

Q3 2024

Financial Results and Business Updates

October 29, 2024



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Innovative, Patient Focused, and Catalyst-Rich Portfolio

\$1B+

Proven commercial product and growing

13

Development programs; 4 in Phase 3 by year end



\$3B+

Establishing leadership position in CNS

5

Anticipate 1 or more new product or indication launches each year over next 5 years

Catalyst-rich pipeline poised to deliver both near-term and long-term value creation



SLEEP/ WAKE

Extending Our Leadership Position

- Compelling new data; conviction in IH - sNDA on track for Q4 2024
- Next-generation formulations of pitolisant to extend franchise beyond 2040
- Potential best-in-class orexin-2 agonist (BP1.15205)

NEURO BEHAVIORAL

Next Major Clinical Catalyst

- Pivotal Phase 3 trial in Fragile X syndrome; topline data on track for mid-2025
- Plan to initiate pivotal Phase 3 trial in 22q deletion syndrome in 2025



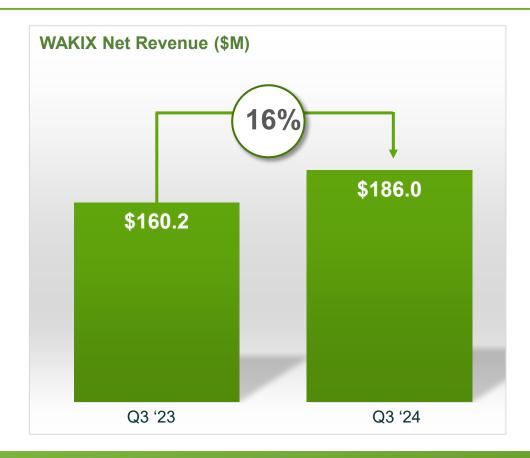
Most Advanced 5-HT2 Development Program

- EPX-100: validated MOA
- Pivotal registrational trial in Dravet syndrome; topline data in 2026
- Pivotal Phase 3 trial in Lennox-Gastaut syndrome to initiate Q4
- EPX-200: proven and confirmed MOA

Innovation driving growth of the portfolio



WAKIX® Net Revenue Performance



HIGHLIGHTS

- Durable double-digit sales growth continuing into year five on the market
- Passed \$2B in cumulative net revenue since launch
- Underlying demand drove continued revenue growth
 - Strong patient interest
 - Continue to add new prescribers and grow WAKIX prescriber base

Reiterating Full Year Guidance of \$700-\$720M

Confident in WAKIX being a potential \$1B+ opportunity in narcolepsy alone



Meaningfully Differentiated Product Profile Key Driver in Strong Durable Growth in Patients on WAKIX®



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

Q3 24 Highlights

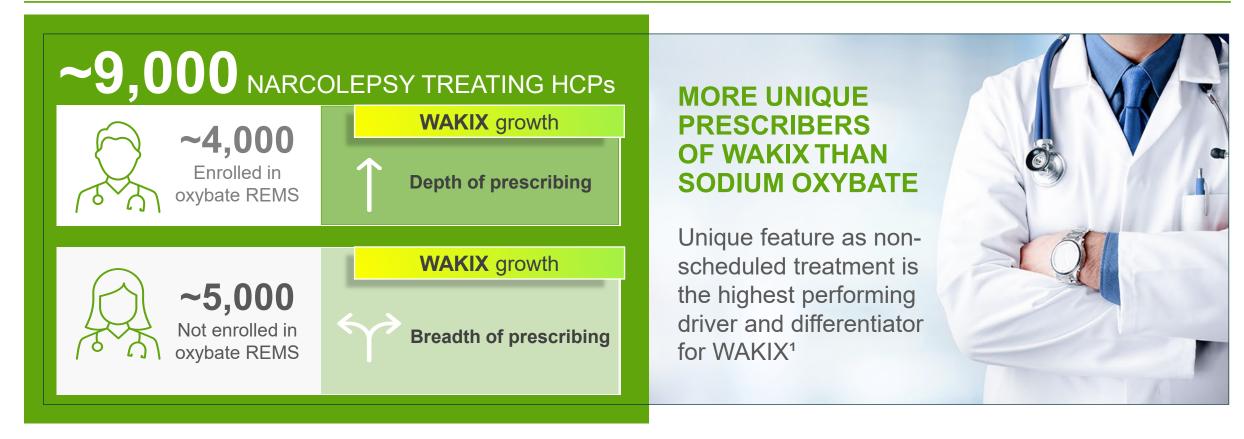


More unique prescribers of WAKIX® than sodium oxybate

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



Unique Prescriber Dynamics Support Continued WAKIX® Growth, Opportunity for Next-Gen Pitolisant Assets in Narcolepsy



