Harmony Biosciences Reports Q3 Financial Results on Track to Achieve More Than $1 Billion WAKIX Net Revenue and Announces Strong Multiple-Ascending Dose Data for Its Orexin Agonist BP-205, Supporting Potential Best-in-Class Profile

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WAKIX® Net Revenue in Q3 of $269 Million; Driven by Strong Demand with 400 Net Patient Adds in the Quarter; Reiterates Full Year Guidance of $1.0B to $1.04B

Repeated Once-Daily Dosing with BP-205 in Multiple-Ascending Dose Study Reinforces Favorable Safety, Tolerability and Pharmacokinetic Profile Observed in Single-Ascending Dose Study

Results from Phase 1b Study in Sleep-Deprived Healthy Volunteers for BP-205 Remain on Track for Q1 2027; Phase 2 Studies in Multiple CNS Indications Expected to Initiate by Mid-2027

Pitolisant GR NDA Under FDA Review, PDUFA Date April 1, 2027; Pitolisant HD Phase 3 Topline Data in 2027, Target PDUFA Date in 2028

Multi-Layered IP Strategy Across Active Legal Proceedings Reinforces Confidence in WAKIX Exclusivity to March 2030

Peter Anastasiou to Succeed Jeffrey Dayno, MD, as President and Chief Executive Officer Effective January 1, 2027

Conference Call and Webcast Today at 8:30 a.m. ET

PLYMOUTH MEETING, Pa., Nov. 04, 2026 (GLOBE NEWSWIRE) -- Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY), today reported third quarter 2026 financial results and preliminary data from its multiple-ascending dose (MAD) clinical study for its potential best-in-class orexin agonist BP-205. WAKIX® (pitolisant) delivered third quarter net revenue of $269 million, driven by strong demand of 400 net patient adds, and the Company remains on track to achieve full-year WAKIX net revenue guidance of $1.0 billion to $1.04 billion.

The encouraging preliminary results from the MAD study with BP-205, following 14 days of repeated once-daily dosing, reinforce the favorable safety, tolerability and pharmacokinetic profile observed in the single-ascending dose (SAD) portion of the study. No liver or visual adverse events were reported, and no clinically significant cardiovascular events or EKG abnormalities were recorded. Harmony remains on track to report Phase 1b data in sleep-deprived healthy volunteers in the first quarter of 2027, followed by the initiation of Phase 2 studies across multiple CNS indications by mid-2027.

Additionally, as announced on October 12, 2026, Peter Anastasiou, Senior Executive Vice President and Chief Operating Officer, will become President and Chief Executive Officer effective January 1, 2027, succeeding Jeffrey Dayno, MD, who will retire on December 31, 2026. This planned leadership transition does not change Harmony's previously communicated strategic priorities or the expected timing of key commercial and pipeline milestones.

“As I prepare to transition the President and CEO role to Peter on January 1, I believe Harmony is operating from a position of strength, with a durable and growing WAKIX franchise, the financial flexibility to invest in innovation, conviction to pursue strategic business development opportunities, and a pipeline led by BP-205 that has the potential to generate significant long-term value,” said Jeffrey Dayno, MD, President and Chief Executive Officer of Harmony Biosciences. “I am proud of the talented team and passionate organization we have built, which position Harmony for continued success in delivering innovative treatments to patients and sustained value for our shareholders.”

Key Drivers of Value Creation

Continued WAKIX Growth in an Evolving Market

Third Quarter 2026 Net Product Revenue for WAKIX

- WAKIX net revenue for the quarter ended September 30, 2026, was $268.9 million, driven by strong patient demand:
  - Estimated average number of patients grew by 400 to 9,350 in Q3, continuing strong recent performance with 5 of the last 6 quarters achieving more than 400 patient additions

    - Executed expansion of field sales, remote sales, field reimbursement and patient outreach teams with all roles hired, trained and fully deployed in Q2
- Growth continues to be demand driven: WAKIX is the only non-scheduled treatment option for excessive daytime sleepiness and cataplexy in adult and pediatric patients with narcolepsy type 1 and 2, supported by more than seven years of clinical experience and coverage for more than 80% of covered lives
- Significant market opportunity remains: approximately 170,000 people in the U.S. are living with narcolepsy, fewer than 50% are diagnosed, and brand penetration is approximately 20%

