UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): November 4, 2026

HARMONY BIOSCIENCES HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39450**	**82-2279923**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

630 W. Germantown Pike, Suite 215
Plymouth Meeting, PA 19462
(Address of principal executive offices) (Zip Code)

(484) 539-9800
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	**HRMY**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 4, 2026, Harmony Biosciences Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2026. A copy of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

On November 4, 2026, the Company posted an investor presentation to its website at ttps://ir.harmonybiosciences.com (the "Investor Presentation"). A copy of the Investor Presentation is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The Company expects to use the Investor Presentation, in whole or in part, and possibly with modifications, in connection with presentations to investors, analysts and others.

The information contained in the Investor Presentation is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission ("SEC") filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Investor Presentation speaks only as of the date of this Current Report on Form 8-K. The Company undertakes no duty or obligation to publicly update or revise the information contained in the Investor Presentation, although it may do so from time to time. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure. In addition, the exhibit furnished herewith contains statements intended as "forward-looking statements" that are subject to the cautionary statements about forward-looking statements set forth in such exhibit. By furnishing the information contained in the Investor Presentation, the Company makes no admission as to the materiality of any information in the Investor Presentation that is required to be disclosed solely by reason of Regulation FD.

This Current Report on Form 8-K and its contents (including Exhibits 99.1 and 99.2) are furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Note Regarding Forward-Looking Statements

Certain statements in this Current Report on Form 8-K constitute "forward-looking statements" within the meaning of the federal securities laws. These statements are based on management's current opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results. These forward looking statements are only predictions, not historical fact, and involve certain risks and uncertainties, as well as assumptions. Actual results, levels of activity, performance, achievements and events could differ materially from those stated, anticipated or implied by such forward-looking statements. While the Company believes that its assumptions are reasonable, it is very difficult to predict the impact of known factors, and, of course, it is impossible to anticipate all factors that could affect actual results. There are many risks and uncertainties that could cause actual results to differ materially from the forward-looking statements made herein including the risks discussed under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, which was filed with the Securities and Exchange Commission ("SEC,") on February 24, 2026, as well as other factors described from time to time in the Company's filings with the SEC. Such forward-looking statements are made only as of the date of this Current Report on Form 8-K. The Company undertakes no obligation to publicly update or revise any forward-looking statement because of new information, future events or otherwise, except as otherwise required by law. If it does update one or more forward-looking statements, no inference should be made that the Company will make additional updates with respect to those or other forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1*	Press release issued by the Company, dated November 4, 2026.
99.2*	Investor Presentation, dated November 4, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* This Exhibit is furnished herewith and will not be deemed "filed" for purposes of Section 18 of the Exchange Act or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act except to the extent that Harmony Biosciences Holdings, Inc. specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HARMONY BIOSCIENCES HOLDINGS, INC.

Date: November 4, 2026

By: /s/ Stephen Mollichella
Stephen Mollichella
Senior Vice President, Controller and Interim Principal Financial Officer

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

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., November 4, 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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Exhibit 99.2