Growing prescriber base for WAKIX with access to full diagnosed patient opportunity



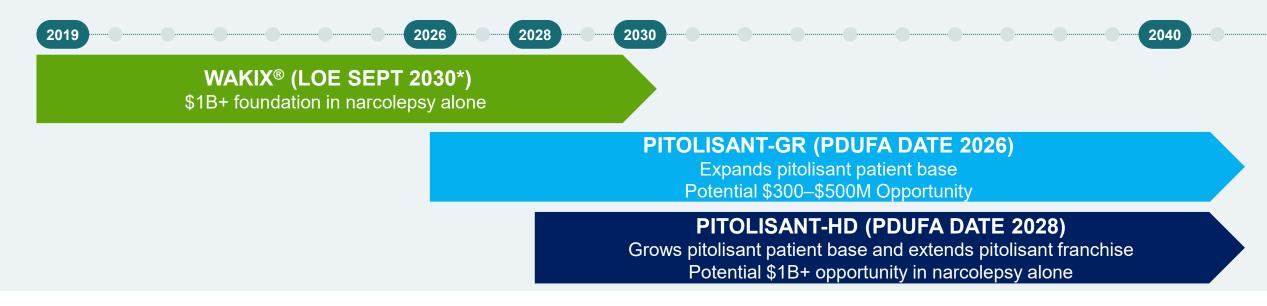
The Pitolisant Franchise: Patient-Centric Drug Development Building Our Leadership Position in Sleep/Wake

75% Residual symptoms¹			Higher dose, enhanced efficacy
Report fatigue²			Fatigue indication
Products require titration Don't achieve clinical benefit		No titration	No titration
Report GI disturbances ^{3,4} Cite nausea as a side effect ⁵		Gastro-resistant coating	Gastro-resistant coating
Cite frustration with side effects ⁶	Well tolerated; safety profile	Well tolerated; safety profile	Well tolerated; safety profile
Only 1 FDA-approved treatment indicated for EDS and cataplexy	EDS and Cataplexy	EDS and Cataplexy	EDS and Cataplexy
FDA-approved treatments are scheduled (CII – CIV)	Non-scheduled	Non-scheduled	Non-scheduled
NARCOLEPSY UNMET NEEDS	WAKIX ^{®*}	Pitolisant-GR	Pitolisant-HD

^{1.} McCullough et al. Novel treatment options in narcolepsy, Chicago Rush Memorial Center - SLEEP 2019 Abstract; 2. Droogleever et al. (2012). Severe fatigue in narcolepsy with cataplexy. Sleep, 21(2), 163-169; 3. Barateau et al., Dauvilliers, 2019; 4. Wang et al., 2023; 4. Zhan et al., 2023; 5. Postmarketing study; 6. Versta Research, Know Narcolepsy Survey ("Know Narcolepsy"), October 2018; * WAKIX attributes based on FDA-approved adult narcolepsy product labelling.



Pitolisant Franchise Poised to Drive Durable Patient and Revenue Growth to the Mid-2040s

