Harmony Biosciences Announces Record Q2 2026 Revenue and Shares Initial Clinical Data for Its Orexin-2 Agonist BP-205 Reinforcing Potential Best-in-Class Profile

WAKIX® Net Revenue Grew 30% Year over Year to $261.3 Million for Second Quarter 2026; Estimated Average Patients Increased 450 to 8,950; Reiterates 2026 WAKIX Net Revenue Guidance of $1.0 Billion to $1.04 Billion

Phase 1 SAD Data for BP-205 Demonstrate Favorable PK and Safety/Tolerability Profiles; Phase 1 MAD Data Expected in Q4 2026

BP-205 IND Open in US; Initiating Phase 1b Study in Sleep-Deprived Healthy Volunteers in Q3; Data Expected Early 2027

Initiating Phase 2 Trials for BP-205 in Mid-2027 to Evaluate Multiple CNS Indications

Pitolisant GR NDA Accepted in July; Target PDUFA Date April 1, 2027

Pitolisant HD On Track for Phase 3 Topline Data in 2027 and Target PDUFA Date in 2028

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

PLYMOUTH MEETING, Pa., August 4, 2026 /Business Wire/ -- Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY) today reported Q2 2026 net revenue for WAKIX® (pitolisant) of $261.3 million, delivering 30% year-over-year growth in its seventh year on the market. These results underscore continued strong demand for WAKIX, disciplined commercial execution across the franchise and sustained momentum through the first half of 2026. Average patients for the quarter were approximately 8,950, an increase in average patients of 450. WAKIX remains on track to achieve full-year net revenue guidance of $1.0 billion to $1.04 billion.

The Company also announced encouraging single ascending dose (SAD) data from its Phase 1 study of BP-205, demonstrating favorable pharmacokinetic (PK) and safety/tolerability profiles that reinforce Harmony's conviction in BP-205 as a potential best-in-class orexin-2 receptor (OX2R) agonist. These data support Harmony's robust orexin development strategy, including initiating Phase 2 studies beginning in mid-2027 to evaluate multiple CNS indications.

"Our record second-quarter revenue reflects sustained demand for WAKIX and keeps us firmly on track to deliver over $1 billion in revenue this year. With this strong foundation, we are aggressively advancing our pipeline, with our orexin-2 agonist BP-205 as the centerpiece, that we believe can create significant long-term value for both patients and shareholders," said Jeffrey M. Dayno, MD, President and Chief Executive Officer of Harmony Biosciences. "The Phase 1 clinical PK and safety/tolerability data for BP-205 that we shared today, together with pre-clinical data demonstrating the highest potency of any orexin-2 agonist currently in the clinic, reinforce our conviction that BP-205 has the potential to be the best-in-class orexin-2 agonist with broad clinical utility across multiple CNS indications."

Bruce C. Corser, MD, Medical Director of the Sleep Management Institute, said, "The Phase 1 single ascending dose pharmacokinetic and safety/tolerability data for BP-205 are compelling. The potential for rapid onset of action and once-daily dosing, along with a favorable safety/tolerability profile, exceptional potency and high selectivity, suggests that BP-205 may have potential clinical utility in indications beyond orexin deficiency. I look forward to following the continued clinical development of this program."

Key Drivers of Value Creation

Continued WAKIX Growth in an Evolving Market

Second Quarter 2026 Net Product Revenue for WAKIX

- Net product revenue for the quarter ended June 30, 2026, was $261.3 million, representing 30% growth vs 2Q25
    - Estimated average number of patients grew 450 to 8,950 in Q2, which is the 2nd highest average patient growth ever
    - Executed expansion of field sales, remote sales, field reimbursement and patient outreach teams with all roles hired, trained and fully deployed in 2Q
    - Launched online portal and changes to reimbursement support process to enable patients to secure WAKIX faster and with higher success rate

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

Advance a Robust, Self-Funded Pipeline

Orexin-2 receptor agonist BP-205 (BP1.15205) is Harmony's OX2R agonist discovered by Teijin Pharma and developed in partnership with Bioprojet. It is designed to deliver a differentiated

profile through its high potency, excellent selectivity, favorable safety/tolerability, and a predictable PK profile with the potential for once-a-day dosing. It is the most potent OX2R agonist currently in clinical development.

