



Q1 2024 Financial Results

April 30, 2024



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Harmony Accelerates Growth Strategy

Three CNS Franchises - Each With Peak Sales Potential of \$1B-\$2B



Sleep/Wake

- **WAKIX potential \$1B+ Net Revenue opportunity** in Narcolepsy alone with LOE out to 2030
- **On track towards pediatric exclusivity** to extend WAKIX exclusivity to September 2030
- **Near term catalysts** with potential new indications for pitolisant
 - **Pediatric Narcolepsy** – June 21, 2024 PDUFA
 - **IH** – sNDA planned for 2H 2024
- **Life cycle management for pitolisant with Next-Gen formulations** to extend the franchise revenue growth potential beyond 2040
 - **NG1** – PDUFA date in 2026
 - **NG2** – On track for PK data in 1H 2024
- **Strengthens leadership position with TPM-1116**, a highly potent and selective oral orexin-2 receptor agonist

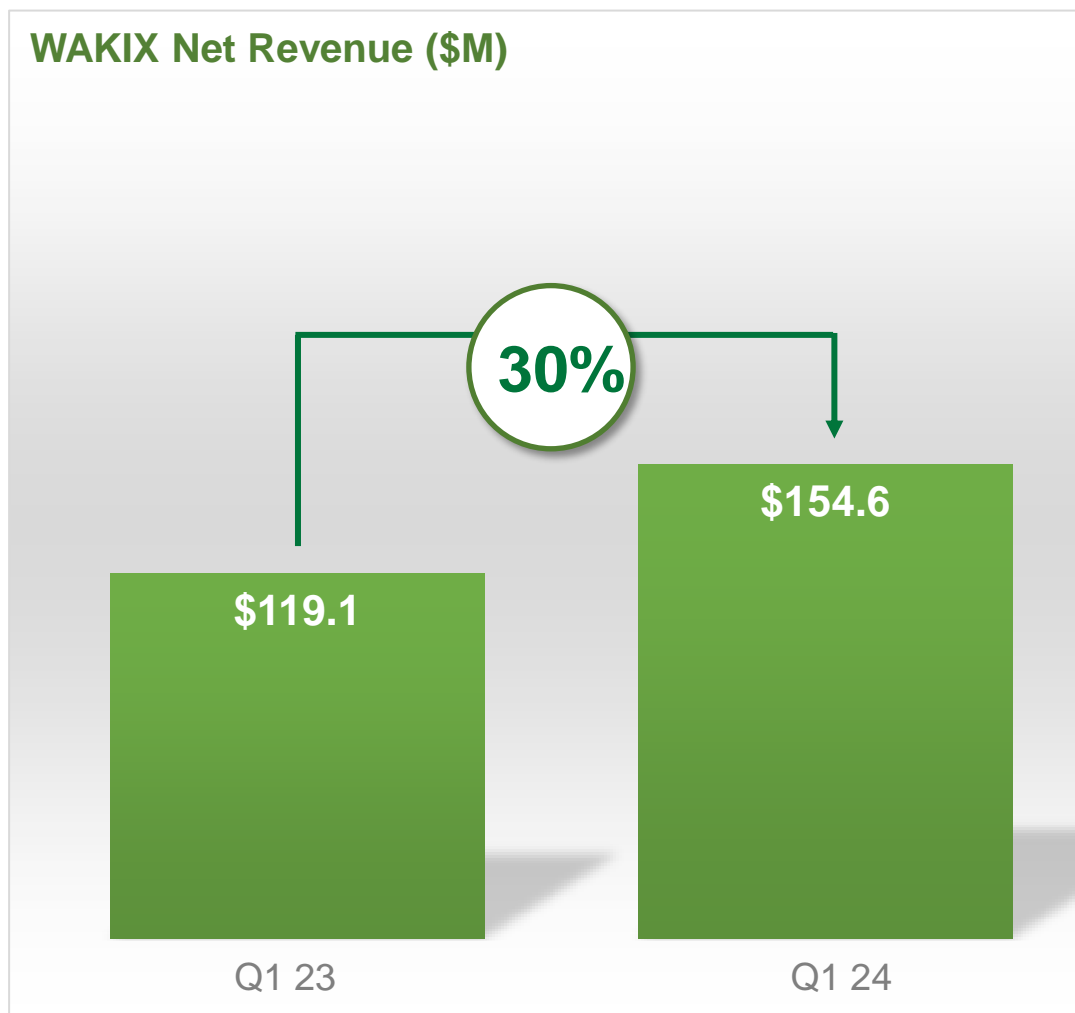
Neurobehavioral

- **ZYN002 in Phase 3 RECONNECT study** for Fragile X syndrome (FXS); topline data expected Mid-2025
- **Phase 3 preparation ongoing** for 22q11.2(22q) deletion syndrome
- **A global opportunity with 80,000 patients** each in FXS and 22q in the U.S. alone

Rare Epilepsy

- Establishes franchise through acquisition of Epygenix Therapeutics Inc.
- Lead product, clemizole hydrochloride (EPX-100), **in pivotal registrational trial for Dravet syndrome (DS)**; topline data expected in 2026
- **Phase 3 trial for Lennox-Gastaut syndrome (LGS)** to initiate 2H 2024
- EPX-100 **has Orphan Drug Designation and Rare Pediatric Disease Designation** from FDA for both DS and LGS
- EPX-200 in IND-enabling stage

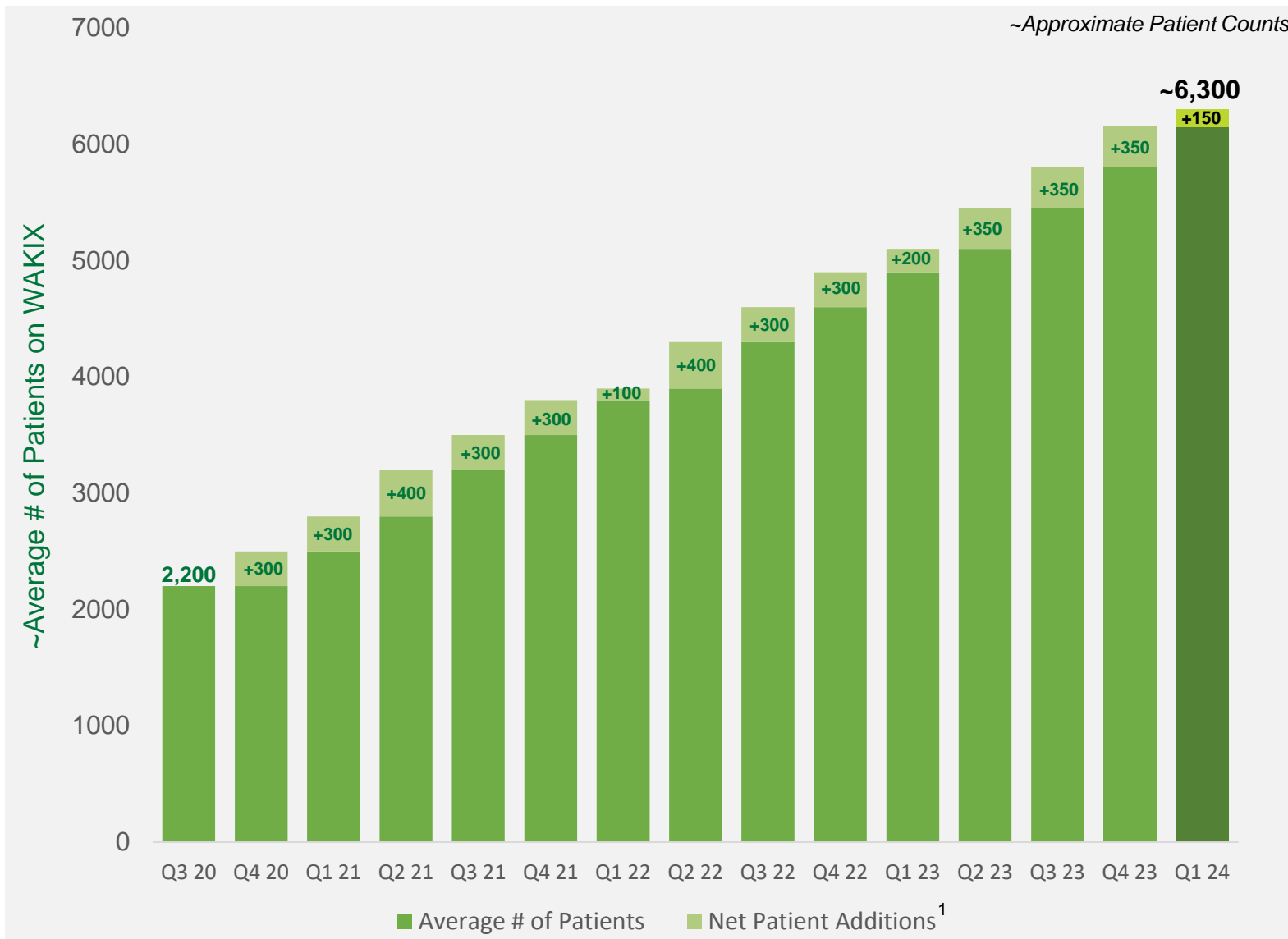
CONFIDENT IN WAKIX BEING A POTENTIAL \$1B+ OPPORTUNITY IN ADULT NARCOLEPSY ALONE



