



**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.





**UNIQUE COMPANY PROFILE**



**WAKIX® APPROACHING  
BLOCKBUSTER STATUS**



**UP TO 5 PHASE 3 REGISTRATIONAL  
TRIALS BY YEAR-END**

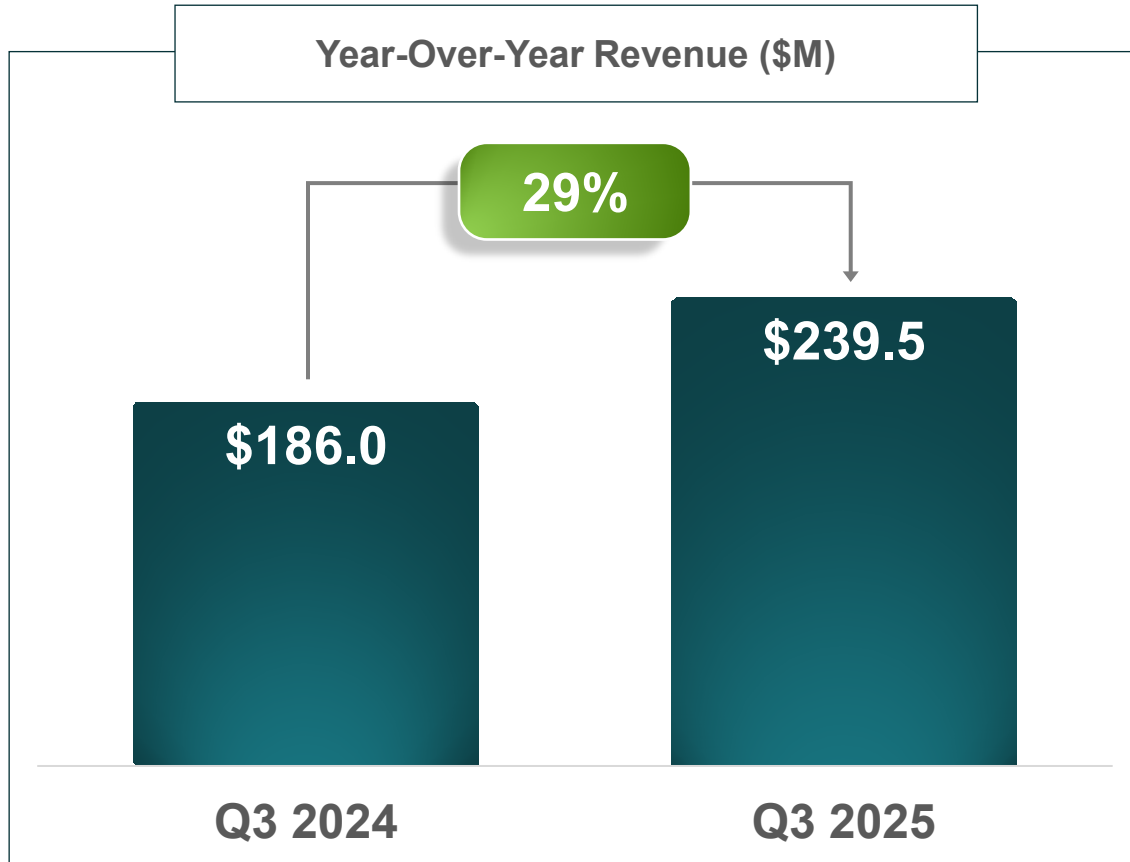


**PROFITABLE, SELF-FUNDING  
BIOTECH**



