# Harmony Biosciences Reports Q1 Financial Results and Confirms 2026 Net Revenue Guidance of Over $1 Billion; Reinforces 2026 Strategic Priorities

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*WAKIX® Net Revenue Grew 17% to $215.4 Million for First Quarter 2026; On Track for Full Year 2026 Net Revenues over $1 Billion*

*Continue to Vigorously Protect WAKIX IP into 2030; Filed Suit Against AET Pharma/Sandoz Regarding Infringement of Amorphous Pitolisant Patent*

*Lifecycle Management Advancing with Pitolisant GR on Track for NDA Filing 2Q26, Pitolisant HD Phase 3 Data in 2027, and Recently Acquired Novel Amorphous Form of Pitolisant to Pursue Broader CNS Indications*

*Potential Best-in-Class Orexin-2 Agonist with BP-205; Phase 1 Clinical PK Data On Track for Mid-2026*

*Renewed Focus on Business Development Opportunities with Emphasis on Revenue Potential in the 2028 to 2032 Timeframe*

*Expansion of the Leadership Team with the Addition of New COO and CFO to Support Scale and Next Phase of Growth*

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

PLYMOUTH MEETING, Pa.--(BUSINESS WIRE)--May 7, 2026-- Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY) today reported Q1 2026 revenue of $215.4 million, delivering 17% year-over-year growth for WAKIX®. Performance during the quarter reflected continued strong demand, offset by market access headwinds observed every Q1, which were more pronounced this year. This follows the strongest three consecutive quarters in franchise history, and the Company reinforced 2026 full year revenue guidance. The Company also outlined progress across four strategic priorities that it believes underpin long-term shareholder value.

“Harmony is well positioned for long-term growth, and we are focused on four key pillars to drive value creation. First, protect the pitolisant franchise to ensure durability into the 2030s, supported by multi-layered intellectual property. Second, continued growth of the pitolisant franchise in an evolving market by advancing new formulations and differentiated approaches to solidify our leadership in the sleep/wake market. Third, drive value from our pipeline, led by BP-205, which has the potential to be a highly differentiated and best-in-class orexin-2 agonist across multiple indications. And fourth, a renewed emphasis on business development with a goal to transact on opportunities with revenue potential in the 2028–2032 timeframe,” said Jeffrey M. Dayno, M.D., President and Chief Executive Officer of Harmony Biosciences. “Executing on these four pillars positions us well to deliver innovative treatments for patients and generate long-term value for shareholders.”

**Key Pillars of Value Creation:**

***Protect the Pitolisant Franchise***

- **ANDA Settlements**: 3 additional ANDA settlements were reached in Q1, bringing the total settlements to 6 of the 7 ANDA filers
- **Acquired New IP:** Acquired exclusive license to an issued patent out to 2042 for a novel amorphous form of pitolisant, providing Harmony with new development opportunities in broader CNS patient populations
- **Strong IP Protection/Exclusivity:** Harmony’s pitolisant IP estate is multi-layered (formulations, methods of use, next-gen applications) and supports WAKIX exclusivity into 2030 (inclusive of 6-months of pediatric exclusivity), with potential protection of the franchise into the 2040s via additional patents/applications
- **Filed Lawsuit:** Harmony Biosciences and Novitium filed a patent infringement lawsuit in April against AET Pharma US and Sandoz, alleging infringement of patents covering an amorphous form of pitolisant hydrochloride

***Continued Pitolisant Franchise Growth in an Evolving Market***

**First Quarter 2026 Net Product Revenue for WAKIX**

- Net product revenue for the quarter ended March 31, 2026, was $215.4 million, compared to $184.7 million for the same period in 2025
    - Average number of patients in Q1 was 8,500; exited the quarter with 8,600 average patients

**On track to achieve >$1 Billion in narcolepsy net sales in 2026**

- Net revenue projected between $1.0 billion to $1.04 billion for the full year ending December 31, 2026
- Received FDA approval of pediatric cataplexy indication on February 13th
    - Commercial team initiated full promotional efforts immediately upon approval
- Pitolisant in Prader-Willi syndrome (PWS)
    - Phase 3 topline data readout expected in 2H 2026
    - Supports Pediatric Exclusivity for WAKIX: Fulfills a key regulatory requirement for six months of additional regulatory exclusivity, extending exclusivity to March 2030