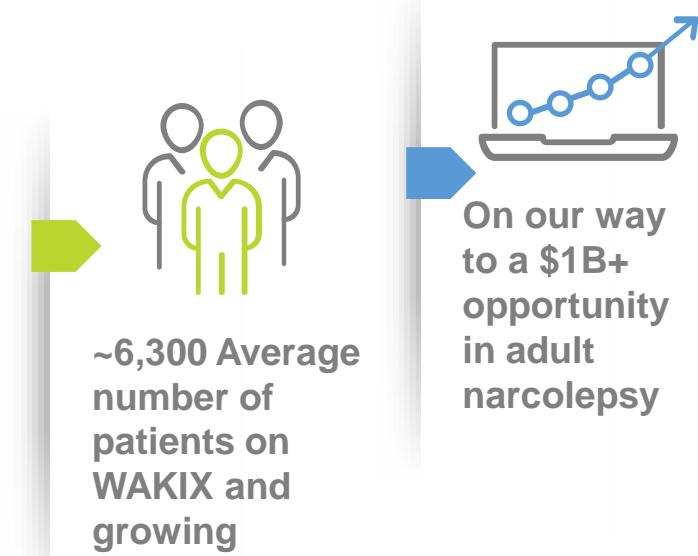
HIGHLIGHTS

- Durable sales into year five on the market with 30% growth year-over-year
- Underlying demand drove continued revenue growth
 - Strong patient interest
 - Continue to add new prescribers and grow WAKIX prescriber base

Solid Business Fundamentals Driving Growth



Q1 24 Highlights

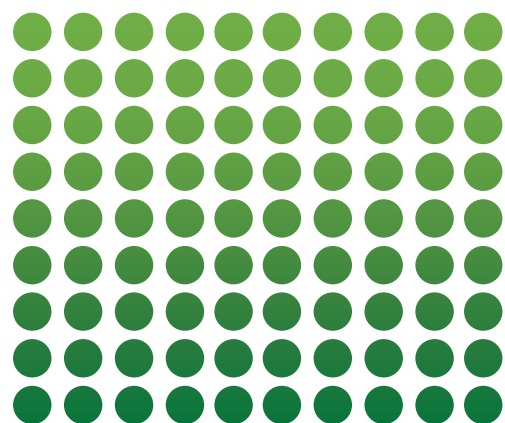


More unique prescribers of WAKIX[®] than sodium oxybate

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

1. Net Patient Additions based on previously disclosed quarterly average number of patients on WAKIX

Prescriber Dynamics Support Continued WAKIX® Growth in Adult Narcolepsy



~9,000
Narcolepsy
Treating HCPs

Harmony Field Sales
Team covers narcolepsy
treating HCP universe

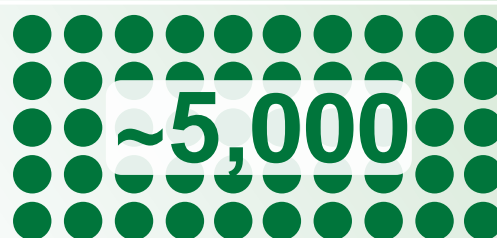
Access to ~100%
of diagnosed adult
patient opportunity



