HARMONY BIOSCIENCES

Q3 2026

Financial Results and Business Update

November 4, 2026

NASDAQ LISTED HRMY

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Forward-Looking Statements

This presentation 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 2026 net product revenue, expectations for the growth and value of WAKIX, the potential profile of our product candidates, our planned and ongoing clinical trials and expected timing of data readouts, anticipated regulatory milestones and product launches, our future results of operations and financial position, our intellectual property, pending litigation and regulatory exclusivity, our planned leadership transition, market opportunity, business strategy, business development, products, prospective products, product approvals, and the plans and objectives of management for future operations. 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, including EPX-100, Pitolisant GR and BP-205; 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 macroeconomic effects and changes in market conditions, including the impact of tariffs, inflation and the risk of recession. 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 24, 2026 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.

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EXECUTING AGAINST FOUR VALUE CREATION PRIORITIES

GROWING

GROW THE WAKIX® FRANCHISE

Continued WAKIX growth in an evolving market

On track to achieve more than $1B full year net revenue

ADVANCING

ADVANCE BP-205 AND THE NEXT WAVE OF INNOVATION

5 Phase 3 registrational trials in 5 distinct rare CNS indications

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Led by BP-205, a potentially best-in-class OX2R agonist

TRANSACTING

EMPHASIS ON BUSINESS DEVELOPMENT

Strong balance sheet and clear conviction to execute on strategic business development opportunities

PROTECTING

PROTECT THE PITOLISANT FRANCHISE

Multi-layered IP strategy across active legal proceedings reinforces confidence in WAKIX exclusivity to March 2030

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TWO KEY HIGHLIGHTS FOR THIS QUARTER

GROWING

STRONG COMMERCIAL QUARTER

$269M

- Third quarter net product revenue for WAKIX
- 40% CAGR over past 5 years
- 400 Net Patient Adds, 9,350 Average Patients

ADVANCING

POTENTIAL BEST-IN-CLASS OX2R

BP-205

- Favorable multiple-ascending dose (MAD) data: 14 days of once-daily dosing reinforce the safety, tolerability and PK profile observed in the SAD study
- Most potent of OX2R agonists currently in the clinic
- Phase 1b sleep-deprived healthy volunteer data expected Q1 2027; Phase 2 studies in multiple CNS indications expected to initiate by mid-2027

Value Inflection: On Track For More Than $1B WAKIX Net Revenue & Multiple BP-205 Data Catalysts Ahead

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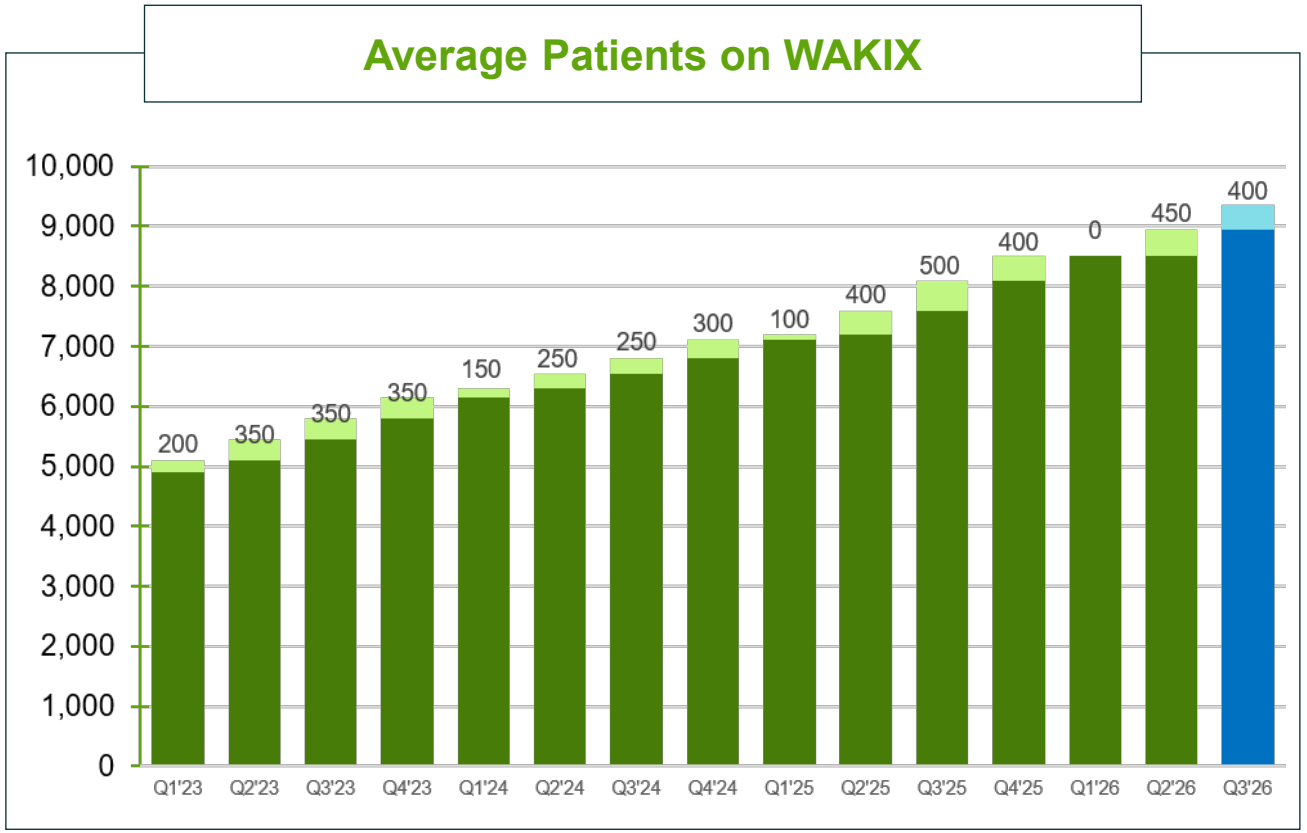
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WAKIX® Differentiation and Strong Execution Drive Performance