**POISED TO ACCELERATE GROWTH  
STRATEGY**

# WAKIX®: Q3 2025 Strong Revenue Growth



## DOUBLE-DIGIT REVENUE GROWTH

in Year 6 on the Market

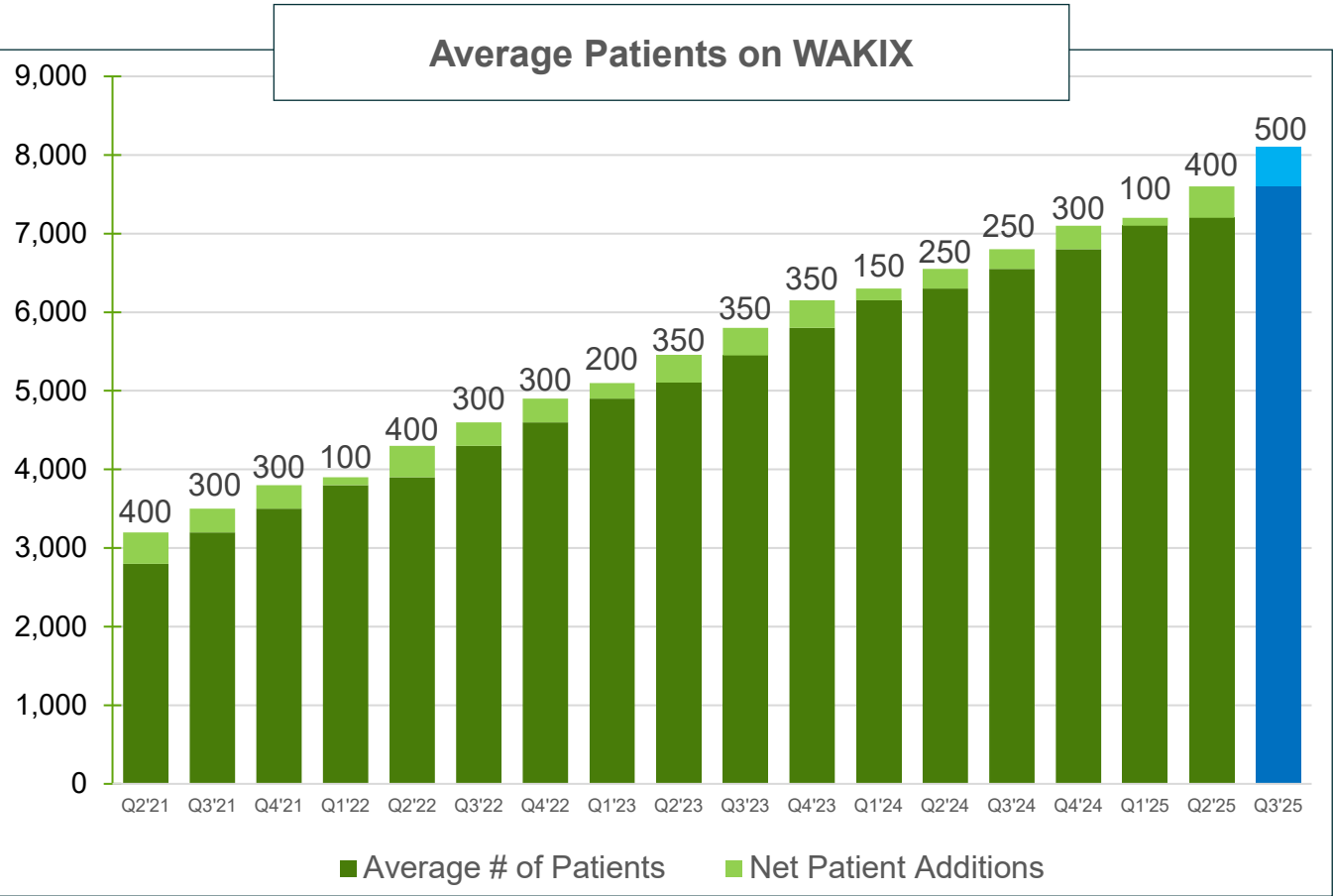
RECENTLY RAISED 2025 FULL YEAR GUIDANCE TO

**\$845M - \$865M**

KEY  
TAKEAWAY