HCPs enrolled in
oxybate REMS



Depth of prescribing
in oxybate REMS
enrolled HCPs

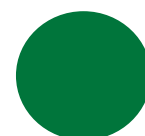


HCPs not
enrolled in
oxybates REMS

**WAKIX
growth**



Breadth of prescribing
in HCPs not enrolled
in oxybate REMS



100% of HCPs surveyed with WAKIX experience stated they would write the **same/increase Rx in next 6 months.**¹



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



Unique feature as **non-scheduled treatment** is the **highest performing driver and differentiator for WAKIX.**¹

1. Harmony Market Research, January 2024

Building a Robust Late-Stage Pipeline



Product / Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Regulatory Filing	Marketed Product	Milestone
WAKIX®							
EDS in Narcolepsy (Adults)	[Progress bar]						
Cataplexy in Narcolepsy (Adults)	[Progress bar]						
Pitolisant							
Pediatric Narcolepsy	[Progress bar]						PDUFA June 21, 2024
Idiopathic Hypersomnia (IH)	[Progress bar]						Submit sNDA 2H2024
Prader-Willi Syndrome (PWS)	[Progress bar]						Initiated Ph3 Trial 1Q2024
Myotonic Dystrophy (DM1)	[Progress bar]						Positive Topline Data 4Q2023
Next Gen Pitolisant Formulation 1 (NG1)	[Progress bar]						BE and Dosing Optimization Studies 4Q2024
Next Gen Pitolisant Formulation 2 (NG2)	[Progress bar]						PK Data 1H2024
TPM -1116							
Sleep/Wake Disorders	[Progress bar]						IND Filing Mid-2025
HBS-102							
PWS	[Progress bar]						POC Data 1H2024
Neurobehavioral							
ZYN002 (Cannabidiol Gel)							
Fragile X Syndrome (FXS)	[Progress bar]						Topline Data Mid-2025
22q11.2 Deletion Syndrome (22q)	[Progress bar]						Ph 3 Prep Ongoing
Rare Epilepsy							
EPX-100							
Dravet Syndrome (DS)	[Progress bar]						Topline Data 2026
Lenox-Gastaut Syndrome (LGS)	[Progress bar]						Initiate Ph3 Trial 2H2024
EPX-200							
Developmental and Epileptic Encephalopathy (DEE)	[Progress bar]						

Extending the Pitolisant Franchise With Next-Gen Formulations (NG1)

Next-Gen Formulation 1

- **Description:** Enteric coated tablet formulation of pitolisant HCl
- **Clinical Development Objectives:**
 - Demonstrate bioequivalence (BE) to WAKIX; Abbreviated development program
 - Dosing optimization
- **Clinical Differentiation:**
 - Enteric coated tablet designed to potentially decrease GI side effects
 - Ability to start dosing at 17.8mg, at the beginning of the therapeutic range with potential to achieve clinical benefit faster
- **Market Opportunity:**
 - Unique product offering for patients to co-exist with WAKIX; accretive opportunity
 - Target patients with previous WAKIX experience
- **PDUFA date expected in 2026**
- **Provisional patent filed with the potential for patent protection out to 2044**

NG1 – Pilot Bioequivalence Study Data

Formulation	Cmax (ng/ml)	AUC _{0-t} (h*ng/ml)	AUC _{0-inf} (h*ng/ml)
Test formulation, NG1 (Enteric Coated Pitolisant Hcl)	15.29	242.27	256.62
Reference formulation, Wakix (Pitolisant Hcl)	14.42	224.12	237.22

- Cmax and AUC, the two important parameters to establish Bioequivalence (BE), are similar between the Test and the Reference formulations indicating the rate and extent of absorption are similar in this pilot study
- Safety and tolerability: No AEs reported either with the test or the reference formulations
- **Next Steps:**
 - Pivotal BE study – Q4 24
 - Dosing Optimization study – Q4 24
 - PDUFA Date – 2026