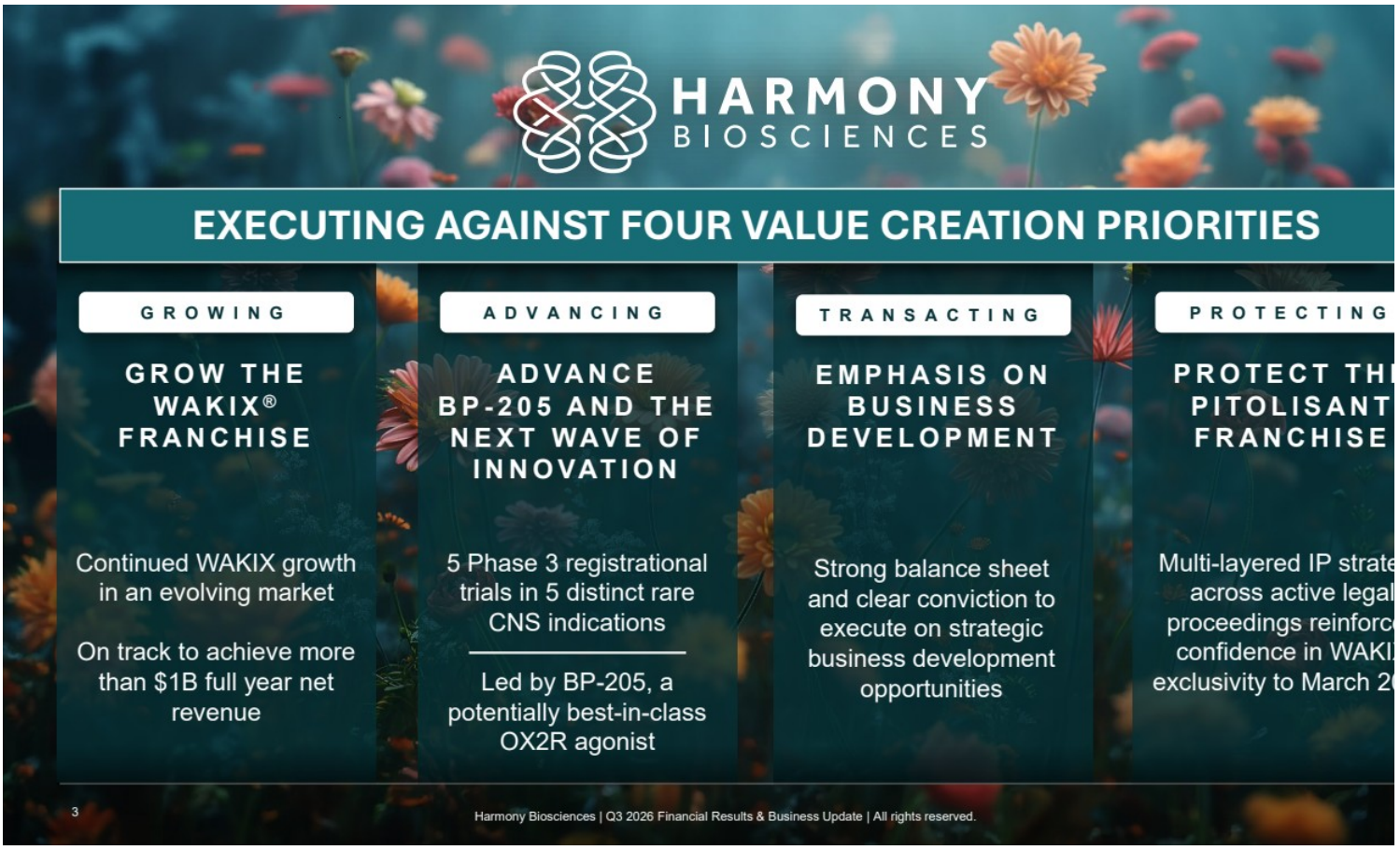


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Forward-Looking Statements

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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HARMONY
BIOSCIENCES
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
Led by BP-205, a potentially best-in-class OX2R agonist
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across active legal
proceedings reinforc
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3
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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

