BECOMING A \$1B+ OPPORTUNITY IN ADULT NARCOLEPSY ALONE WITH THE POTENTIAL TO CONTRIBUTE UP TO AN ADDITIONAL \$1B, IF APPROVED IN OTHER CURRENT PITOLISANT LIFECYCLE MANAGEMENT PROGRAMS

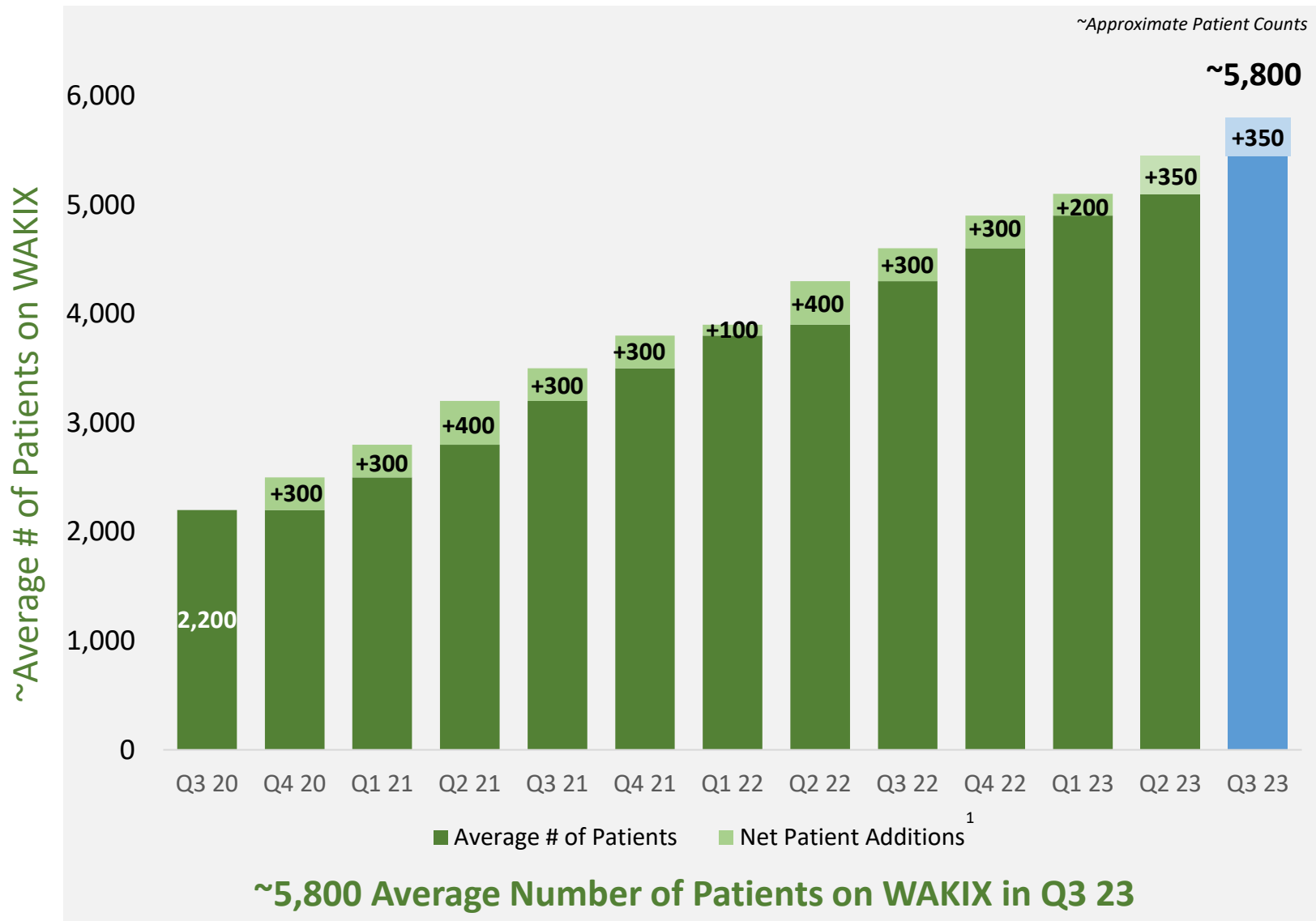
WAKIX QUARTERLY NET REVENUE (\$M)