**Pitolisant GR (gastro-resistant): On track to extend pitolisant franchise into the 2040s**

- NDA submission on track for Q2 2026; anticipated PDUFA date in Q1 2027
    - Approximately 80-90% of patients with narcolepsy experience GI symptoms as part of their disease
    - Pitolisant GR is designed with enteric coating meant to reduce the potential for GI side effects in patients prone to GI symptoms
    - Enables patients to initiate treatment at a therapeutic dose without titration, an important clinical differentiation
- Utility patents filed to extend franchise into the 2040s

**Pitolisant HD (high dose): Opportunity to expand 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 expand franchise into the 2040s

**Exploring novel 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 and new modes of delivery in preparation for Phase 1 PK study

***Drive Value from our Robust Pipeline***

**Orexin-2 receptor agonist BP-205 (BP1.15205)**

- BP-205 is Harmony's lead OX2R agonist, built upon a novel chemical scaffold, with the potential for best-in-class therapy:
    - The most potent OX2R agonist currently in clinical development
    - The high potency enables the potential for significantly lower dosing than current OX2R assets under development
        - Potential for once-daily dosing across NT1, NT2 and IH (supported by favorable preclinical PK profile)
    - High selectivity for OX2R over OX1R and across 150 other receptors of interest
        - Potential for favorable safety/tolerability profile (supported by preclinical safety pharmacology and toxicology data)
- Phase 1 SAD/MAD clinical study ongoing in Europe; on track for clinical PK, safety, and tolerability data from SAD phase in mid-2026
- U.S. IND submission planned for mid-2026
- Plan to initiate Phase 1b study in sleep-deprived healthy volunteers in 2H 2026
- Exploring use outside of sleep/wake, including cognition, ADHD, mood, and fatigue

**EPX-100 (clemizole hydrochloride)**

- One of the most advanced development programs in the 5HT2 (serotonin) agonist class
- 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**
        - Encore safety and effectiveness data from the open-label extension study in DS that showed clinically meaningful reduction in seizures and a favorable safety and tolerability profile was presented at AAN meeting in April 2026
        - Both trials are currently enrolling in North America, Europe, China and India
- Topline data anticipated in 1H 2027 and potential PDUFA date in 2028

***Renewed 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 CNS adjacencies beyond rare disease
- Supported by a strong balance sheet and clear conviction to execute on strategic business development opportunities
- Strong liquidity position of $870.5 million in cash, cash equivalents, and investments as of March 31, 2026

**Personnel Updates**

- Appointed Peter Anastasiou as Chief Operating Officer (effective April 2, 2026) and Glenn Reicin as Chief Financial Officer (effective April 14, 2026), supporting continued focus on strategic growth

**First Quarter 2026 Financial Results**

Harmony Biosciences reported net product revenue of $215.4 million for the quarter ended March 31, 2026, compared to $184.7 million for the same period in 2025, representing 17% year-over-year growth. This performance reflects both continued demand for WAKIX within the large narcolepsy market opportunity (approximately 80,000 diagnosed patients in the U.S.) and the product's broad clinical utility. The continued success has been driven by strong execution across the organization from sales effectiveness to marketing and promotion and supported by broad payer coverage and how the company supports patients over time.

Cost of product sold was $44.5 million in the first quarter of 2026, or 20.7% as a percentage of net product revenue, as compared to $32.0 million, or 17.3%, for the same quarter in 2025, representing a 39% increase. The increase in cost of product sold as a percentage of net product revenue was driven by new royalties related to the Novitium license agreement.

Net income for the quarter was $32.5 million, or $0.55 per diluted share, compared to $45.6 million, or $0.78 per diluted share, in Q1 2025. The decline in earnings was entirely driven by the licensing agreements entered into during Q1 2026.

Harmony’s operating expenses include the following:

- Research and Development expenses were $69.4 million in the first quarter of 2026, as compared to $34.5 million for the same quarter in 2025, representing a 101% increase; the increase was primarily driven by $32.0 million in expenses related to up-front payments for license agreements that were entered into during Q1 2026, providing new development opportunities, which had an after-tax impact to earnings of $0.45 per share
- Sales and Marketing expenses were $31.7 million in the first quarter of 2026, as compared to $30.7 million for the same quarter in 2025, representing a 3% increase
- General and Administrative expenses were $32.5 million in the first quarter of 2026, as compared to $31.2 million for the same quarter in 2025, representing a 4% increase
- Total Operating Expenses were $133.6 million in the first quarter of 2026, as compared to $96.5 million for the same quarter in 2025, representing a 38% increase

As of March 31, 2026, Harmony had cash, cash equivalents and investments of $870.5 million, compared to $882.5 million as of December 31, 2025. The reduction was primarily due to up-front payments for license agreements and payment of ANDA settlements during Q1 2026.