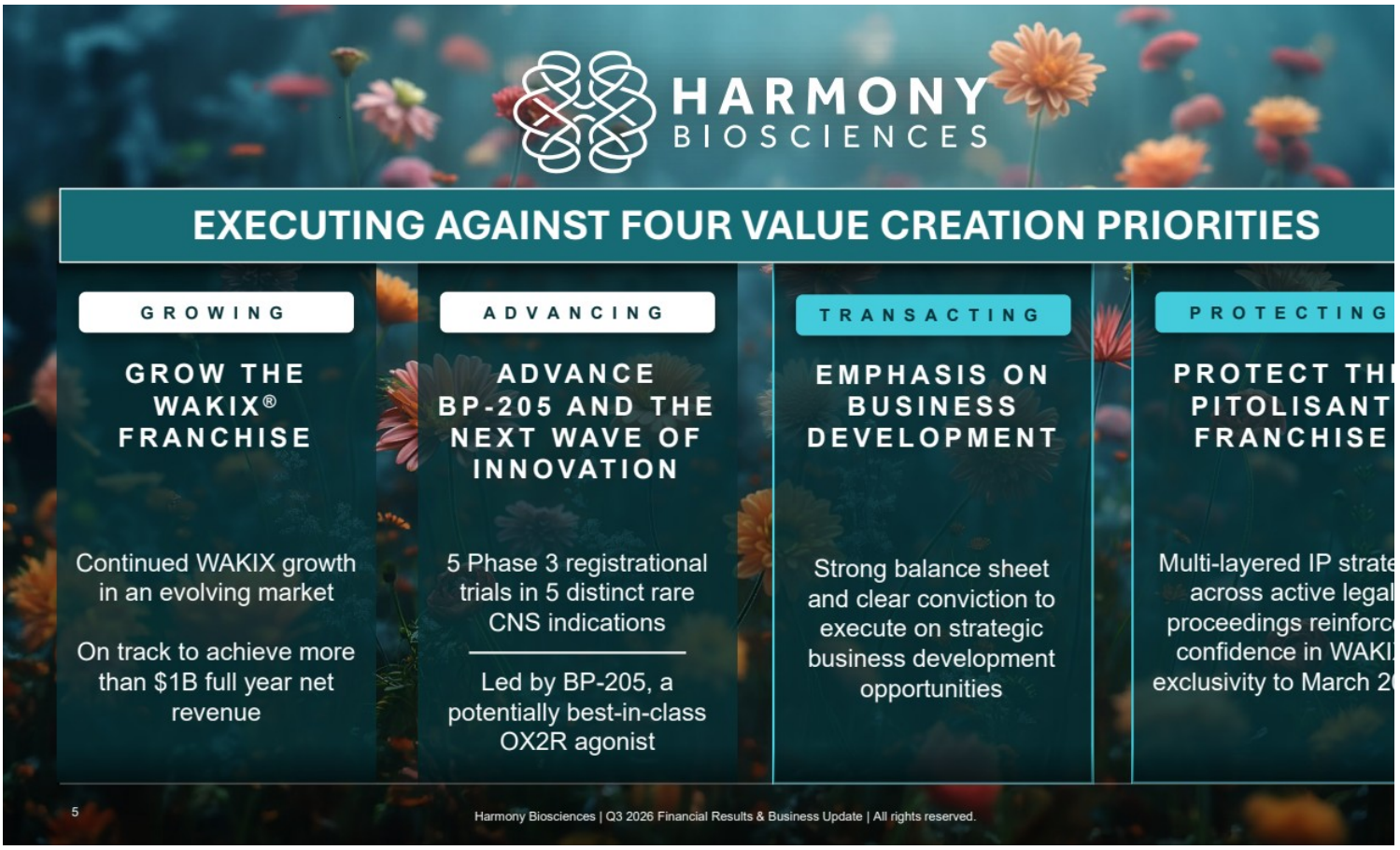
POTENTIAL BEST-IN-CLASS OX2R

BP-205

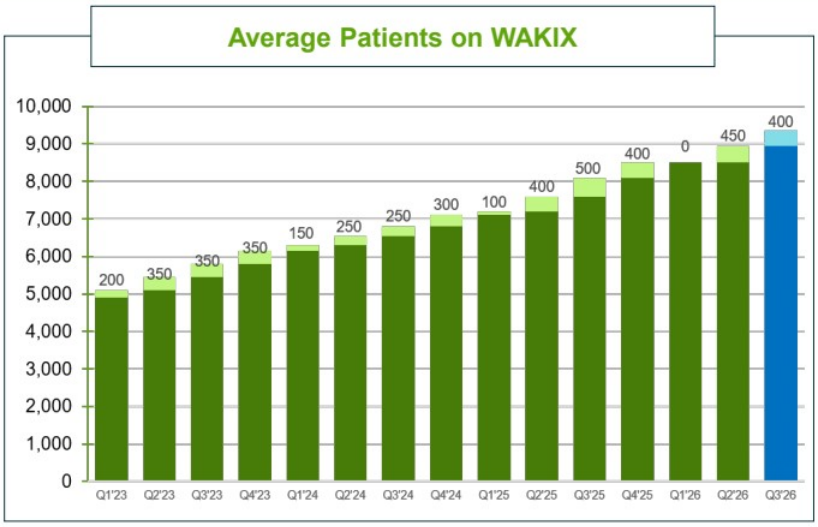
- Favorable multiple-ascending dose (MAD) data: 14 days of once-daily dosing reinforce the safety, tolerability and PK profile observed in the SAD study
- Most potent of OX2R agonists currently in the clinic
- Phase 1b sleep-deprived healthy volunteer data expected Q1 2027; Phase 2 studies in multiple 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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WAKIX® Differentiation and Strong Execution Drive Performance