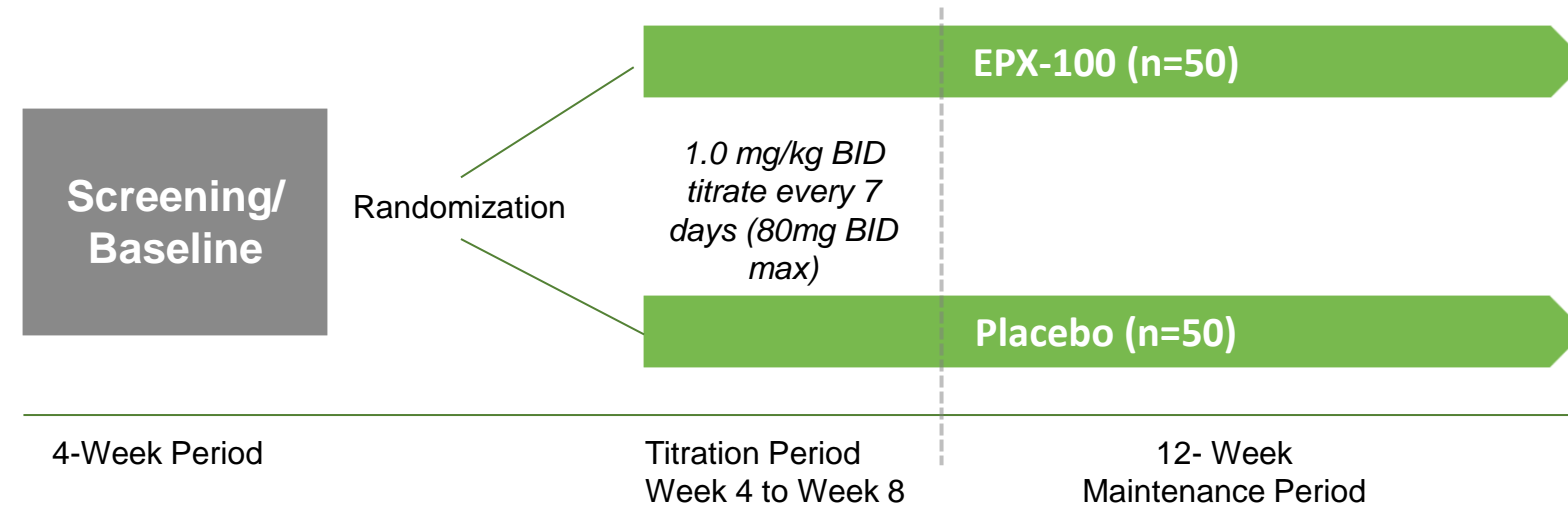
Extending the Pitolisant Franchise With Next-Gen Formulations (NG2)

ON TRACK FOR DATA IN FIRST HALF OF 2024

Next-Gen Formulation 2

- **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:** Pilot PK study initiated in Q4 23; data available in 1H 24

ARGUS Study in Dravet Syndrome



Trial Design:

- Randomized, double-blind, placebo-controlled, parallel-group study
- 1:1 clemizole hydrochloride: placebo
- ~100 patients; Age 2 years or older

Objectives / Endpoints:

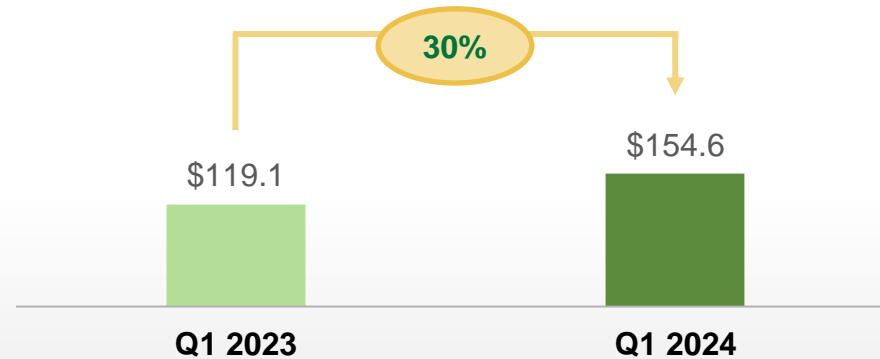
- **Primary objective:** To evaluate the efficacy of EPX-100 compared with placebo as adjunctive therapy in children and adult participants with Dravet Syndrome
- **Primary endpoint:** Mean percent change between EPX-100 vs placebo in countable convulsive seizure frequency (CCSF)
- **Secondary Objective:** To evaluate the difference between EPX100 vs placebo in the number of countable convulsive seizure-free days relative to baseline
- **Secondary Endpoint:** The number of countable convulsive seizure-free days in the titration and maintenance phase relative to baseline