DIFFERENTIATED PRODUCT

EXPANDED TEAM

BROAD PAYER ACCESS

- **$269M net revenue in Q3 '26**
- **400 net patient adds, 9,350 average patients**
- **400+ net patient adds in 5 of the last 6 quarters**

KEY TAKEAWAY

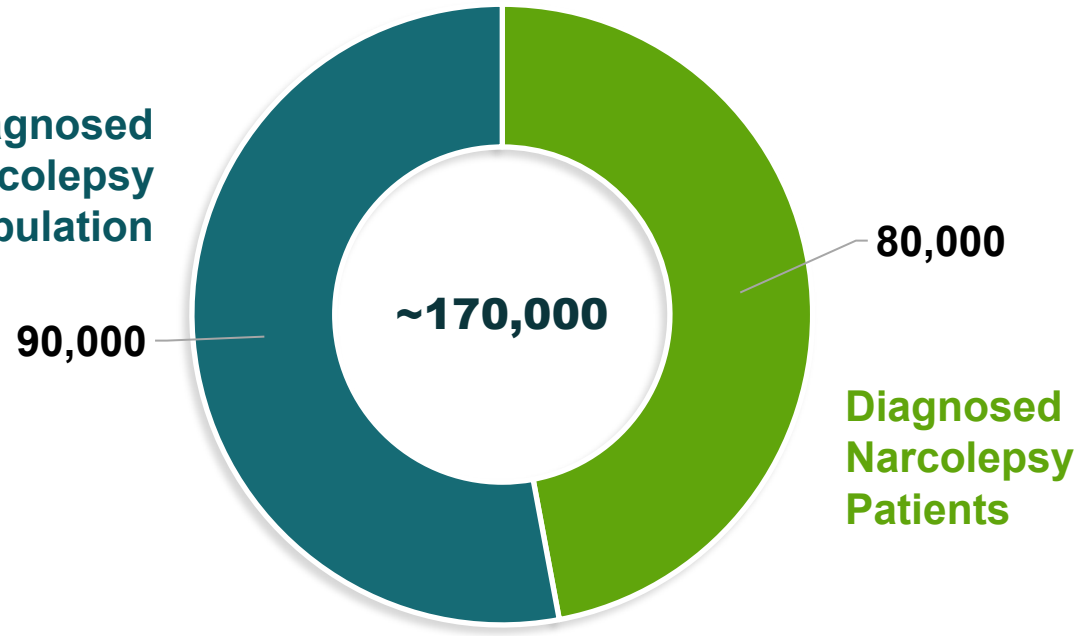
Continued Demand-Driven Growth in Q3 '26

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Growth Opportunity Across the Narcolepsy Market

People Living With Narcolepsy in the U.S.[1]