On Track to Achieve 2026 WAKIX Net Revenue Guidance of $1.0 Billion to $1.04 Billion

Advance Robust, Self-Funded Pipeline

BP-205 (Orexin-2 receptor agonist)

BP-205 MAD Study Design and Preliminary Results

- 14-day double-blind, randomized, placebo-controlled study that evaluated once-daily doses of BP-205 at 0.1 mg, 0.6 mg, 1 mg, and 3 mg across six cohorts (4 male and 2 female); a total of 94 healthy volunteers participated in this study
- BP-205 was rapidly absorbed, with a mean $T_{(max)}$ of approximately 60 minutes (range 30 to 90 minutes) supportive of the potential for rapid onset of efficacy
- The mean effective half-life ($T_{1/2}$) after 14-day repeat dosing was observed to be approximately 29 hours; no clinically meaningful change compared to the half-life in the SAD study and supportive of once-daily dosing
- BP-205 was generally well tolerated across all doses evaluated: headache was the most common adverse event occurring in approximately 25% of participants
- On-target adverse events of insomnia were reported in less than 20% of participants at all doses evaluated, were mild in severity and did not lead to discontinuation
- On-target adverse events of urinary frequency and urgency were reported in less than 20% of participants at the 1mg and 3mg doses only; these events were mild in severity and did not lead to discontinuation
- No liver or visual adverse events were reported, and no clinically significant cardiovascular events or EKG abnormalities were recorded
- There were no serious or severe adverse events
- The complete MAD study results will be presented at an upcoming medical meeting
- Next steps in BP-205 development:
    - Phase 1b study in sleep-deprived healthy volunteers initiated in Q3 in the US; data expected in Q1 2027
    - Expect to initiate Phase 2 studies to evaluate multiple CNS indications by mid-2027
- Poster presented by Bioprojet at the SLEEP EU 2026 meeting showed an *in-vivo* synergistic effect of orexin and histamine on wakefulness in a narcoleptic mouse model; this suggests concomitant use of an orexin-2 agonist and pitolisant as a potential therapeutic approach for patients with central disorders of hypersomnolence

- BP-205, Harmony's investigational OX2R agonist, was discovered by Teijin Pharma and is being developed in partnership with Bioprojet

Pitolisant GR (gastro-resistant) Tablets: On track to launch in 1H 2027

- NDA accepted by the FDA with PDUFA date of April 1, 2027
    - Enables patients to initiate treatment at a therapeutic dose without titration, an important clinical differentiation
- Utility patents filed to extend pitolisant franchise into the 2040s

Pitolisant HD (high dose): Opportunity to extend the pitolisant franchise with differentiated labeling

- Phase 3 registrational clinical trials ongoing in narcolepsy (ONSTRIDE 1) and idiopathic hypersomnia (IH) (ONSTRIDE 2):
    - Topline data expected in 2027 and anticipated PDUFA date in 2028
    - Enhanced formulation with optimized PK profile, enteric coating and higher dose to drive greater efficacy
    - Pursuing differentiated labeling: fatigue in narcolepsy and sleep inertia in IH
- Utility patents filed to extend pitolisant franchise into the 2040s

WAKIX (pitolisant): Phase 3 trial in Prader-Willi syndrome (PWS) (TEMPO)

- Topline data expected in mid-2027 and anticipated PDUFA date in 2028
- On track for pediatric exclusivity: completion of TEMPO study fulfills the second and last requirement agreed with FDA for WAKIX pediatric exclusivity, which would provide for an additional six months of regulatory exclusivity for

WAKIX

Exploring amorphous form of pitolisant to pursue broader CNS indications

- This opportunity is based on our exclusive license to Novitium's issued amorphous pitolisant patent with protection until 2042
- Continued efforts to optimize formulation and new modes of delivery

EPX-100 (clemizole hydrochloride)

- Actively enrolling in two Global Phase 3 registrational trials in rare epilepsies:
    - Lennox-Gastaut syndrome (LGS) – the LIGHTHOUSE Study
    - Dravet syndrome (DS) – the ARGUS Study
- Topline data expected in mid-2027 and anticipated PDUFA date in 2028
- Updated 18-month data from the open-label extension part of the ARGUS study to be presented at the American Epilepsy Society (AES) Annual Meeting in December 2026