## Q3 23 HIGHLIGHTS

- Q3 23 Net Revenue of \$160.3M; strongest revenue quarter in Harmony's history
- Underlying demand drove continued double-digit revenue growth of 37% vs. Q3 22
  - Strong patient interest
  - Continue to add new prescribers and grow WAKIX prescriber base

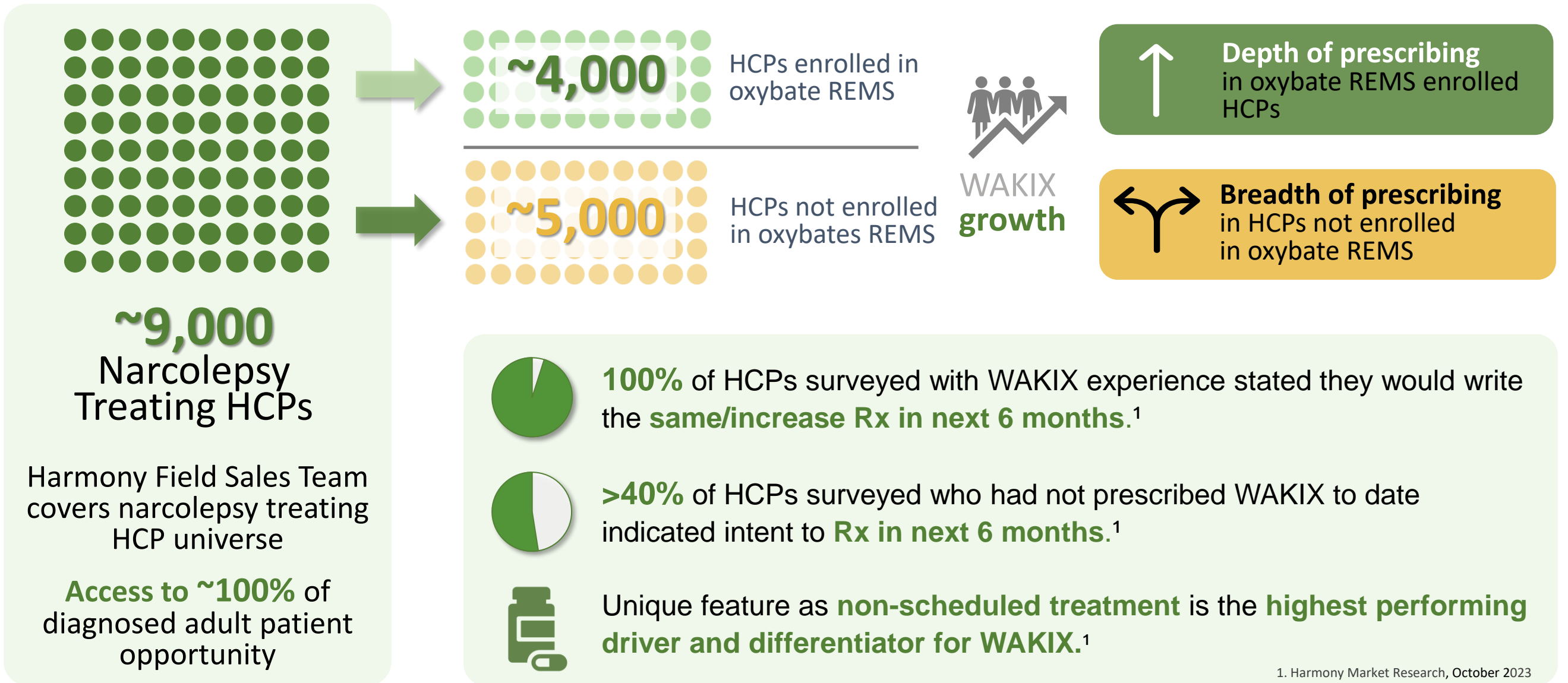
# Continued Strong Growth In Average Number of Patients on WAKIX®