Financial Highlights

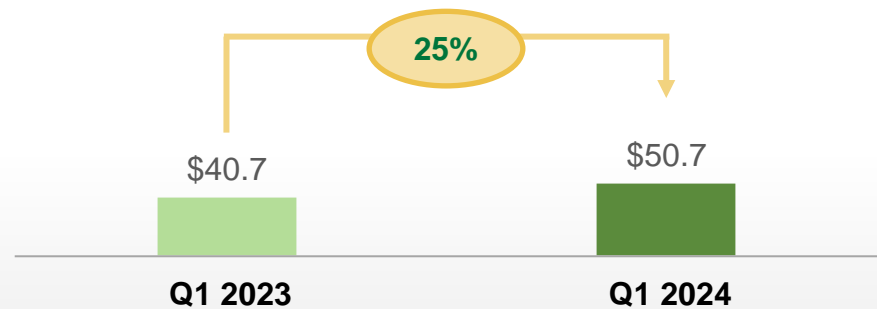
(In millions, USD)

Three Months Ended
March 31, 2024

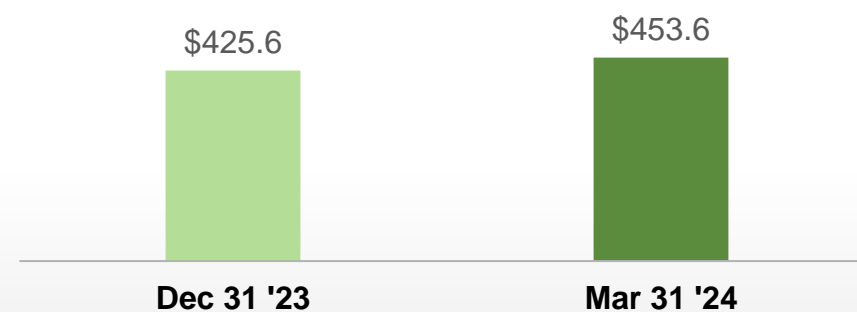
Net Product Revenue



Non-GAAP Adjusted Net Income⁽¹⁾



Cash, Cash Equivalents & Investments



HIGHLIGHTS

- Durable sales into year five on the market with 30% growth year-over-year
- Improved profitability
- Continued cash generation resulting in a strong balance sheet

(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 March 31,		% Change
	2024	2023	
<small>Totals may not foot due to rounding</small>			
Net Product Revenue	\$154.6	\$119.1	30%
Cost of Product Sold	27.5	20.8	32%
Total Operating Expenses	\$75.1	\$57.9	30%
R&D Expense	22.2	13.3	67%
S&M Expense	27.2	22.6	21%
G&A Expense	25.7	22.1	16%
Net Income	\$38.3	\$29.5	30%
Cash, cash equivalents & investments	\$453.6		

GAAP vs NON-GAAP Reconciliation



<i>(In millions, USD)</i>	Three Months Ended March 31,	
	2024	2023
Totals may not foot due to rounding		
GAAP net income	\$38.3	\$29.5
Non-cash interest expense ⁽¹⁾	0.2	0.4
Depreciation	0.2	0.1
Amortization ⁽²⁾	6.0	6.0
Stock-based compensation expense	10.4	6.6
Licensing fees and milestone payments ⁽³⁾	-	0.8
Income tax effect related to Non-GAAP adjustments ⁽⁴⁾	(4.4)	(2.5)
Non-GAAP adjusted net income	\$50.7	\$40.7
GAAP net income per diluted share	\$0.67	\$0.48
Non-GAAP adjusted net income per diluted share	\$0.88	\$0.67
Weighted average number of shares of common stock used in non-GAAP diluted per share	57,597,627	61,221,511

(1) Includes amortization of deferred finance charges.

(2) Includes amortization of intangible asset related to WAKIX.