DIFFERENTIATED PRODUCT

EXPANDED TEAM

BROAD PAYER ACCESS

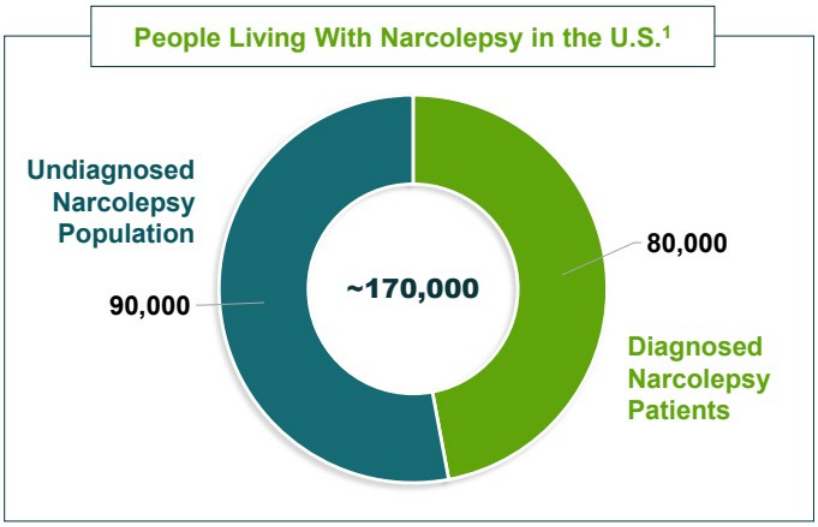
- **$269M net revenue in**
- **400 net pati adds, 9,350 average pat**
- **400+ net pa adds in 5 of last 6 quart**

KEY TAKEAWAY

Continued Demand-Driven Growth in Q3 '26

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Growth Opportunity Across the Narcolepsy Market



LARGE MARKET OPPORTUNITY

- ~170K total narcolepsy patients
- <50% diagn patients
- ~20% brand penetration in polypharı market

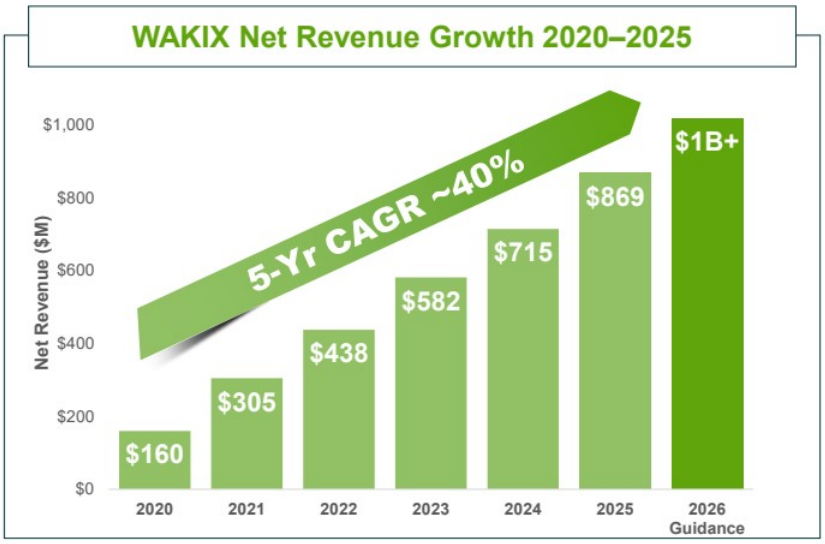
1. https://narcolepsynetwork.org/ accessed Feb 2024

KEY TAKEAWAY

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

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Reiterating 2026 WAKIX Net Revenue Guidance