## Q3 23 HIGHLIGHTS

- Average Number of Patients on WAKIX increased to **~5,800**
  - **+350** from reported in Q2 23
- Continued growth in depth and breadth of prescriber base beyond HCPs enrolled in oxybate REMS program
- Strong payer coverage to support continued growth

# Prescriber Dynamics Support Continued WAKIX® Growth in Adult Narcolepsy



# Development Pipeline

Product / Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Regulatory Filing	Marketed Product	Milestone
<b>WAKIX®</b>							
EDS in Narcolepsy (Adults)							
Cataplexy in Narcolepsy (Adults)							
<b>Pitolisant</b>							
Pediatric Narcolepsy <sup>1</sup>							Submit sNDA 4Q2023
Idiopathic Hypersomnia (IH)							Full Dataset Review Ongoing
Prader-Willi Syndrome (PWS)							Initiate Ph3 1Q2024
Myotonic Dystrophy (DM)							Topline data 4Q2023
New Pitolisant Assets							Initiate Studies 4Q2023
<b>Zygel™</b>							
Fragile X Syndrome (FXS)							
22q11.2 Deletion Syndrome (22q)							
<b>HBS-102</b>							
PWS							Preclinical POC study initiated 3Q2022

# Extending the Pitolisant Franchise

Anticipate Data in First Half of 2024

## Formulation 1

- **Opportunity:** Extend franchise beyond 2040, with potential for new IP and opportunity to explore additional indications
- **Formulation:** Enhanced formulation designed to deliver an optimized PK profile and a higher dosage strength
- **Program:** Full development program
- **Status:** First-in-Human study commenced in Q4 2023