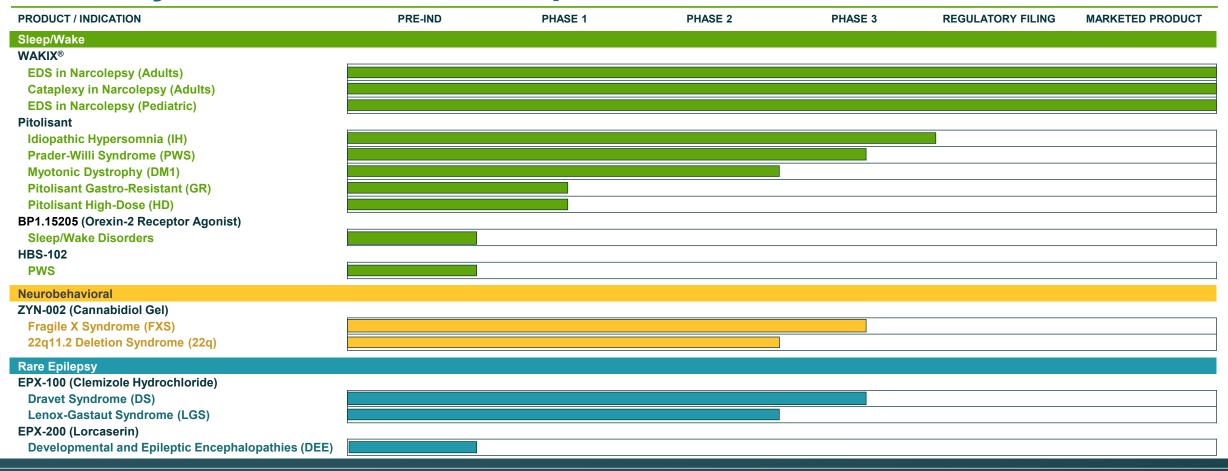


- Two meaningfully differentiated product profiles building off WAKIX with PDUFAs prior to LOE
- Provisional patents filed out to 2044 to extend durable patient and net revenue growth
 - Pursuing other indications (IH, DM1) to drive incremental patient, net revenue growth
 - Pitolisant franchise strengthens leadership position in sleep/wake
 - Poised to deliver durable patient growth and significant revenue to the mid 2040s



^{*}Based on pediatric exclusivity

Harmony Biosciences: R&D Pipeline



3 CNS FRANCHISES

8 ASSETS

13 DEVELOPMENT PROGRAMS

PHASE 3 PROGRAMS
BY YEAR END



Idiopathic Hypersomnia: Strong Benefit/Risk Proposition

IH: DISORDER WITH HIGH UNMET NEED

REAL WORLD DATA

Experience from a large clinic & Compassionate Use program

FAVORABLE BENEFIT/RISK PROFILE











COMPELLING TOTALITY OF DATA FROM INTUNE STUDY

a Phase 3 pivotal study in IH

ESTABLISHED SAFETY

Non-scheduled and simple dosing regimen

On-track for sNDA submission in 4Q 2024



OX2R Agonist BP1.15205: Potential Best-in-Class Asset

Potent on-target effects





High potency with potential efficacy in various sleep disorders and other indications

Highly desirable QD dosing



Potentially better AE profile

Potential approval in early 2030s





Potential for combination drug development:

pitolisant-HD and BP1.15205

Potential best-in-class OX2R agonist with possibility for broad clinical utility; on track for IND submission mid-2025



Epilepsy Franchise: Deliver Meaningful Treatment Options to Patients with Serious Unmet Medical Needs

ACQUISITION OF EPYGENIX

EPX-100 AND EPX-200

POTENTIAL FOR FAVORABLE

risk/benefit proposition

ON TRACK

to initiate EPX-100 Phase 3 study in Lennox-Gastaut syndrome (LGS) in Q4 2024



EPX-100 and EPX-200:

Established serotonergic (5HT2)
MoA

EPX-100: LEAD INDICATION IN DRAVET SYNDROME (DS)

Pivotal registrational study on track for topline data in 2026



Epilepsy Franchise: Most Advanced and Promising Development Programs in DEEs

EPX-100 (clemizole hydrochloride)

- Established serotonergic (5-HT2) mechanism of action
- Pre-clinical evidence for efficacy supporting broad utility in DEEs
- BID dosing and liquid formulation: Clinically relevant for patients with DEEs and their caregivers
- Two decades on market in 1960's/70's with no safety signals; Promising preliminary safety and tolerability profile from ongoing Phase 3 registrational trial in DS
- On-track for DS Topline data in 2026
- On-track to initiate Phase 3 registrational trial in LGS by end of 2024
- Granted Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) for both DS & LGS