LARGE MARKET OPPORTUNITY

- **~170K total narcolepsy patients**
- **<50% diagnosed patients**
- **~20% brand penetration in polypharmacy market**

1. https://narcolepsynetwork.org/ accessed Feb 2024

KEY TAKEAWAY

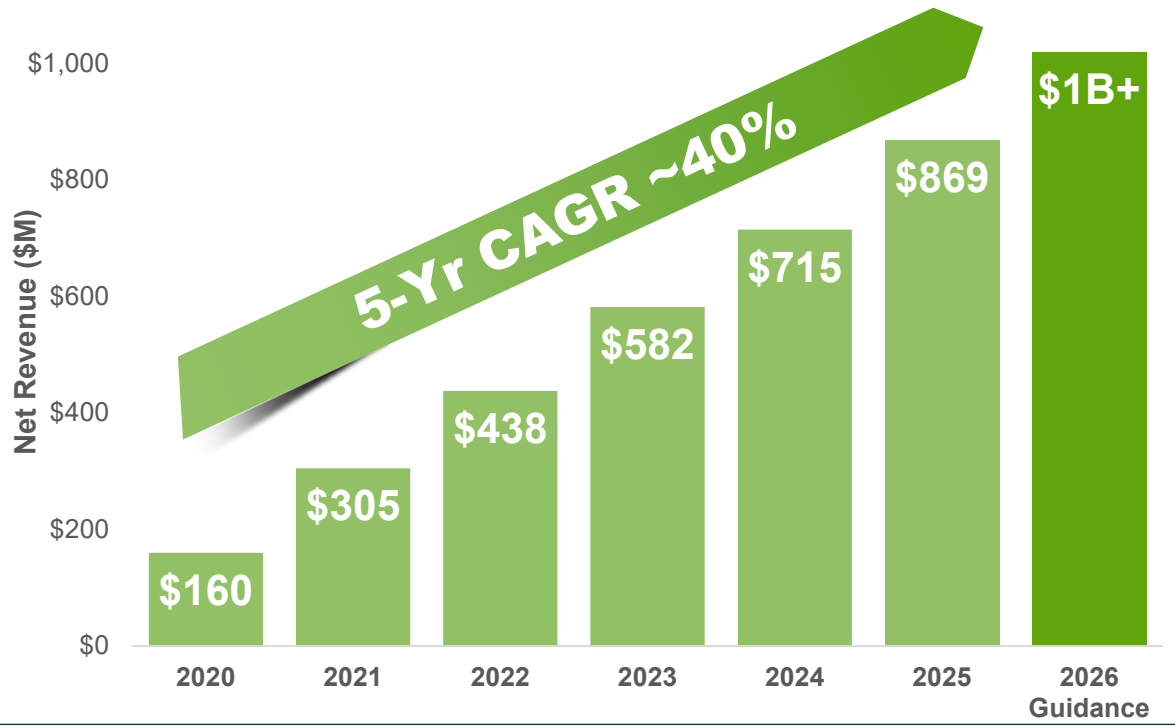
Significant Growth Opportunity Remains for WAKIX and Next-Gen Pitolisant Formulations

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Reiterating 2026 WAKIX Net Revenue Guidance

WAKIX Net Revenue Growth 2020–2025



$1.00B-$1.04B

2026 NET REVENUE GUIDANCE



Wakix pitolisant tablets

On Track to Achieve $1B+ in Net Sales

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Advancing BP-205 and a Catalyst-Rich Pipeline for Long-Term Growth

PRODUCT	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	REGULATORY FILING
BP-205 (Orexin-2 Receptor Agonist)	Multiple CNS Indications					
Pitolisant	Pitolisant Gastro-Resistant (GR) in Narcolepsy					
	Prader-Willi Syndrome (PWS)					
	Pitolisant High-Dose (HD) in Narcolepsy					
	Pitolisant High-Dose (HD) in Idiopathic Hypersomnia					
	Pitolisant Amorphous Form					
CBS105^	Treatment-Resistant Narcolepsy					
EPX-100 (Clemizole Hydrochloride)	Dravet Syndrome (DS)					
	Lennox-Gastaut Syndrome (LGS)					
CBS104^	Refractory Epilepsy					

^Research collaboration with CiRC Biosciences.