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)
- Therapeutic areas of interest include Sleep Disorders, Epilepsy, Rare/Orphan CNS, and broader CNS indications
- Supported by a strong balance sheet and clear conviction to execute on strategic business development opportunities

Protect the Pitolisant Franchise

- Multi-layered strategy: Harmony is asserting its pitolisant IP in active legal proceedings, with each case covering different components of our multi-layered IP strategy:
    - Polymorph and method of use ('197 and '947): The bench trial in the AET ANDA litigation closing arguments were held on October 22, 2026; ruling is expected around the time of the 30-month stay (February 2027)
    - Amorphous form ('920): Harmony Biosciences and Novitium filed a lawsuit alleging patent infringement in April against AET Pharma US and its marketing partner Sandoz; the licensed Novitium patent provides protection to 2042. A scheduling conference was held on October 21. The amorphous '920 patent trial has not yet been scheduled, but would be expected to be scheduled for some time in 2029
    - Yesterday, November 3, the judge scheduled a preliminary injunction hearing on January 26, 2027, with an expected decision by February 14, 2027 when the 30- month stay expires. This schedule is identical to the preliminary injunction schedule Harmony proposed to the judge on October 26
- In Q1 this year, we obtained the exclusive rights to a patent covering methods of making amorphous pitolisant hydrochloride from our licensee MSN Labs. That patent was issued by the PTO in Q3. The patent strengthens our patent portfolio and protects our development efforts for a new amorphous pitolisant hydrochloride product
- Together with settlements with 6 of the 7 ANDA filers, these actions reinforce Harmony's confidence in WAKIX exclusivity to March 2030 (inclusive of 6 months of pediatric exclusivity)

Third Quarter 2026 Financial Results

Harmony Biosciences reported WAKIX net revenue of $268.9 million for the quarter ended September 30, 2026, compared to $239.5 million for the quarter ended September 30, 2025, representing a 12% increase over the same period. This performance reflects continued strong demand for WAKIX within the large narcolepsy market opportunity (approximately 80,000 diagnosed patients in the U.S.), disciplined commercial execution across the franchise and the product's broad clinical utility. Based on our results for the first nine months of 2026, WAKIX remains on track to achieve full-year net revenue of $1.0 billion to $1.04 billion.

Cost of product sold was $80.7 million in the third quarter of 2026, or 30% as a percentage of WAKIX net revenue, as compared to $59.7 million, or 25%, for the same quarter in 2025, representing a 35% increase. The increase in cost of product sold as a percentage of net product revenue was primarily driven by new royalties related to the Novitium license agreement.

Net income for the third quarter was $48.2 million, or $0.81 per diluted share, compared to $50.9 million, or $0.87 per diluted share, for the same quarter in 2025. The decline in earnings was primarily driven by an increase in milestone charges and the new MSN royalty charges during the third quarter of 2026 as compared to the same quarter in 2025.

Harmony's operating expenses include the following:

- Research and Development expenses were $71.7 million in the third quarter of 2026, as compared to $55.0 million

for the same quarter in 2025, representing a 30% increase; this was primarily driven by a $25.0 million charge related to a milestone achieved for the MSN license agreement, partially offset by a $15.0 million charge related to a clinical milestone achieved for ZYN002 in the prior year period;
- Sales and Marketing expenses were $34.7 million in the third quarter of 2026, as compared to $29.5 million for the same quarter in 2025, representing an 18% increase, primarily driven by the expansion of our field-based teams;
- General and Administrative expenses were $27.7 million in the third quarter of 2026, as compared to $29.8 million for the same quarter in 2025, representing a 7% decrease; primarily driven by a decline in stock-based compensation expense; and
- Total Operating expenses were $134.0 million in the third quarter of 2026, as compared to $114.3 million for the same quarter in 2025, representing a 17% increase.

As of September 30, 2026, Harmony had cash, cash equivalents and investments of $1,051.6 million, compared to $882.5 million as of December 31, 2025.

Capital Allocation Priorities

- Invest in R&D pipeline, especially BP-205 development plan
- Success-based R&D milestone payments
- Strategic business development to expand pipeline and diversify commercial portfolio

2026 WAKIX Net Revenue Guidance
Reiterated full year guidance of $1.0 billion to $1.04 billion.

Conference Call Today at 8:30 a.m. ET
Harmony is hosting its third quarter 2026 financial results conference call and webcast today, beginning at 8:30 a.m. Eastern Time. The live and replay webcast of the call will be available on the investor relations page of our website https://ir.harmonybiosciences.com/.

