

HARMONY
BIOSCIENCES

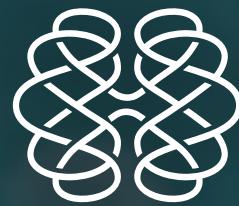
Q3 2025

Financial Results & Business Update

November 4, 2025

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding our full year 2024 net product revenue, expectations for the growth and value of WAKIX, plans to submit an sNDA for pitolisant in idiopathic hypersomnia; our future results of operations and financial position, business strategy, products, prospective products, product approvals, the plans and objectives of management for future operations and future results of anticipated products. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: our commercialization efforts and strategy for WAKIX; the rate and degree of market acceptance and clinical utility of pitolisant in additional indications, if approved, and any other product candidates we may develop or acquire, if approved; our research and development plans, including our plans to explore the therapeutic potential of pitolisant in additional indications; our ongoing and planned clinical trials; our ability to expand the scope of our license agreements with Bioprojet Société Civile de Recherche ("Bioprojet"); the availability of favorable insurance coverage and reimbursement for WAKIX; the timing of, and our ability to obtain, regulatory approvals for pitolisant for other indications as well as any other product candidates; our estimates regarding expenses, future revenue, capital requirements and additional financing needs; our ability to identify, acquire and integrate additional products or product candidates with significant commercial potential that are consistent with our commercial objectives; our commercialization, marketing and manufacturing capabilities and strategy; significant competition in our industry; our intellectual property position; loss or retirement of key members of management; failure to successfully execute our growth strategy, including any delays in our planned future growth; our failure to maintain effective internal controls; the impact of government laws and regulations; volatility and fluctuations in the price of our common stock; the significant costs and required management time as a result of operating as a public company; the fact that the price of Harmony's common stock may be volatile and fluctuate substantially; statements related to our intended share repurchases and repurchase timeframe and the significant costs and required management time as a result of operating as a public company. These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 25, 2025, and our other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.