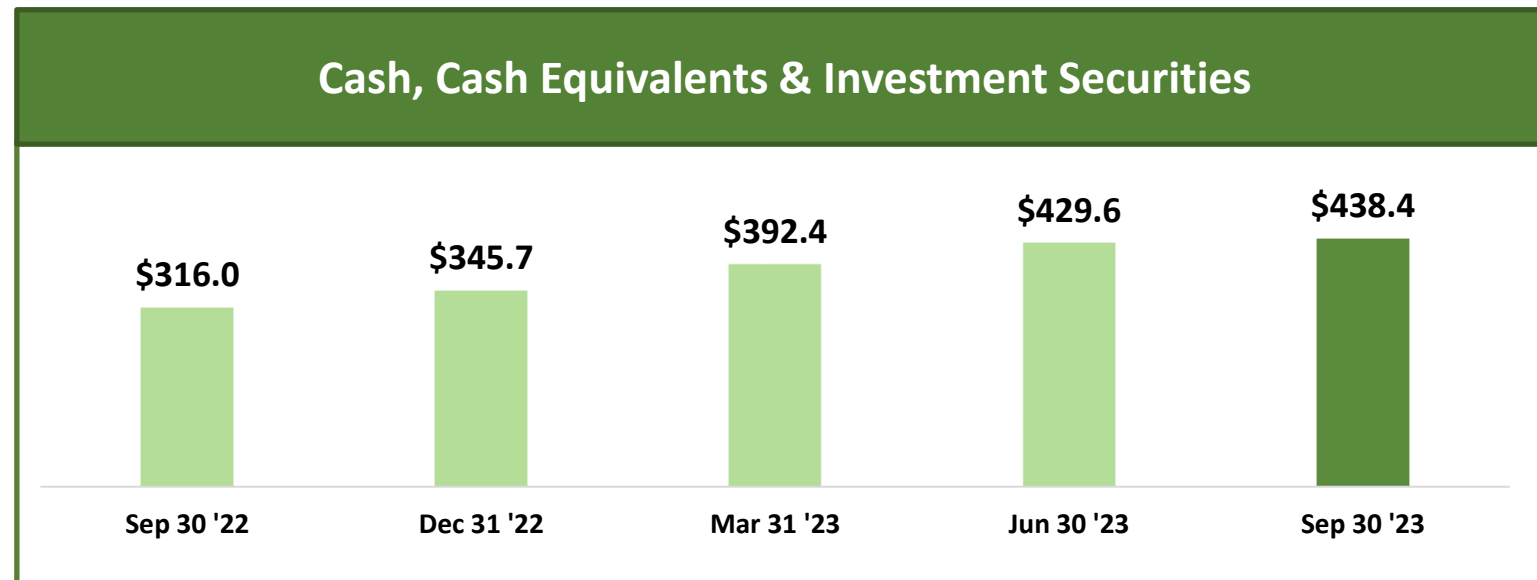
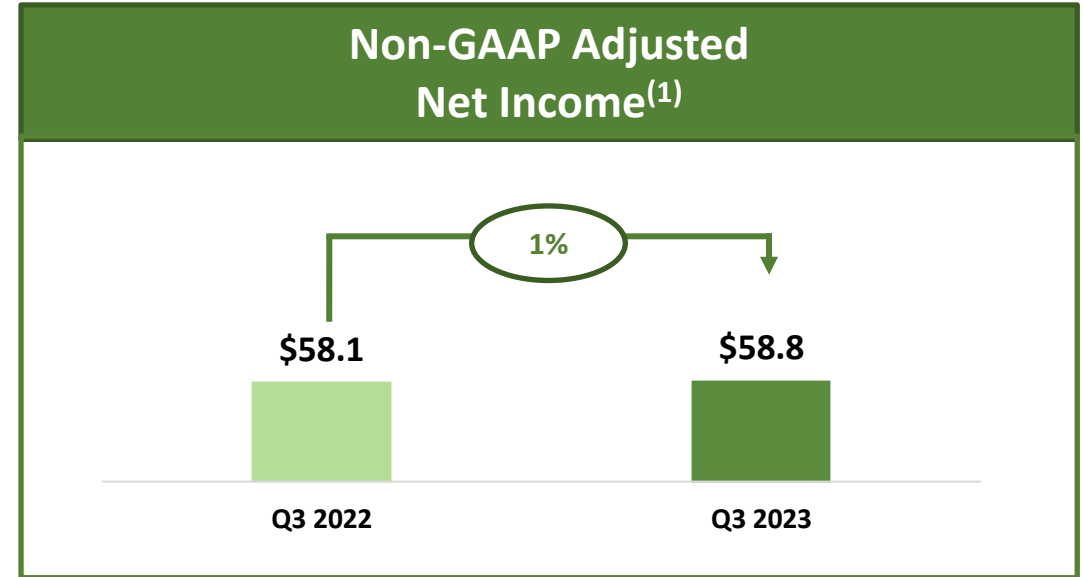
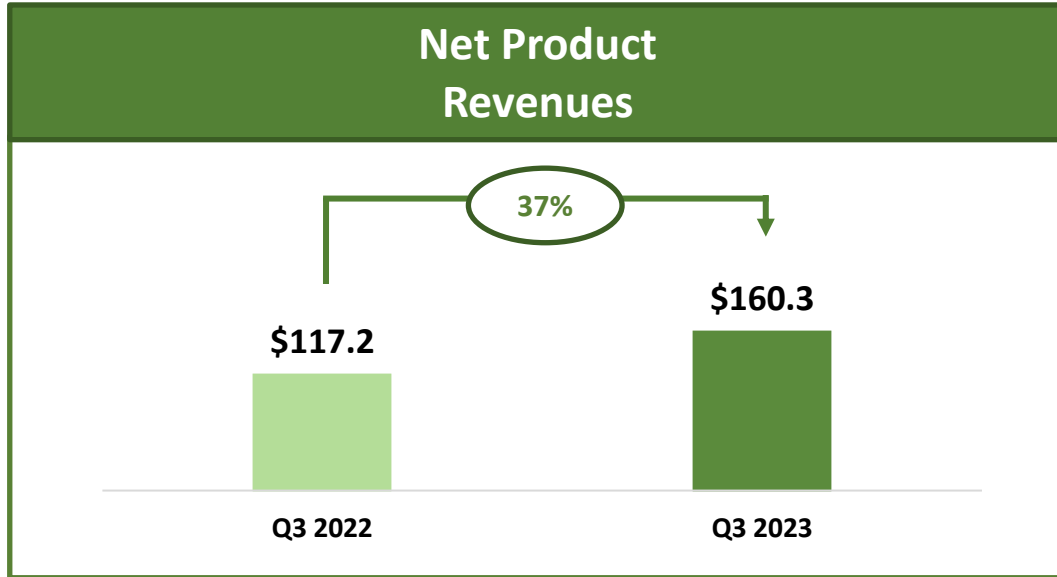
## Formulation 2