Innovative Clinical-Stage Pipeline With Multiple Catalysts 2026–2028

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BP-205: Multiple-Ascending Dose (MAD) Phase 1 Study in Healthy Volunteers



RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, HEALTHY PARTICIPANTS

14 days of repeated once-daily dosing

DOSES EVALUATED

BP-205 0.1 mg, 0.6 mg, 1 mg and 3 mg once daily in 94 healthy volunteers

BUILDS ON THE SINGLE-ASCENDING DOSE (SAD) STUDY

SAD study evaluated single doses of 0.2 mg to 6.0 mg in 72 healthy volunteers

PRELIMINARY RESULTS

Complete MAD study results to be presented at an upcoming medical meeting

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BP-205: Multiple-Ascending Dose (MAD) Phase 1 Study Data Highlights



PRELIMINARY DATA AFTER 14 DAYS OF DAILY DOSING (0.1 TO 3 MG):

- **Rapid absorption with a mean T_{max} of ~60 minutes (range 30 to 90 minutes)**
  - Supports potential for rapid onset of efficacy
- **Mean effective $T_{1/2}$ of ~29 hours after 14 days of dosing**
  - No clinically meaningful change vs. SAD; supports once-daily dosing
- **Dose-related exposure and target engagement AEs**
  - Potential to deliver efficacy at low clinical doses
- **Generally well tolerated across all doses evaluated**
  - No serious or severe TEAEs
  - No liver or visual AEs; no clinically significant cardiovascular events or EKG abnormalities
  - Most common AE was headache (~25% of participants)
- **On-target AEs were mild and did not lead to discontinuation**
  - Insomnia in <20% of participants, observed at all doses
  - Urinary frequency/urgency in <20% of participants, at 1 and 3 mg only

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BP-205 Development Plan

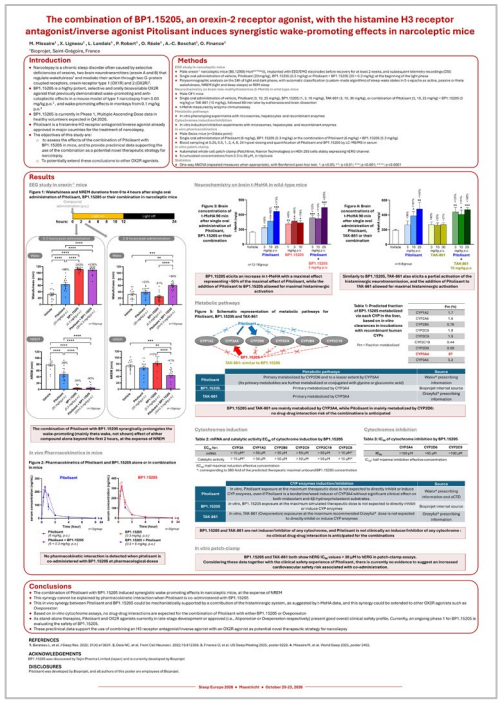


- ✓ **Q3 2026: ENCOURAGING SINGLE-ASCENDING DOSE (SAD) DATA**
- ✓ **Q4 2026: FAVORABLE PRELIMINARY PHASE 1 MAD RESULTS**
- **Q1 2027: PHASE 1B DATA IN SLEEP-DEPRIVED HEALTHY VOLUNTEERS**
- **MID-2027: TO INITIATE PHASE 2 STUDIES IN MULTIPLE CNS INDICATIONS**

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Combination of BP-205 and Pitolisant: Synergistic Wake-Promoting Effects

Poster Presented by Bioprojet at SLEEP EU 2026



The combination of BP1.15205, an orexin-2 receptor agonist, with the histamine H3 receptor antagonist/inverse agonist Pitolisant induces synergistic wake-promoting effects in narcoleptic mice

Introduction

Methods

Results

Conclusions

REFERENCES

ACKNOWLEDGEMENTS

DISCLOSURES

Source: Missaire M, et al. Sleep Europe 2026, Maastricht, October 20-23, 2026. Preclinical data.