HARMONY
BIOSCIENCES

UNIQUE COMPANY PROFILE



WAKIX® APPROACHING
BLOCKBUSTER STATUS



UP TO 5 PHASE 3 REGISTRATIONAL
TRIALS BY YEAR-END



PROFITABLE, SELF-FUNDING
BIOTECH



POISED TO ACCELERATE GROWTH
STRATEGY

WAKIX®: Q3 2025 Strong Revenue Growth



DOUBLE-DIGIT REVENUE GROWTH

in Year 6 on the Market

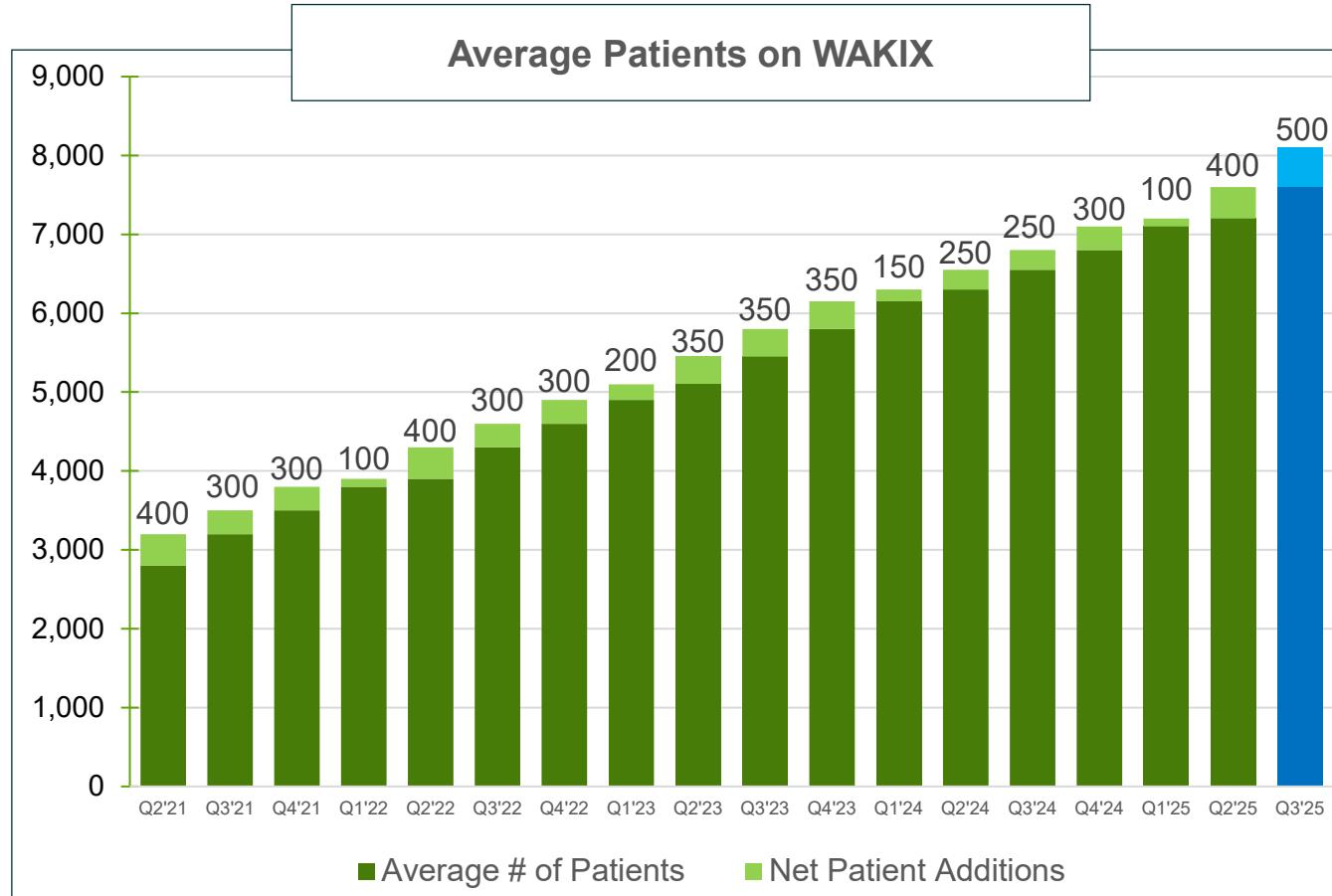
RECENTLY RAISED 2025 FULL YEAR GUIDANCE TO

\$845M - \$865M

KEY
TAKEAWAY

WAKIX® Rapidly Approaching Blockbuster Status

Differentiated Product and Strong Execution Drives Growth



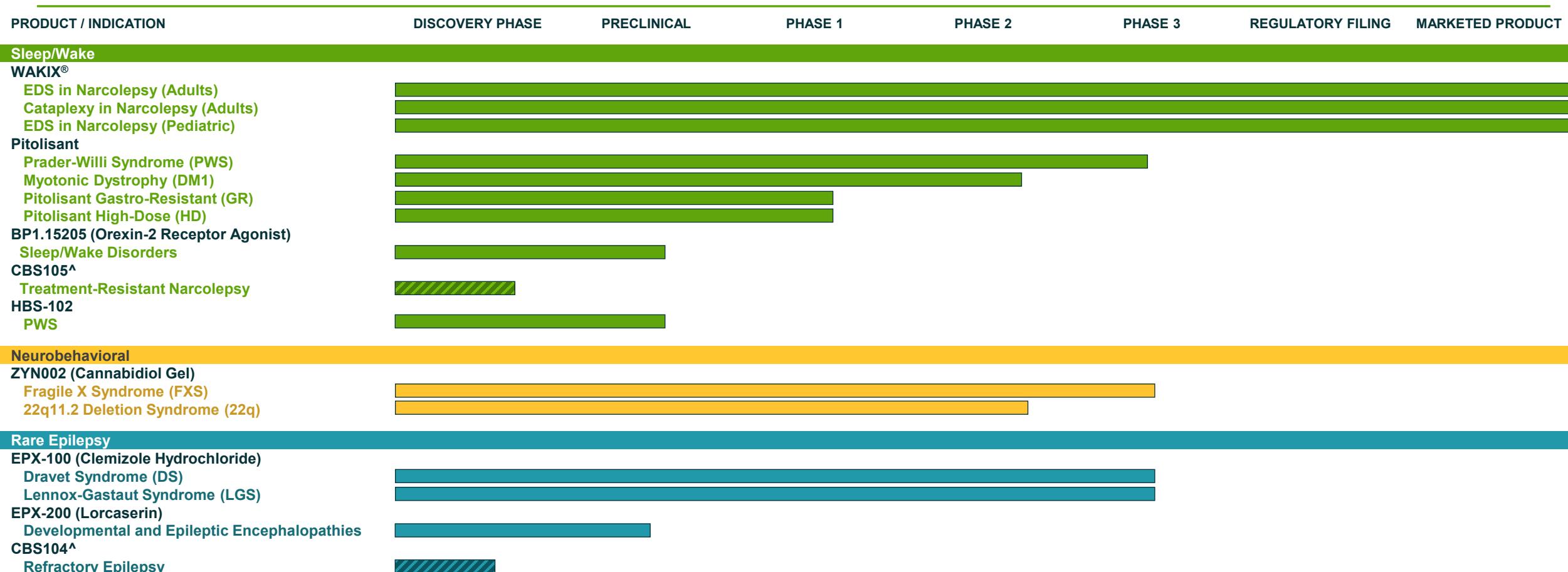
Q3 2025 HIGHLIGHTS

- ~500 average patient adds represents highest quarterly increase since launch
- 8,100 average patients on WAKIX
- Highly differentiated product – only non-scheduled treatment option
- Growing depth & breadth of prescribers
- Strong payer coverage of >80% of lives
- Sharpened sales execution, messaging and patient support activities

KEY TAKEAWAY

Highest Quarterly Increase in Average Patients Since Launch

Innovative Late-Stage Pipeline



*Includes additional ongoing clinical and regulatory programs; ^Research collaboration with CiRC Biosciences.

3 CNS
FRANCHISES

8 ASSETS

13 DEVELOPMENT
PROGRAMS*

5 PHASE 3 PROGRAMS
BY YEAR END

SLEEP/WAKE

Extending Our Leadership Position