**WAKIX® Rapidly Approaching Blockbuster Status**

# Differentiated Product and Strong Execution Drives Growth



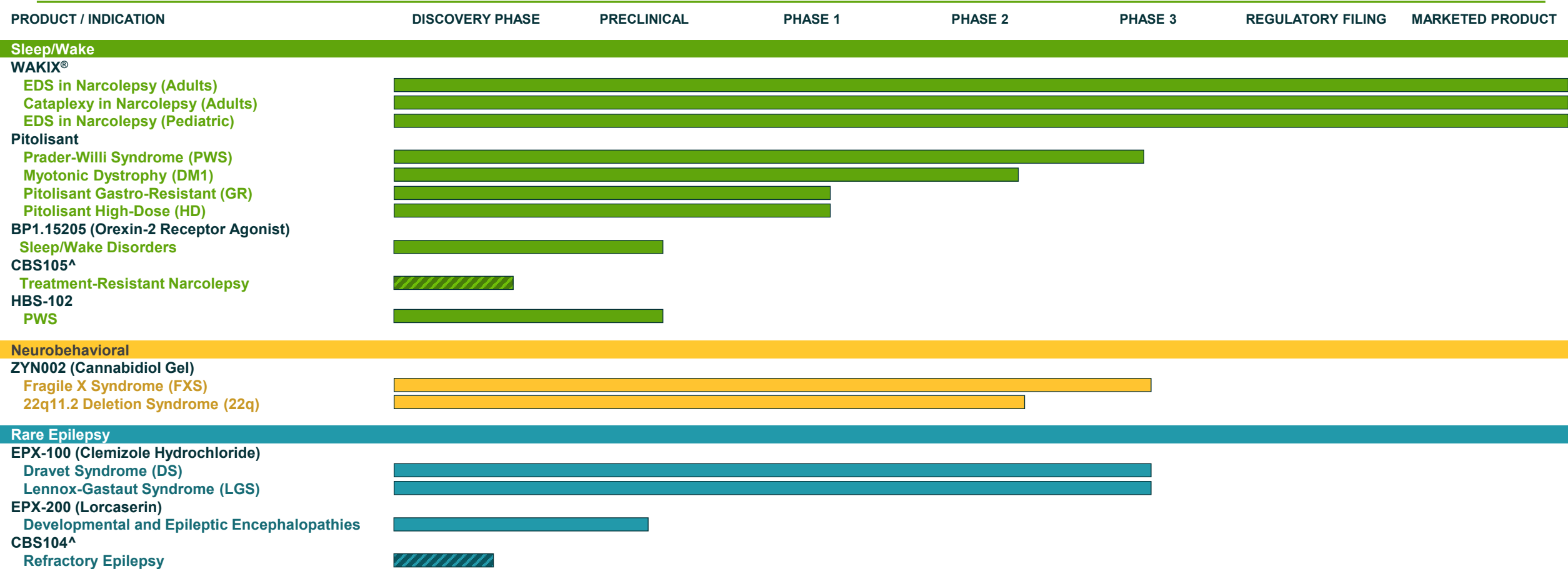
## Q3 2025 HIGHLIGHTS

- ~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-HT<sub>2</sub> 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**