PRECLINICAL DATA

- ***In-vivo*** **data in the narcoleptic mice model showed synergistic wake-promoting effects with BP-205 (OX2R agonist) and pitolisant (histaminergic) MoA**
- **Pitolisant on top of BP-205 drove maximal histamine release (+205%) vs BP-205 (+94%) or pitolisant (+173%) alone**
- **Combining an OX2R agonist with histaminergic MoA (e.g., pitolisant) could be a new therapeutic approach for patients with narcolepsy and other central disorders of hypersomnolence**

KEY TAKEAWAY

Potential New Therapeutic Approach in Central Disorders of Hypersomnolence

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Next-Generation Pitolisant Programs



PITOLISANT GR – NDA UNDER FDA REVIEW; ON TRACK TO LAUNCH IN 1H 2027

PDUFA date April 1, 2027

PITOLISANT HD – ONGOING PHASE 3 REGISTRATIONAL STUDIES IN NARCOLEPSY AND IH

TLD expected in 2027; Anticipated PDUFA in 2028

UTILITY PATENTS FILED FOR BOTH GR AND HD

Potential to extend the pitolisant franchise into the 2040s

PITOLISANT PHASE 3 STUDY IN PWS (TEMPO): ON TRACK FOR PEDIATRIC EXCLUSIVITY

TLD expected in mid-2027; Anticipated PDUFA in 2028

AMORPHOUS FORM OF PITOLISANT

- Licensed Novitium patent provides protection to 2042
- Formulation optimization and new modes of delivery ongoing

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



ESTABLISHED 5-HT2 (SEROTONIN) AGONIST MECHANISM OF ACTION

ONGOING PHASE 3 TRIALS IN LENNOX-GASTAUT SYNDROME & DRAVET SYNDROME

TLD expected mid-2027; Anticipated PDUFA dates in 2028

18-MONTH ARGUS OPEN-LABEL EXTENSION DATA

Updated data to be presented at AES Annual Meeting in December 2026

SAFETY: POTENTIAL TO OFFER A UNIQUE RISK/BENEFIT PROPOSITION

No additional laboratory or special safety monitoring

BID DOSING REGIMEN

Convenient for patients and caregivers

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Emphasis on Business Development



TWO CATEGORIES OF OPPORTUNITY

- Assets that can add near-term revenue in 2028 to 2032 to support our self-funded model
- Innovative pipeline assets that drive long-term value creation (e.g., BP-205)

LEVERAGE CORE COMPETENCIES

THERAPEUTIC AREAS OF INTEREST

- Sleep Disorders
- Epilepsy
- Rare/Orphan CNS
- Broader CNS indications

AGNOSTIC TO DEAL TYPE

- M&A, licensing, etc.

STRONG BALANCE SHEET WITH ~ $1.05B IN CASH

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Protect the Pitolisant Franchise



STRONG IP PROTECTS WAKIX TO MARCH 2030, INCLUSIVE OF PEDIATRIC EXCLUSIVITY

- Asserting pitolisant IP in active legal proceedings, each covering a different aspect

SETTLEMENTS WITH 6 OF 7 ANDA FILERS

ANDA CASE: DEFENDING POLYMORPH ‘197 AND METHOD OF USE ‘947 PATENTS

- ANDA litigation closing arguments held on October 22, 2026; ruling expected around the end of the 30-month stay (February 2027)

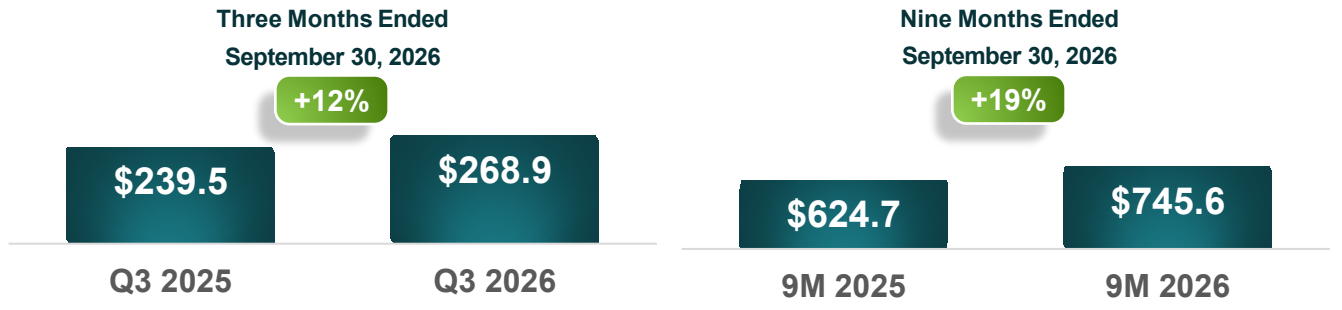
AMORPHOUS ‘920 PATENT INFRINGEMENT

- Harmony and Novitium filed patent infringement lawsuit in April against AET Pharma US and its marketing partner Sandoz; licensed Novitium patent provides protection to 2042
- Trial for '920 patent case not scheduled yet; likely to be scheduled for some time in 2029
- Preliminary injunction hearing scheduled for January 26, 2027; ruling expected by February 14, ahead of the 30-month stay