- **Pitolisant HD:** IND submission completed; to initiate Phase 3 registrational trials in narcolepsy and IH Q4 2025; utility patents filed with potential protection until 2044
- **Pitolisant GR:** Pivotal BE study topline data readout Q4 2025; Dosing optimization study completed with positive topline data; utility patents filed with potential protection until 2044
- **BP1.15205:** potential best-in-class orexin-2 agonist; FIH study to commence Q4 2025, clinical data anticipated 2026

NEURO BEHAVIORAL

Ongoing Review of RECONNECT Phase 3 Data

- The ZYN002 phase 3 RECONNECT study in Fragile X syndrome did not meet the primary endpoint of improvement in social avoidance primarily due to a higher-than-expected placebo response rate; a review of the full data set is ongoing
- The ZYN002 development program in 22q11.2 deletion syndrome (22q) has been paused pending the full review of the RECONNECT data

EPILEPSY

One of the Most Advanced 5-HT2 Development Program

- **EPX-100:** Phase 3 registrational trials ongoing in Dravet syndrome (ARGUS study) & Lennox-Gastaut syndrome (LIGHTHOUSE study)
 - Presenting efficacy, safety and tolerability data from the ARGUS open label extension study at the American Epilepsy Society Meeting in December
 - Topline data anticipated in 2026 from the ARGUS and the LIGHTHOUSE studies