To participate in the call, please dial 800-347-6865 (domestic) or 203-518-9757 (international or alternate), and reference passcode HRMYQ326.

About Harmony Biosciences
Harmony Biosciences is developing and commercializing innovative medicines for both rare and broad CNS disorders, and we are becoming an enduring leader in neuroscience. Our first medicine, WAKIX® (pitolisant), is the first and only FDA-approved non-scheduled treatment for excessive daytime sleepiness or cataplexy in patients 6 years of age and older with narcolepsy. Its launch ranks among the most successful in the history of orphan drugs. Building on our success and profitability, we are continuing to advance our novel clinical-stage pipeline, led by BP-205, an investigational orexin-2 receptor agonist with best-in-class potential across a broad range of CNS disorders. With a strong balance sheet, we have the capacity and conviction to pursue strategic business development opportunities. Harmony is guided by an unwavering commitment to patients and driven to create long-term value for shareholders. For more information, visit: www.harmonybiosciences.com.

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 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.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Net product revenue	$ 268,917	$ 239,455	$ 745,584	$ 624,677
Cost of product sold	80,686	59,650	188,396	129,797
Gross profit	188,231	179,805	557,188	494,880
Operating expenses:				
Research and development	71,663	54,962	187,642	139,661
Sales and marketing	34,721	29,549	100,535	90,333
General and administrative	27,650	29,807	88,207	94,974
Total operating expenses	134,034	114,318	376,384	324,968
Operating income	54,197	65,487	180,804	169,912
Other expense, net	(316)	(106)	(496)	(575)
Interest expense	(3,060)	(3,621)	(9,364)	(11,103)
Interest income	8,428	5,730	21,257	16,070
Income before income taxes	59,249	67,490	192,201	174,304
Income tax expense	(11,053)	(16,625)	(36,086)	(38,103)
Net income	$ 48,196	$ 50,865	$ 156,115	$ 136,201
Unrealized (loss) income on investments	(1,213)	118	(2,286)	291
Comprehensive income	$ 46,983	$ 50,983	$ 153,829	$ 136,492
EARNINGS PER SHARE:				
Basic	$ 0.83	$ 0.88	$ 2.68	$ 2.36
Diluted	$ 0.81	$ 0.87	$ 2.63	$ 2.32
Weighted average number of shares of common stock - basic	58,409,880	57,550,902	58,271,509	57,655,272
Weighted average number of shares of common stock - diluted	59,679,319	58,717,910	59,272,602	58,738,361

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	September 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 647,099	$ 752,502
Investments, short-term	124,039	22,838
Trade receivables, net	127,739	96,787
Inventory, net	5,871	5,357
Prepaid expenses	18,101	16,014
Other current assets	11,981	13,516
Total current assets	934,830	907,014

NONCURRENT ASSETS:		
Investments, long-term	280,467	107,127
Intangible assets, net	71,535	89,418
Deferred tax asset	161,365	149,699
Other noncurrent assets	30,048	18,373
Total noncurrent assets	543,415	364,617
TOTAL ASSETS	$ 1,478,245	$ 1,271,631
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 26,919	$ 17,693
Accrued compensation	14,886	18,443
Accrued expenses	208,062	191,039
Current portion of long-term debt	20,000	20,000
Other current liabilities	1,675	4,957
Total current liabilities	271,542	252,132
NONCURRENT LIABILITIES:		
Long-term debt, net	129,104	143,663
Other noncurrent liabilities	5,367	5,618
Total noncurrent liabilities	134,471	149,281
TOTAL LIABILITIES	406,013	401,413
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at September 30, 2026 and December 31, 2025, respectively; 58,720,081 and 57,726,170 shares issued and outstanding at September 30, 2026, and December 31, 2025, respectively	1	1
Additional paid in capital	757,153	708,968
Accumulated other comprehensive (loss) income	(1,940)	346
Retained earnings	317,018	160,903
TOTAL STOCKHOLDERS' EQUITY	1,072,232	870,218
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,478,245	$ 1,271,631

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