- Phase 1 SAD topline data in healthy volunteers support Best-in-Class potential
    - A short time to maximum plasma concentration (Tmax) in the range of 30 to 75 minutes
        - Potential for rapid onset of efficacy
    - Mean half-life ($T_{1/2}$) of approximately 25h across dose groups
        - Supports once-a-day dosing and potential for durable efficacy throughout the day and into the early evening
    - Dose proportional exposure in maximum observed plasma concentration (Cmax) and area under the curve (AUC)
        - Predictable systemic exposure across the doses tested
    - No age or gender differences in PK parameters
        - Supports no dose adjustment for elderly or female patients
    - Generally safe and well tolerated with no serious or severe TEAEs
        - No cardiovascular, hepatic or visual abnormalities
        - The most common AEs were headache, fatigue, and diarrhea in approximately 10%, 4%, and 3% of the participants, respectively

- Next steps in BP-205 development
    - Multiple ascending dose (MAD) data in healthy volunteers expected in Q4
    - US IND open; initiate Phase 1b study in sleep-deprived healthy volunteers in Q3; data expected in early 2027

- Commitment to investing in robust development program for BP-205
    - Initiating Phase 2 studies to evaluate multiple potential CNS indications in mid-2027

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

- NDA accepted by FDA in July; target PDUFA date of April 1, 2027
    - Designed with enteric coating meant to reduce the potential for GI side effects in patients with narcolepsy, 80 – 90% of whom experience GI symptoms as part of their disease
    - 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; anticipated PDUFA date in 2028

    - Enhanced formulation with optimized PK profile, enteric coating and higher dose to drive greater efficacy
    - 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 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 the exclusive license to Novitium's issued amorphous pitolisant patent with protection until 2042
- Current efforts focused on formulation optimization, new modes of delivery, and an ongoing Phase 1 PK study

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 1H 2027 and anticipated PDUFA dates in 2028

Emphasis on Business Development

- Focused on opportunities with revenue potential in 2028–2032
- Prioritizing assets in Phase 3, in-registration, or on-market
- Therapeutic areas of interest include Sleep/Wake, Epilepsy, Rare/Orphan CNS, and broader CNS indications
- Supported by a strong balance sheet and clear conviction to execute on strategic business development opportunities
- Strong liquidity position of $962.5 million in cash, cash equivalents, and investments as of June 30, 2026

Protect the Pitolisant Franchise

- **Strong IP Protection/Exclusivity:** Harmony's pitolisant IP estate is multi-layered (formulations, methods of use, next-gen applications) and supports WAKIX exclusivity to March 2030 (inclusive of 6-months of pediatric exclusivity), with potential protection of the franchise through other formulations into the 2040s via additional patents/applications
- **ANDA Settlements**: Settled with 6 of the 7 ANDA filers
- **Ongoing Litigation:**

- AET ANDA litigation for “polymorph” (‘197) and “method of use” (‘947) patents: The bench trial concluded, the post-trial briefs are public, and the judge has called for closing arguments from both sides on October 22, 2026
- Harmony Biosciences and Novitium filed a patent infringement lawsuit in April against AET Pharma US and AET’s marketing partner Sandoz, alleging infringement of patents covering an amorphous form of pitolisant hydrochloride (‘920)

Second Quarter 2026 Financial Results

Harmony Biosciences reported net product revenue of $261.3 million for the quarter ended June 30, 2026, compared to $200.5 million for the same period in 2025, representing 30% year-over-year growth. 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. The continued success of WAKIX has been driven by strong demand and commercial execution. Based on our results for the first half 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 $63.2 million in the second quarter of 2026, or 24.2% as a percentage of net product revenue, as compared to $38.2 million, or 19.0%, for the same quarter in 2025, representing a 66% 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 second quarter was $75.4 million, or $1.28 per diluted share, compared to $39.8 million, or $0.68 per diluted share, for the same quarter in 2025.

Harmony’s operating expenses include the following:

- Research and Development expenses were $46.6 million in the second quarter of 2026, as compared to $50.2 million for the same quarter in 2025, representing a 7% decrease; this was primarily driven by a $15.0 million up-front payment related to the agreement with CiRC that was entered into during the second quarter of 2025, for which there was no corresponding amount in the current year period;
- Sales and Marketing expenses were $34.1 million in the second quarter of 2026, as compared to $30.1 million for the same quarter in 2025, representing a 13% increase, primarily driven by the expansion of our field-based teams;
- General and Administrative expenses were $28.1 million in the second quarter of 2026, as compared to $33.9 million for the same quarter in 2025, representing a 17% decrease; this was primarily driven by a charge related to an ANDA settlement in the second quarter of 2025, for which there was no corresponding amount in the current year period; and
- Total Operating expenses were $108.8 million in the second quarter of 2026, as compared to $114.2 million for the same quarter in 2025, representing a 5% decrease

As of June 30, 2026, Harmony had cash, cash equivalents and investments of $962.5 million, compared to $882.5 million as of December 31, 2025.