EPX-200 (liquid formulation of lorcaserin)

- Established serotonergic (5-HT2) mechanism of action; selective 5-HT2C agonist
- Pre-clinical and clinical evidence for efficacy
- Safety and tolerability from short- and long-term studies
- Pre-IND stage of development
- Granted ODD for DS in US and EU; ODD and RPDD for LGS in US



EPX-100 (Clemizole HCI): Overview and Clinical Development Programs

EPX-100 or Clemizole HCI once marketed as a 1st generation antihistamine in the 1960s Sunsetted in 1970s with the introduction of newer antihistamines — no significant post-marketing safety signals

Modulation of serotonin signal (5HT2A/2B/2C)² established MoA for DEE













Development as an NCE, including completion of preclinical studies prior to human clinical trials¹

Supported by published work from Dr. Baraban et al. at UCSF, funded by NIH³

No additional cardiac or lab monitoring necessary

Ongoing Phase 3 study in DS; initiation of Phase 3 study in LGS in Q4 2024, IP to 2038

- Established MoA; potential for favorable risk/benefit profile in DEEs
- On track for topline data in DS and LGS in 2026
- EPX-100 granted ODD and RPDD for both DS and LGS



^{1.} Harmony data on file; 2. Griffin et al Brain, 2017; 3. Baraban et al Nature Communications, 2019.

EPX-100: Preliminary Safety and Tolerability Data Compared to Select Approved Drugs in DS and LGS

	Epidiolex ¹	Fintepla ²	EPX-100 ³	
Decreased appetite	16–22%	8%	0%	
Diarrhea	9–20%	6%	16%	
Somnolence	23–25%	11%	12%	
LFT monitoring	Required	n/a	n/a	
REMS (CVD and PAH)	n/a	+	n/a	
Echocardiography	n/a	Prior to initiation and every 6 months thereafter	n/a	

CVD: cardiac valvular disease PAH: pulmonary arterial hypertension

Does not represent Head-to-Head comparison

EPX-100: Preliminary safety/tolerability profile suggests no need for additional lab or cardiac monitoring; potential for favorable risk/benefit profile



^{1.} Epidiolex PI: AEs in patients treated with Epidiolex in clinical trials; 2. Fintepla PI: MC AEs in >5% of patients and more than placebo in placebo-controlled trials; 3. Harmony Biosciences data on file.