Advancement of late-stage, catalyst-rich pipeline



Pitolisant HD: Phase 3 Registrational Trials in Narcolepsy & IH – Q4 2025

Q4 2025

Initiation of Phase 3
Registrational Trials
of Pitolisant HD
• Narcolepsy
• IH

ENHANCED FORMULATION WITH OPTIMIZED PK PROFILE AND HIGHER DOSE

Designed to address the need for greater efficacy in excessive daytime sleepiness (EDS) in patients with central disorders of hypersomnolence

PROGRAMS TO PURSUE A DIFFERENTIATED LABEL

Fatigue in narcolepsy; sleep inertia in IH

IND SUBMITTED; NARCOLEPSY AND IH PHASE 3 REGISTRATIONAL TRIALS TO BE INITIATED Q4 2025

Topline data readouts anticipated 2027; PDUFA dates targeted for 2028

UTILITY PATENTS FILED TO EXTEND PITOLISANT FRANCHISE INTO 2040s

Pitolisant GR: Fast To Market Strategy Designed to Demonstrate Bioequivalence to WAKIX® Formulation



Q1 2027
Target PDUFA Date

PIVOTAL BIOEQUIVALENCE STUDY COMPLETED

Topline Data in Q4 2025

DOSING OPTIMIZATION STUDY COMPLETED

100% of the patients (46/46) able to initiate pitolisant GR at the therapeutic dose, 17.8mg, without titration; No safety or tolerability issues reported

NDA SUBMISSION EARLY 2026

TARGET PDUFA Q1 2027

ZYN002: Pharmaceutically Manufactured Synthetic Cannabinoid Gel in FXS



**Data Review ongoing:
RECONNECT
Phase 3 Trial**

ZYN002: INNOVATIVE PRODUCT PROFILE

100% synthetic, pharmaceutically manufactured cannabidiol (CBD), devoid of THC, in a patent-protected, permeation-enhanced gel formulation

RECENTLY COMPLETED PHASE 3 RECONNECT STUDY

RECONNECT phase 3 study in FXS did not meet the primary endpoint of improvement in social avoidance primarily due to a higher-than-expected placebo response rate; a review of the full data set is ongoing

- The ZYN002 development program in 22q11.2 deletion syndrome (22q) has been paused pending the full review of the RECONNECT data

MARKET OPPORTUNITY

~80,000 patients in the US with FXS; worldwide rights

VERY HIGH UNMET NEED

No approved products for FXS

EPX-100: One of Most Advanced 5-HT2 (Serotonin) Agonist Programs in DEEs

2026

Anticipate Topline Data from Ongoing Global Phase 3 Trials

- DS
- LGS



ESTABLISHED 5-HT2 (SEROTONIN) AGONIST MECHANISM OF ACTION

MoA validated via the zebrafish model

PHASE 3 STUDIES IN DS AND LGS

Recruitment ongoing for Phase 3 registrational trials in patients with Dravet syndrome (ARGUS study) and Lennox-Gastaut syndrome (LIGHTHOUSE study)

- Anticipate topline data in 2026

SAFETY: POTENTIAL TO OFFER A VERY UNIQUE RISK/BENEFIT PROPOSITION

No additional laboratory or special safety monitoring

BID DOSING REGIMEN

Convenient for patients and caregivers

Catalyst-Rich Pipeline Driving Value Beyond 2025

Q4 2025

Pitolisant HD
Initiation of Phase 3
registrational trials in
narcolepsy and IH

Pitolisant GR
Pivotal BE topline data

2026

Pitolisant PWS
Phase 3 TLD
EPX-100 DS/LGS
Phase 3 topline data (TLD)

OX2R
Phase 1 clinical PK data

2027 – 2028

Pitolisant GR PDUFA (2027)
Pitolisant-HD
Phase 3 TLD in narcolepsy and IH
(2027)