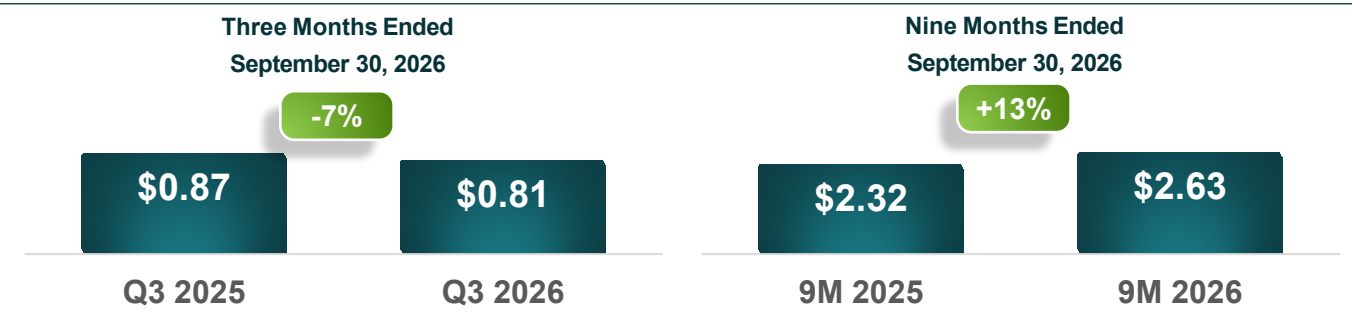
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Financial Summary Q3 2026

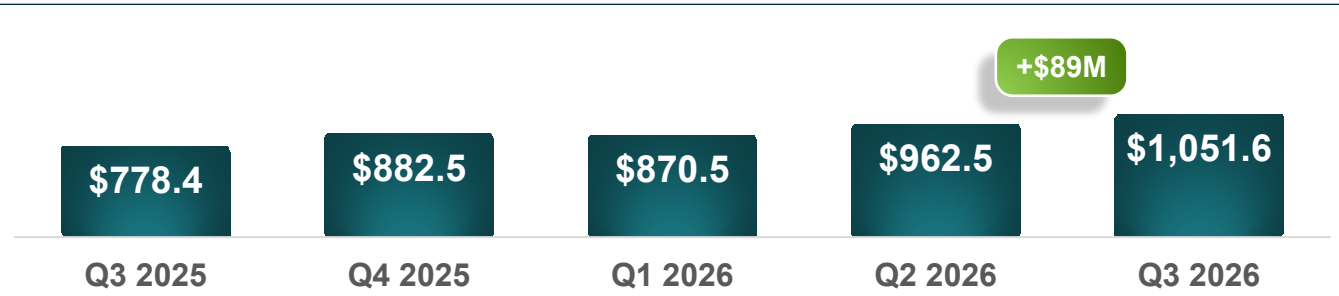
Net Product Revenue



Diluted Earnings per Share



Cash, Cash Equivalents & Investments



(In millions, USD)

- Continued sales growth in Q3 supported by strong underlying demand for WAKIX.
- Reiterating full year WAKIX net revenue guidance of $1.0B - $1.04B for 2026.
- Cash generation of $89M in Q3, sustaining our strong balance sheet.
- We intend to deploy cash to drive our BP-205 development plans, as well as to transact on potential business development opportunities.

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Financial Summary Q3 2026

Totals may not foot due to rounding	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	% Change	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	% Change
Net Product Revenue	**$268.9**	**$239.5**	**12%**	**$745.6**	**$624.7**	**19%**
Cost of Product Sold	80.7	59.7	35%	188.4	129.8	45%
Total Operating Expenses	**$134.0**	**$114.3**	**17%**	**$376.4**	**$325.0**	**16%**
R&D Expense	71.7	55.0	30%	187.7	139.7	34%
Sales & Marketing Expense	34.7	29.5	18%	100.5	90.3	11%
G&A Expense	27.7	29.8	-7%	88.2	95.0	-7%
Net Income	**$48.2**	**$50.9**	**-5%**	**$156.1**	**$136.2**	**15%**
Cash, cash equivalents & investments	**$1,051.6**	**$778.4**	**35%**			

(In millions, USD)

- Cost of Product Sold increase due to new royalties related to Novitium License Agreement signed in Q1 2026.
- R&D Expense:
  - Q3 increase primarily due to $25.0M charge for MSN license milestone.
  - Partially offset by $15.0M charge for ZYN002 milestone in prior year quarter.
- Sales & Marketing Expenses increase primarily due to expansion of our field-based team.
- G&A Expense decrease primarily due to lower stock-based compensation.