2026 Net Product Revenue Guidance
Reiterated 2026 WAKIX net revenue guidance of $1.0 billion to $1.04 billion.

Conference Call Today at 8:30 a.m. ET
Harmony is hosting its second 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 live call by phone, dial: 800-347-6865 (primary) or 203-518-9757 (alternate); conference ID is HRMYQ226.

About Harmony Biosciences
Harmony Biosciences is a pharmaceutical company dedicated to developing and commercializing innovative therapies for patients with rare neurological diseases who have unmet medical needs. Driven by novel science, visionary thinking, and a commitment to those who feel overlooked, Harmony Biosciences is nurturing a future full of therapeutic possibilities that may enable patients with rare neurological diseases to truly thrive. Established by Paragon Biosciences, LLC, in 2017 and headquartered in Plymouth Meeting, Pa., we believe that when empathy and innovation meet, a better future can begin; a vision evident in the therapeutic innovations we advance, the culture we cultivate, and the community programs we foster. For more information, please 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, our planned and ongoing clinical trials and expected timing of data readouts, anticipated regulatory milestones, our future results of operations and financial position, business strategy, 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 June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Net product revenue	$ 261,280	$ 200,489	$ 476,667	$ 385,222
Cost of product sold	63,198	38,153	107,710	70,147
Gross profit	198,082	162,336	368,957	315,075
Operating expenses:				
Research and development	46,596	50,159	115,979	84,699
Sales and marketing	34,120	30,073	65,814	60,784
General and administrative	28,050	33,924	60,557	65,167
Total operating expenses	108,766	114,156	242,350	210,650
Operating income	89,316	48,180	126,607	104,425
Other expense, net	(53)	(193)	(180)	(469)
Interest expense	(3,070)	(3,646)	(6,304)	(7,482)
Interest income	7,072	5,296	12,829	10,340
Income before income taxes	93,265	49,637	132,952	106,814
Income tax expense	(17,834)	(9,861)	(25,033)	(21,478)
Net income	$ 75,431	$ 39,776	$ 107,919	$ 85,336
Unrealized (loss) income on investments	(314)	(6)	(1,073)	173
Comprehensive income	$ 75,117	$ 39,770	$ 106,846	$ 85,509
EARNINGS PER SHARE:				
Basic	$ 1.30	$ 0.69	$ 1.86	$ 1.49
Diluted	$ 1.28	$ 0.68	$ 1.84	$ 1.46
Weighted average number of shares of common stock - basic	57,933,818	57,469,775	57,876,756	57,390,298
Weighted average number of shares of common stock - diluted	58,755,359	58,427,134	58,769,504	58,468,717

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

	June 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 549,769	$ 752,502
Investments, short-term	118,022	22,838
Trade receivables, net	110,995	96,787
Inventory, net	6,360	5,357
Prepaid expenses	19,311	16,014
Other current assets	9,877	13,516
Total current assets	814,334	907,014
NONCURRENT ASSETS:		
Investments, long-term	294,668	107,127
Intangible assets, net	77,496	89,418
Deferred tax asset	156,765	149,699
Other noncurrent assets	29,821	18,373
Total noncurrent assets	558,750	364,617
TOTAL ASSETS	$ 1,373,084	$ 1,271,631
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 21,684	$ 17,693
Accrued compensation	12,091	18,443
Accrued expenses	169,128	191,039
Current portion of long-term debt	20,000	20,000
Other current liabilities	11,167	4,957
Total current liabilities	234,070	252,132
NONCURRENT LIABILITIES:		
Long-term debt, net	133,961	143,663
Other noncurrent liabilities	5,810	5,618
Total noncurrent liabilities	139,771	149,281
TOTAL LIABILITIES	373,841	401,413
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at June 30, 2026 and December 31, 2025, respectively; 58,120,695 and 57,726,170 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively	1	1
Additional paid in capital	731,147	708,968
Accumulated other comprehensive (loss) income	(727)	346
Retained earnings	268,822	160,903
TOTAL STOCKHOLDERS' EQUITY	999,243	870,218
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 1,373,084	$ 1,271,631

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