$1.00B-$1.04B

2026 NET REVENUE GUIDANCE

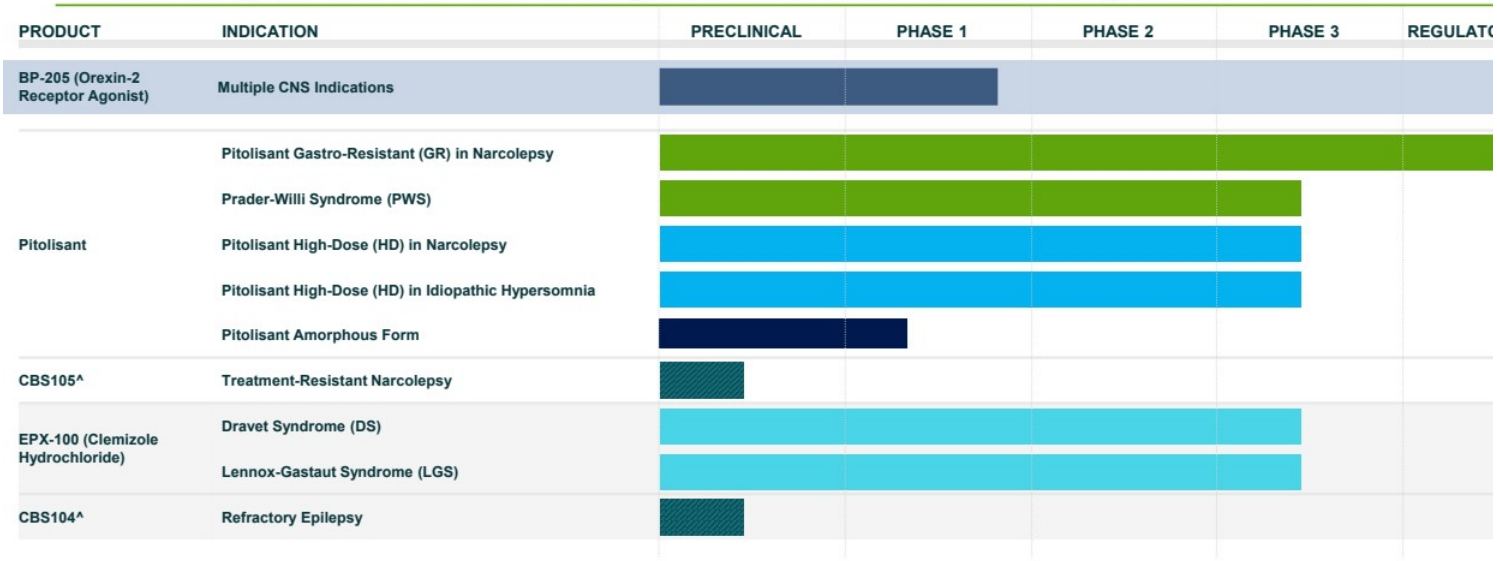


Wakix pitolisant tablets

On Track to Achieve $1B+ in Net Sales

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



^Research collaboration with CiRC Biosciences.

Innovative Clinical-Stage Pipeline With Multiple Catalysts 2026–2(

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



RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLL 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) STU

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

PRELIMINARY RESULTS

Complete MAD study results to be presented at an upcoming med 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 dosin
- **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 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 o

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BP-205 Development Plan

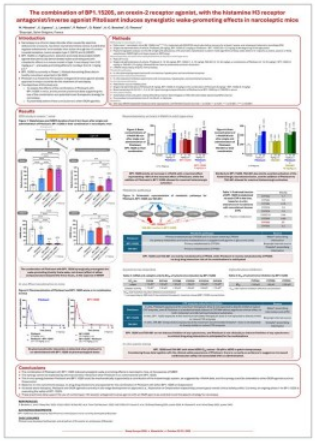


- ✔ **Q3 2026: ENCOURAGING SINGLE-ASCENDING DOSE (SAD) DATA**
- ✔ **Q4 2026: FAVORABLE PRELIMINARY PHASE 1 MAD RESULTS**
- **Q1 2027: PHASE 1B DATA IN SLEEP-DEPRIVED HEALTHY VOLUNTEERS**
- **MID-2027: TO INITIATE PHASE 2 STUDIES IN MULTIPLE CNS INDICATIONS**

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

Poster Presented by Bioprojet at SLEEP EU 2026



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 effect 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 l a new therapeutic approach for patients w 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 TRAC TO LAUNCH IN 1H 2027

PDUFA date April 1, 2027

PITOLISANT HD – ONGOING PHASE 3 REGISTRATIONA 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 TR 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 DE



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/BENE 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 suppo 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 aroun 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



(In millions, USD)