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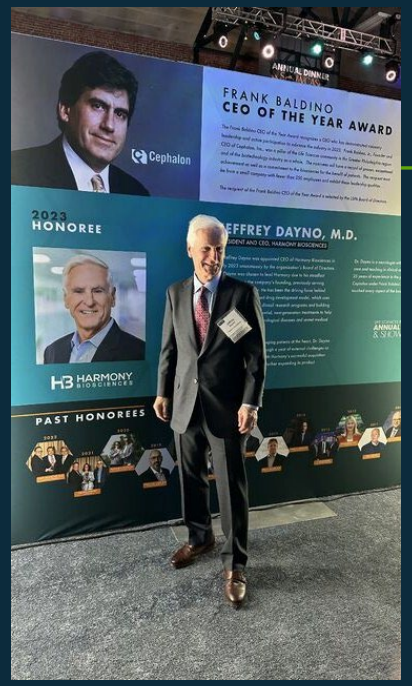
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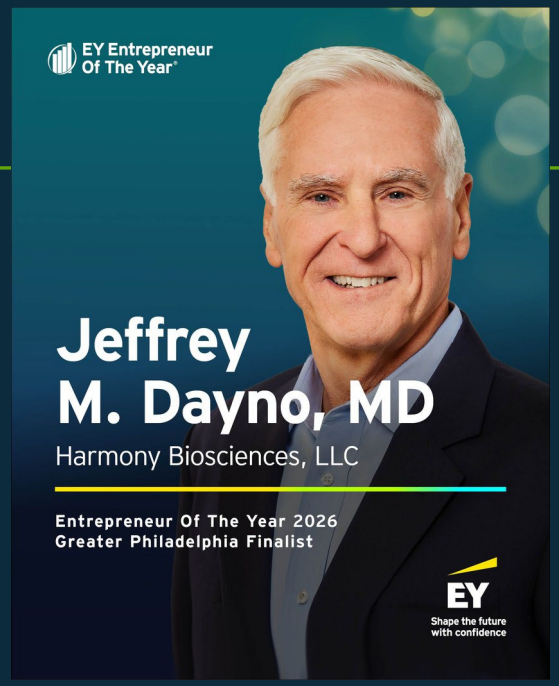
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FRANK BALDINO
CEO OF THE YEAR AWARD
Cephalon
2023
HONOREE
PAST HONOREES
HARMONY BIOSCIENCES


EY Entrepreneur Of The Year
Jeffrey M. Dayno, MD
Harmony Biosciences, LLC
Entrepreneur Of The Year 2026
Greater Philadelphia Finalist
EY
Shape the future with confidence

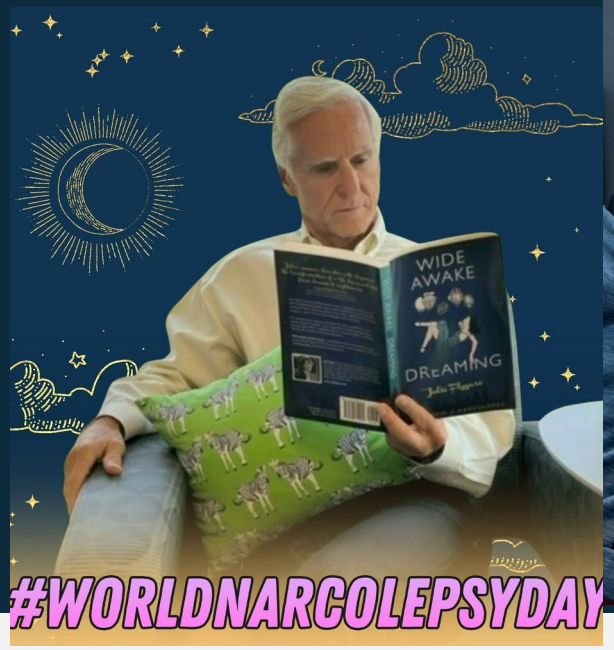







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