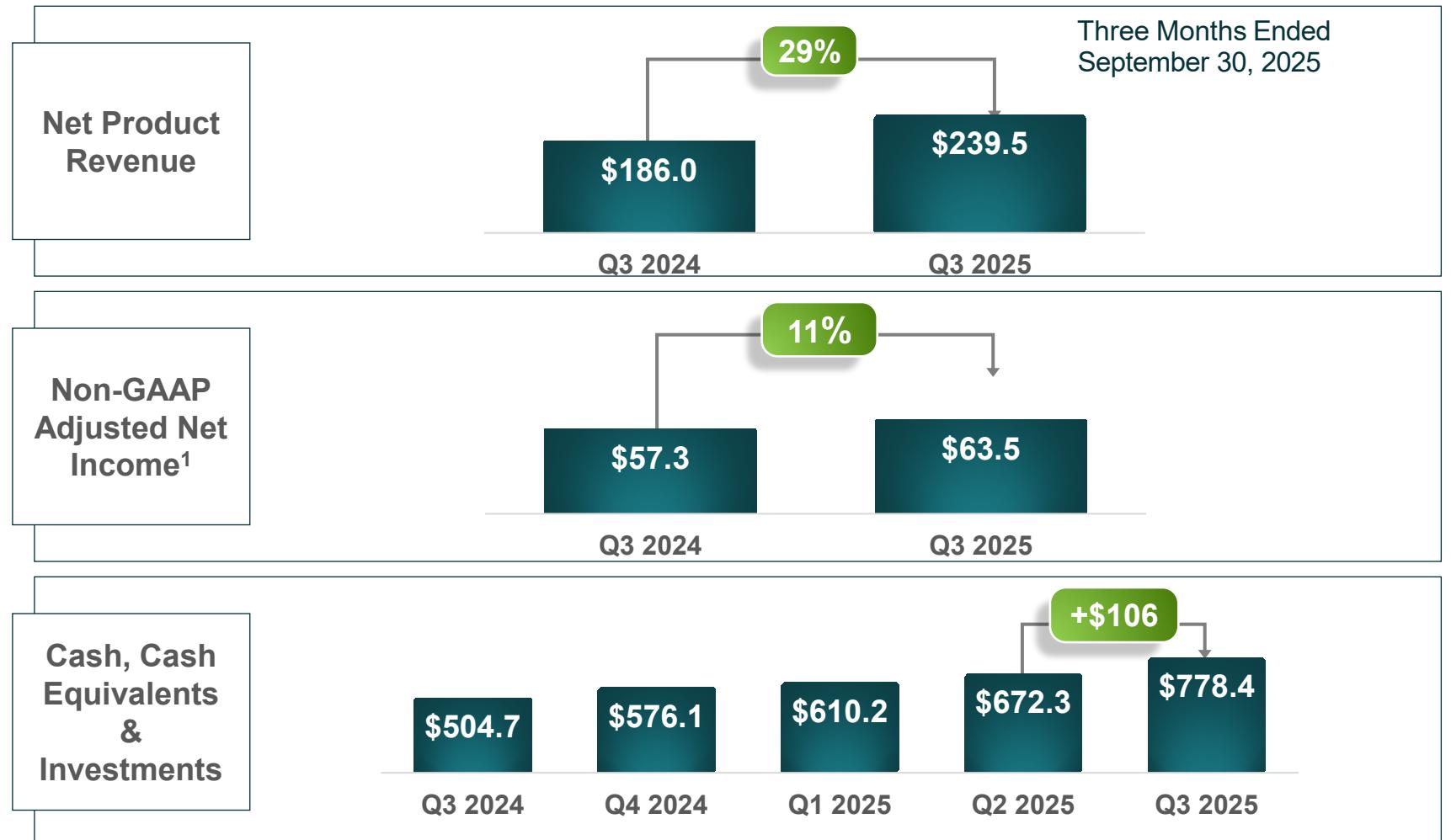
Pitolisant-HD PDUFA narcolepsy
and IH (2028)