- **Opportunity:** Fast to market strategy for narcolepsy within WAKIX lifecycle
- **Formulation:** Modified formulation with potential clinical differentiation
- **Program:** Abbreviated development program
- **Status:** Phase 1 PK study expected to start in Q4 2023



# Financial Highlights

(In millions, USD)



(1) Non-GAAP Adjusted Net Income= GAAP Net Income excluding non-cash interest expense, depreciation, amortization, stock-based compensation, other non-operating items and tax effect of these items.

# Financial Summary

<i>(In millions, USD)</i>	Three Months Ended September 30,		% Change
	2023	2022	
Totals may not foot due to rounding			
<b>Net Product Revenues</b>	<b>\$160.3</b>	<b>\$117.2</b>	<b>37%</b>
Cost of Product Sold	32.3	23.0	41%
<b>Total Operating Expenses</b>	<b>\$63.5</b>	<b>\$82.3</b>	<b>(23%)</b>
R&D Expense	17.5	40.5	(57%)
S&M Expense	23.4	20.5	14%
G&A Expense	22.5	21.3	6%
<b>Net Income <sup>(1)</sup></b>	<b>\$38.5</b>	<b>\$87.9</b>	<b>(46%)</b>
<b>Cash, cash equivalents &amp; investment securities</b>	<b>\$438.4</b>		

# GAAP vs NON-GAAP Reconciliation

<i>(In millions, USD)</i>	Three Months Ended September 30,	
	2023	2022
Totals may not foot due to rounding		
<b>GAAP net income</b>	<b>\$38.5</b>	<b>\$87.9</b>
Non-cash interest expense <sup>(1)</sup>	2.2	0.4
Depreciation	0.1	0.1
Amortization <sup>(2)</sup>	6.0	6.0
Stock-based compensation expense	7.9	7.0
Licensing fee <sup>(3)</sup>	-	30.0
Loss on debt extinguishment	9.8	-
Valuation allowance release	-	(74.5)
Income tax effect related to Non-GAAP adjustments <sup>(4)</sup>	(5.7)	1.2
<b>Non-GAAP adjusted net income</b>	<b>\$58.8</b>	<b>\$58.1</b>
<b>GAAP reported net income per diluted share</b>	<b>\$0.63</b>	<b>\$1.44</b>
<b>Non-GAAP adjusted net income per diluted share</b>	<b>\$0.97</b>	<b>\$0.95</b>
Weighted average number of shares of common stock used in non-GAAP diluted per share	60,681,676	61,207,625

(1) Includes amortization of deferred finance charges

(2) Includes amortization of intangible asset related to WAKIX

(3) Amount represents upfront licensing fee incurred upon closing the 2022 Licensing and Commercialization Agreement with Bioprojet.

(4) Calculated using the reported effective tax rate for the periods presented less impact of discrete items

# Executing on Our Growth Strategy

**\$1B+ Commercial Opportunity for WAKIX® in Adult Narcolepsy**



**Up to \$1B Opportunity in Pitolisant LCM Programs (IH, PWS, DM1)**



**Expanding and Diversifying the Pipeline; Advancing New Pitolisant Assets**



**Strong Financial Position (\$438M) to Maximize Shareholder Value**





Thank You