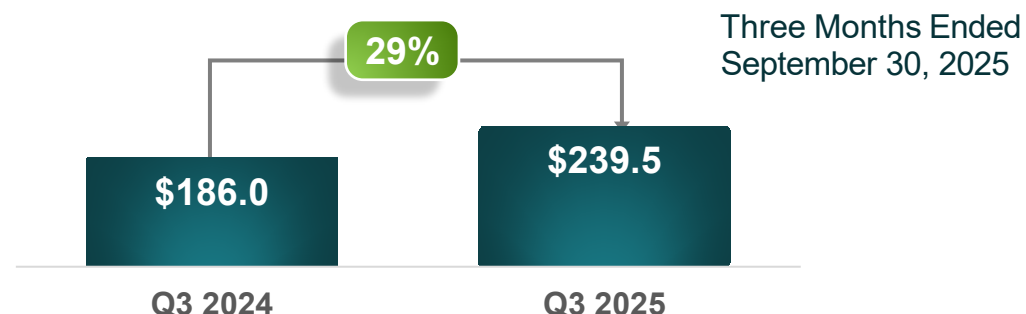
**Pitolisant PWS PDUFA**

## KEY TAKEAWAY

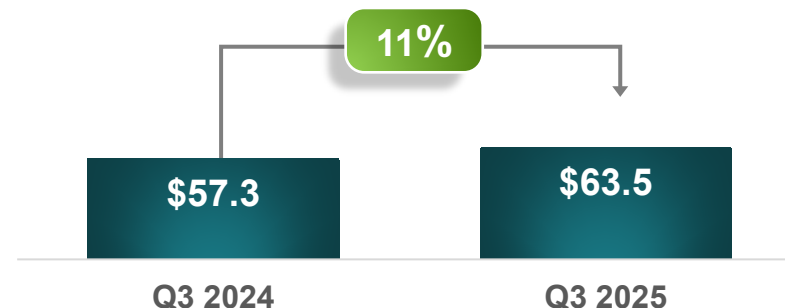
**Pipeline Poised to Deliver Multiple New Product or Indication Launches Over the Next Several Years**

# Financial Highlights Q3 2025

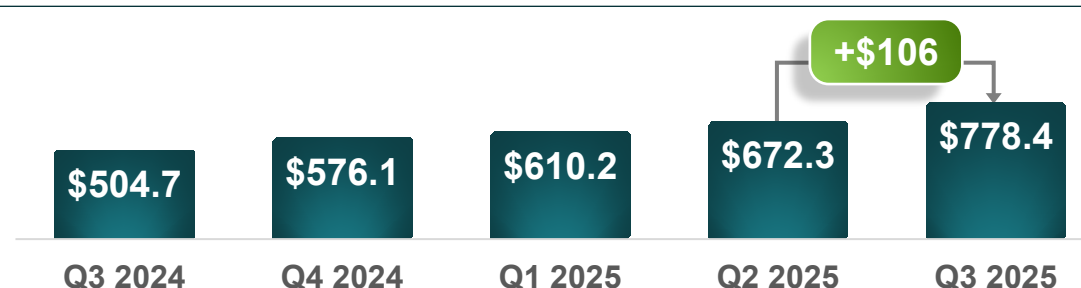
## Net Product Revenue



## Non-GAAP Adjusted Net Income<sup>1</sup>



## Cash, Cash Equivalents & Investments



(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.

## UNIQUE COMPANY PROFILE

**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

Totals may not foot due to rounding	Three Months Ended September 30,		% Change	Nine Months Ended September 30,		% Change
	2025	2024		2025	2024	
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				
<b>GAAP net income<sup>1</sup></b>	<b>\$50.9</b>	<b>\$46.1</b>	<b>\$136.2</b>	<b>\$96.0</b>
Non-cash interest expense <sup>2</sup>	0.2	0.2	0.5	0.5
Depreciation	0.0	0.1	0.0	0.3
Amortization <sup>3</sup>	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 <sup>4</sup>	(4.3)	(6.4)	(11.6)	(15.0)
<b>Non-GAAP adjusted net income<sup>1</sup></b>	<b>\$63.5</b>	<b>\$57.3</b>	<b>\$177.7</b>	<b>\$132.5</b>
<b>GAAP net income per diluted share</b>	<b>\$0.87</b>	<b>\$0.79</b>	<b>\$2.32</b>	<b>\$1.66</b>
<b>Non-GAAP adjusted net income per diluted share</b>	<b>\$1.08</b>	<b>\$0.99</b>	<b>\$3.02</b>	<b>\$2.29</b>
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



N E W R O L O G Y