EPX-100 DS/LGS PDUFA
Pitolisant PWS PDUFA

KEY TAKEAWAY

Pipeline Poised to Deliver Multiple New Product or Indication Launches Over the Next Several Years

Financial Highlights Q3 2025



(In millions, USD)

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

**29% REVENUE
GROWTH**

Year 6 on the market

**2025 FULL YEAR
REVENUE GUIDANCE**

\$845M-\$865M

**STRONG
PROFITABILITY**

4+ Years

**SIGNIFICANT CASH
GENERATION**

\$778M+ Cash,
Cash Equivalents
and Investments

Financial Summary Q3 2025

	Three Months Ended September 30,		% Change	Nine Months Ended September 30,		% Change
	2025	2024		2025	2024	
Totals may not foot due to rounding						
Net Product Revenue	\$239.5	\$186.0	29%	\$624.7	\$513.5	22%
Cost of Product Sold	59.7	42.8	39%	129.8	102.4	27%
Total Operating Expenses	\$114.3	\$81.6	40%	\$325.0	\$276.0	18%
R&D Expense	55.0	25.4	117%	139.7	111.2	26%
S&M Expense	29.5	27.6	7%	90.3	83.3	8%
G&A Expense	29.8	28.6	4%	95.0	81.5	17%
Net Income	\$50.9	\$46.1	10%	\$136.2	\$96.0	42%
Cash, cash equivalents & investments	\$778.4	\$504.7	54%			

(In millions, USD)

GAAP vs NON-GAAP Reconciliation Q3 2025

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Totals may not foot due to rounding				
GAAP net income¹	\$50.9	\$46.1	\$136.2	\$96.0
Non-cash interest expense ²	0.2	0.2	0.5	0.5
Depreciation	0.0	0.1	0.0	0.3
Amortization ³	6.0	6.0	17.9	17.9
Stock-based compensation expense	10.8	11.4	34.7	32.8
Income tax effect related to Non-GAAP adjustments ⁴	(4.3)	(6.4)	(11.6)	(15.0)
Non-GAAP adjusted net income¹	\$63.5	\$57.3	\$177.7	\$132.5
GAAP net income per diluted share	\$0.87	\$0.79	\$2.32	\$1.66
Non-GAAP adjusted net income per diluted share	\$1.08	\$0.99	\$3.02	\$2.29
Weighted average number of shares of common stock used in non-GAAP diluted per share	58.7	58.1	58.7	57.8

(In millions, USD)

(1) Includes a \$15.0 million IPR&D charge related to a clinical milestone achieved for ZYN002 during the three and nine months ended September 30, 2025. Includes a \$15.0 million IPR&D charge related to an upfront fee incurred upon closing the CiRC research collaboration agreement for the nine months ended September 30, 2025. Includes a \$1.0 million IPR&D charge related to a preclinical milestone achieved for HBS-102 during the three and nine months ended September 30, 2024. Includes a \$25.5 million charge related to an upfront license fee incurred upon closing the 2024 Bioprojet Sublicense Agreement and a \$17.1 million IPR&D charge related to the acquisition of Epygenix for the nine months ended September 30, 2024. (2) Includes amortization of deferred finance charges. (3) Includes amortization of intangible asset related to WAKIX. (4) Calculated using the reported effective tax rate for the periods presented less impact of discrete items.

DELIVER ON PROMISE TO PATIENTS

Commitment to patients

Addressing unmet medical needs

Delivering meaningful treatment options

Helping patients thrive

DELIVER STRONG VALUE TO SHAREHOLDERS

Executional excellence

Innovative, catalyst-rich pipeline

Profitable, self-funding biotech

Meaningful investment opportunity



NEW WORLDLOGY