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

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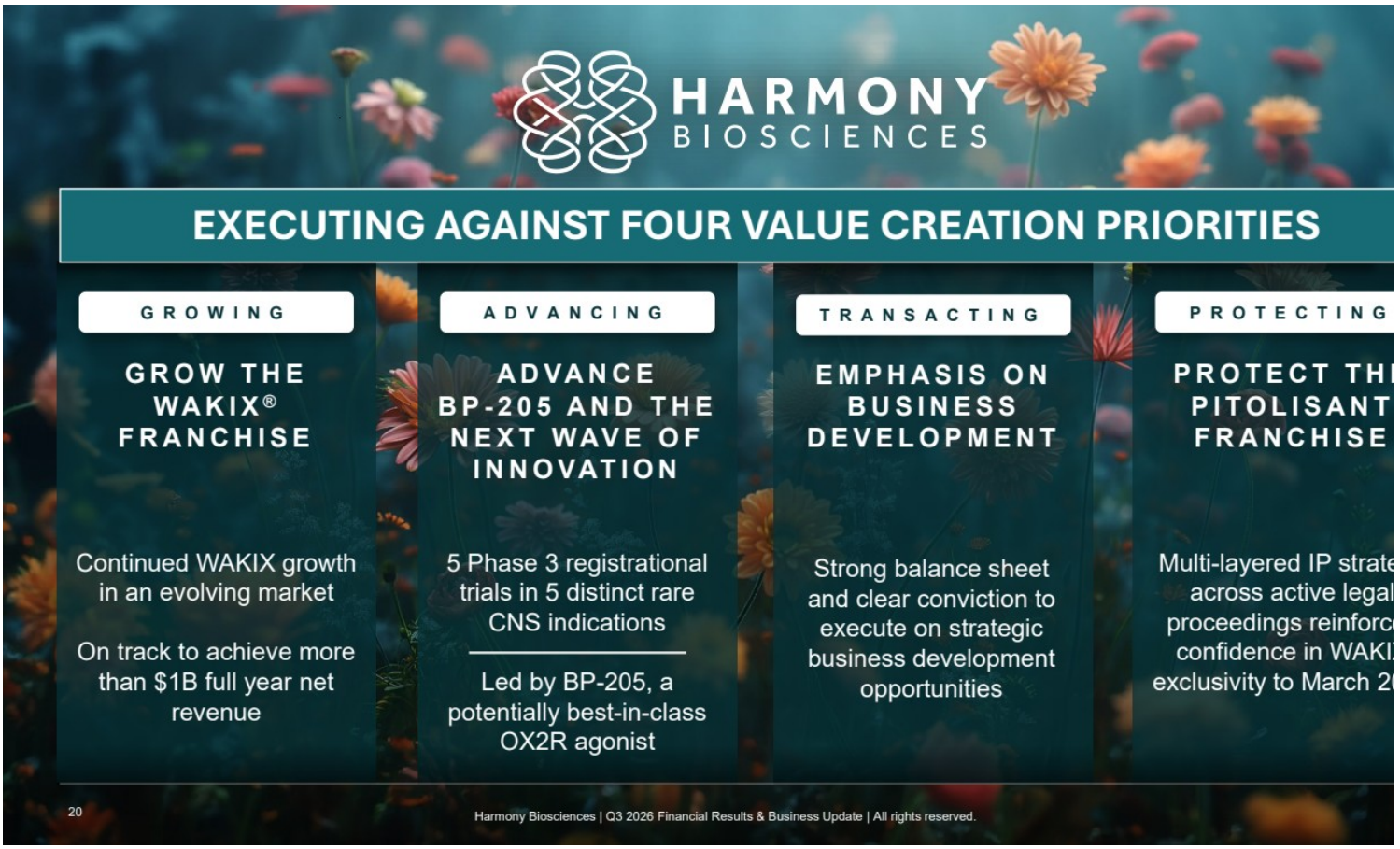
Financial Summary Q3 2026

Totals may not foot due to rounding	Three Months Ended September 30,		% Change	Nine Months Ended September 30,		% Change
	2026	2025		2026	2025	
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 incr due to new royalties relat Novitium License Agreem signed in Q1 2026.
- R&D Expense:
  - Q3 increase primarily to $25.0M charge for M license milestone.
  - Partially offset by $15. charge for ZYN002 milestone in prior year quarter.
- Sales & Marketing Expen increase primarily due to expansion of our field-bas team.
- G&A Expense decrease primarily due to lower sto based compensation.

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JEFFREY DAYNO, M.D.
PAST HONOREES
EY Entrepreneur Of The Year
Jeffrey M. Dayno, MD
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Entrepreneur Of The Year 2026
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