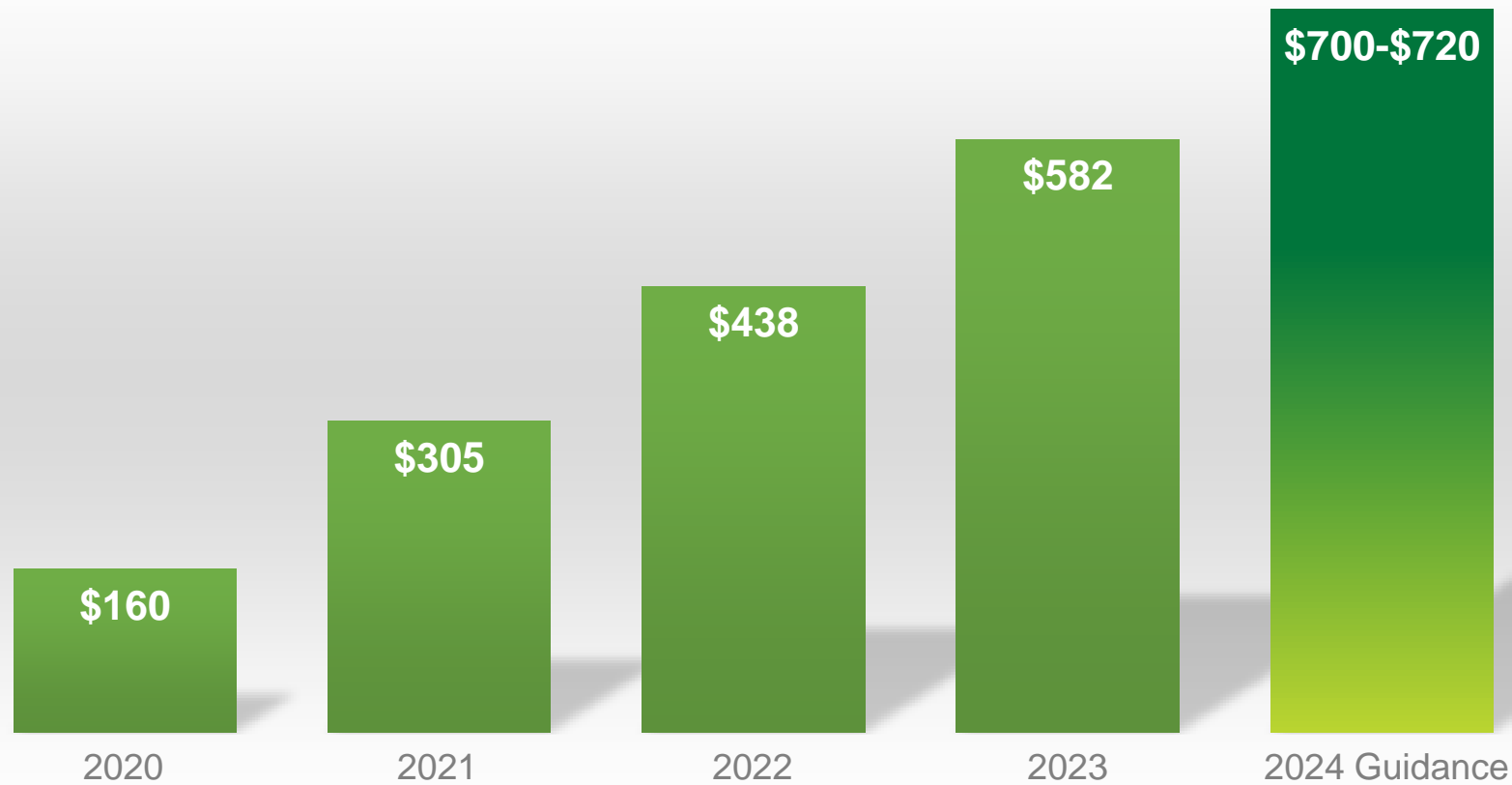
(3) Includes milestone payment related to HBS-102 preclinical milestone in March 2023.

(4) Calculated using the reported effective tax rate for the periods presented less impact of valuation allowance release and discrete items.

Reiterates 2024 Net Revenue Guidance

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

WAKIX ANNUAL NET REVENUE (\$M)



Reiterates
2024 Guidance

\$700-\$720M



*Thank
You!*