EPX-200 (liquid lorcaserin): Overview

EPX-200: Safety and tolerability established in short- and long-term studies

Selective 5HT-2C Agonist¹ established MoA for DEEs

Clinical data in DEEs³











Pre-IND

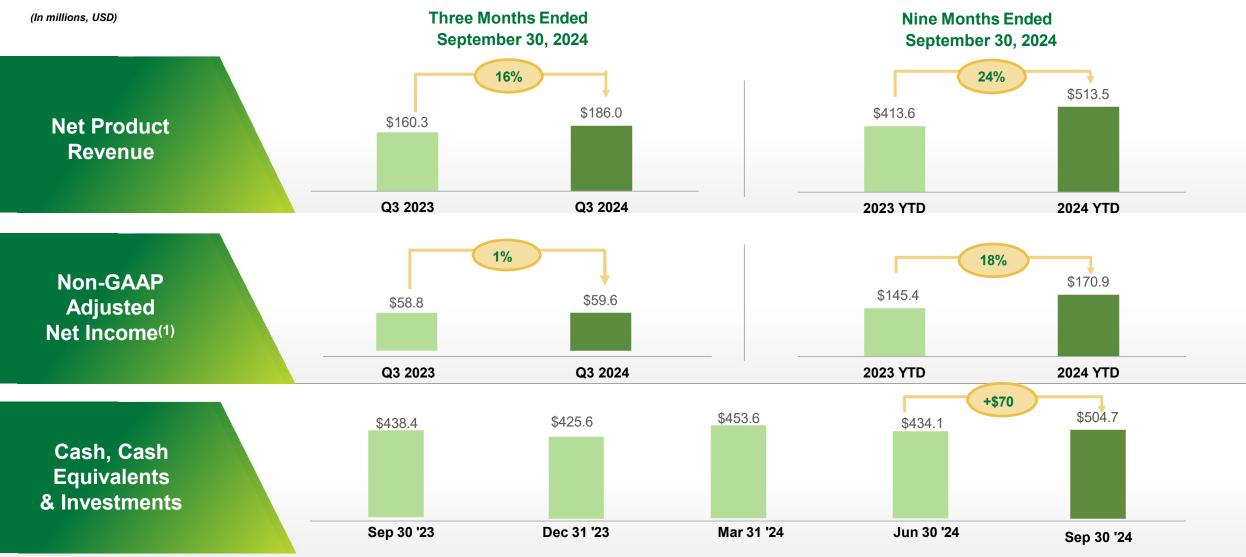
Liquid formulation and BID dosing

Supported by published work from Dr. Baraban et al. at UCSF, funded by NIH²

- Established MoA; potential for favorable risk/benefit profile in DEEs
- Pre-IND stage of development
- EPX-200 granted ODD for DS in US and EU; ODD and RPDD for LGS in US

^{1.} Griffin et al Brain Communications, 2019; 2. Baraban et al Nature Communications, 2019.; 3 Tolete, Devinsky et al, Neurology 2018

Financial Highlights





Financial Summary

(In millions, USD)	Three Months Ended September 30,		% Change	Nine Months Ended September 30,		% Change
Totals may not foot due to rounding	2024	2023		2024	2023	
Net Product Revenue	\$186.0	\$160.3	16%	\$513.5	\$413.6	24%
Cost of Product Sold	42.8	32.3	32.5%	102.4	78.1	31%
Total Operating Expenses	\$81.6	\$63.5	29%	\$276.0	\$183.7	50%
R&D Expense (1)	25.4	17.5	45%	111.2	45.8	143%
S&M Expense	27.6	23.4	18%	83.3	70.5	18%
G&A Expense	28.6	22.5	27%	81.5	67.4	21%
Net Income	\$46.1	\$38.5	20%	\$96.0	\$102.2	(6%)
Cash, cash equivalents & investments	\$504.7					

NM denotes not meaningful % change



⁽¹⁾ 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 nine months ended September 30, 2024

GAAP vs NON-GAAP Reconciliation

(In millions, USD)	Three Months Ended September 30,		Nine Months Ended September 30,	
Totals may not foot due to rounding	2024	2023	2024	2023
GAAP net income	\$46.1	\$38.5	\$96.0	\$102.2
Non-cash interest expense ⁽¹⁾	0.2	2.2	0.5	3.1
Depreciation	0.0	0.1	0.3	0.4
Amortization ⁽²⁾	6.0	6.0	17.9	17.9
Stock-based compensation expense	11.5	8.0	32.9	22.3
Licensing fee and milestone payments(3)	1.0	-	26.5	0.8
Loss on debt extinguishment®	-	9.8		9.8
Transaction related costs ⁽⁴⁾	-	-	17.1	-
Income tax effect related to Non-GAAP adjustments(5)	(5.1)	(5.7)	(20.2)	(11.0)
Non-GAAP adjusted net income	\$59.6	\$58.8	\$170.9	\$145.4
GAAP net income per diluted share	\$0.79	\$0.63	\$1.66	\$1.68
Non-GAAP adjusted net income per diluted share	\$1.03	\$0.97	\$2.96	\$2.39
Weighted average number of shares of common stock used in non-GAAP diluted per share	58,103,963	60,681,676	57,754,016	60,892,992

⁽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 2024 Bioprojet Sublicense Agreement and milestones related to HBS102 in September 2024 and March 2023.

⁽⁴⁾ Includes IPR&D charge related to the acquisition of Epygenix.

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

⁽⁶⁾ ncludes loss on extinguishment of the Blackstone Credit Agreement.

DELIVER ON PROMISE TO PATIENTS

Commitment to patients

Addressing unmet medical needs

Delivering meaningful treatment options

Helping patients thrive

DELIVER STONG VALUE TO SHAREHOLDERS

Innovative

Catalyst-rich pipeline

Profitable biotech company

Meaningful investment opportunity