**2026 Net Product Revenue Guidance**

Reiterated 2026 WAKIX Net Revenue Guidance of $1.0 Billion – $1.04 Billion

**Conference Call Today at 8:30 a.m. ET**

Harmony is hosting its first 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: (888) 596-4144 (domestic) or (646) 968-2525 (international, alternate); reference passcode **6626692**.

**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, plans to submit an sNDA for pitolisant in idiopathic hypersomnia; plans to submit an NDA for Pitolisant GR; plans to submit an IND for BP-205; 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, including EPX-100, Pitolisant GT 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 March 31, | |
|---|---|---|
| | **2026** | **2025** |
| Net product revenue | $ 215,387 | $ 184,733 |
| Cost of product sold | 44,512 | 31,994 |
| Gross profit | 170,875 | 152,739 |
| Operating expenses: | | |
| Research and development | 69,383 | 34,540 |
| Sales and marketing | 31,694 | 30,711 |
| General and administrative | 32,507 | 31,243 |
| Total operating expenses | 133,584 | 96,494 |
| Operating income | 37,291 | 56,245 |
| Other (expense) income, net | (127) | (276) |
| Interest expense | (3,234) | (3,836) |
| Interest income | 5,757 | 5,044 |
| Income before income taxes | 39,687 | 57,177 |
| Income tax expense | (7,199) | (11,617) |
| Net income | $ 32,488 | $ 45,560 |
| Unrealized (loss) income on investments | (759) | 179 |
| Comprehensive income | $ 31,729 | $ 45,739 |
| EARNINGS PER SHARE: | | |
| Basic | $ 0.56 | $ 0.79 |
| Diluted | $ 0.55 | $ 0.78 |
| Weighted average number of shares of common stock - basic | 57,819,060 | 57,309,938 |

| | | |
|---|---|---|
| Weighted average number of shares of common stock - diluted | 58,776,297 | 58,524,566 |

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

| | March 31, 2026 | December 31, 2025 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 589,398 | $ 752,502 |
| Investments, short-term | 51,520 | 22,838 |
| Trade receivables, net | 108,222 | 96,787 |
| Inventory, net | 5,281 | 5,357 |
| Prepaid expenses | 16,801 | 16,014 |
| Other current assets | 7,595 | 13,516 |
| Total current assets | 778,817 | 907,014 |
| NONCURRENT ASSETS: | | |
| Investments, long-term | 229,555 | 107,127 |
| Intangible assets, net | 83,457 | 89,418 |
| Deferred tax asset | 153,562 | 149,699 |
| Other noncurrent assets | 26,433 | 18,373 |
| Total noncurrent assets | 493,007 | 364,617 |
| TOTAL ASSETS | $ 1,271,824 | $ 1,271,631 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Trade payables | $ 28,600 | $ 17,693 |
| Accrued compensation | 6,726 | 18,443 |
| Accrued expenses | 150,107 | 191,039 |
| Current portion of long-term debt | 20,000 | 20,000 |
| Other current liabilities | 11,907 | 4,957 |
| Total current liabilities | 217,340 | 252,132 |
| NONCURRENT LIABILITIES: | | |
| Long-term debt, net | 138,814 | 143,663 |
| Other noncurrent liabilities | 5,321 | 5,618 |
| Total noncurrent liabilities | 144,135 | 149,281 |
| TOTAL LIABILITIES | 361,475 | 401,413 |
| COMMITMENTS AND CONTINGENCIES (Note 13) | | |
| STOCKHOLDERS' EQUITY: | | |
| Common stock—$0.00001 par value; 500,000,000 shares authorized at March 31, 2026, and December 31, 2025, respectively; 57,867,389 and 57,726,170 shares issued and outstanding at March 31, 2026, and December 31, 2025, respectively | 1 | 1 |
| Additional paid in capital | 717,370 | 708,968 |
| Accumulated other comprehensive (loss) income | (413) | 346 |
| Retained earnings | 193,391 | 160,903 |
| TOTAL STOCKHOLDERS' EQUITY | 910,349 | 870,218 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | $ 1,271,824 | $ 1,271,631 |

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