



Harmony Biosciences Reports Strong 2024 Financial Results and Reiterates 2025 Net Revenue Guidance; Highlights 2025 Catalysts in Sleep/Wake and Fragile X Syndrome Development Programs

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WAKIX® (pitolisant) Net Revenue of \$201.3 Million for Fourth Quarter and \$714.7 Million for Full Year 2024; Representing Growth of 23% in Year-Five on the Market

2025 WAKIX Net Revenue Guidance Between \$820 - \$860 Million; On Track Toward a Potential \$1 Billion+ Opportunity

Committed to Leadership in Sleep/Wake with Next Generation Pitolisant Formulations and Orexin 2 Receptor Agonist; Phase 3 Registrational Trials with Pitolisant HD in Narcolepsy and IH to Initiate in Q4 2025

Topline Data Readout from Phase 3 Registrational Trial with ZYN002 in Fragile X Syndrome On Track for Q3 2025

Pitolisant Patent Position Strengthened with Favorable Settlement of First Generic Litigation

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

PLYMOUTH MEETING, Pa.--(BUSINESS WIRE)--Feb. 25, 2025-- Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY) today announced a record \$201.3 million in net product revenues for the fourth quarter 2024, and full year 2024 net revenues of \$714.7 million, ending the year with \$576 million in cash, cash equivalents and investments on the balance sheet. The company has guided 2025 WAKIX® net revenues to \$820 - \$860 million, targeting a \$1B+ opportunity with WAKIX in narcolepsy alone.

"2025 is set up to be a transformational year for Harmony, as our robust, late-stage pipeline comes into focus and we advance our long-term growth strategy," said Jeffrey M. Dayno, M.D., President and Chief Executive Officer of Harmony Biosciences. "This year will bring major milestones for Harmony, with the topline data readout from our Phase 3 registrational trial with ZYN002 in Fragile X syndrome expected in Q3 and the potential, if successful, to bring the first approved treatment to the Fragile X patient community. In Q4, we will be initiating two Phase 3 registrational trials with our next gen Pitolisant HD formulation in both narcolepsy and idiopathic hypersomnia, potentially extending the pitolisant franchise out to the 2040s and further solidifying our leadership in sleep/wake. Taken together, these catalysts underscore the importance of 2025 as a pivotal year in Harmony's long-term growth strategy. With at least one new product candidate or indication launch each year over the coming years, our pipeline has the potential to deliver over \$3 billion in net revenue as the leading CNS company focused on developing and delivering innovative treatments for patients with unmet needs."

Franchise Highlights

Sleep/Wake Franchise

WAKIX in Narcolepsy

- Net Sales were \$201.3M for Q4 2024 and \$714.7M for FY 2024
- 2025 Net Revenue projected between \$820 to \$860 million
- Settlement reached in first Abbreviated New Drug Application (ANDA) litigation, giving Novugen Pharma a license to sell its generic product beginning in January 2030 or earlier under certain circumstances
 - This settlement reinforces the strength and durability of Harmony's intellectual property portfolio and its vigorous defense of its patent estate
- On track to obtain pediatric exclusivity which, if granted, would add an additional 6 months of regulatory exclusivity

Pitolisant HD (high-dose)

- Higher dose and optimized pharmacokinetic profile designed to address the need for greater efficacy in excessive daytime sleepiness (EDS) and other symptoms in patients with central disorders of hypersomnolence
- Phase 3 registrational trial in narcolepsy to include endpoint on narcolepsy-related fatigue in pursuit of differentiated label
 - Trial to initiate in Q4 2025; topline data readout anticipated in 2027 with potential PDUFA date in 2028
- Phase 3 registrational trial in IH to include endpoint on sleep inertia in pursuit of differentiated label
 - Trial to initiate in Q4 2025; topline data readout anticipated in 2027 with potential PDUFA date in 2028

- Provisional IP filed out to 2044 for narcolepsy and IH

Pitolisant GR (gastro-resistant)

- Pivotal bioequivalence study on track to initiate Q1 2025
 - Topline data readout anticipated in Q3 2025 with potential PDUFA in 2026
- Provisional IP filed out to 2044

Orexin-2 receptor agonist (BP1.15205)

- Potential to be best-in-class orexin-2 receptor agonist based on a novel chemical scaffold, preclinical potency, selectivity and safety data, as well as its potential for once-a-day dosing
- Preclinical safety and efficacy data to be presented at SLEEP 2025 (June)
- IMPD submission on track for mid-2025; first-in-human study expected to initiate 2H 2025

Neurobehavioral Franchise

ZYN002

- Innovative product profile: pharmaceutically manufactured synthetic cannabidiol devoid of THC
- The RECONNECT study is designed to confirm the positive findings from the prespecified analysis of the primary outcome in the subgroup of patients with complete methylation from the Phase 2/3 CONNECT study
- Potential to be the first and only approved treatment for patients with Fragile X syndrome (FXS) (80,000 patients in the U.S.), and also possess global rights
- Topline data readout from Phase 3 registrational trial of ZYN002 in FXS (RECONNECT study) in Q3 2025 with potential PDUFA date in 2026
- Phase 3 registrational trial in 22q11.2 deletion syndrome (22q) to initiate in 2025

Rare Epilepsy Franchise

EPX-100 (clemizole hydrochloride)

- Most advanced development program in the 5HT2 (serotonin) agonist class
- Topline data readout from Phase 3 registrational trial in Dravet syndrome (ARGUS Study) anticipated in 2026
- Topline data for Phase 3 registrational trial in patients with Lennox-Gastaut syndrome (LIGHTHOUSE study) anticipated in 2026

EPX-200 (lorcaserin hydrochloride)

- Proven mechanism of action in developmental and epileptic encephalopathies (DEEs) confirmed via non-clinical and clinical data
- Currently in IND enabling stage

Fourth Quarter 2024 Financial Results

Net product revenues for the quarter ended December 31, 2024, were \$201.3 million, compared to \$168.4 million for the same period in 2023. The 20% growth versus the same period in 2023 is primarily attributed to strong commercial sales of WAKIX driven by continued organic demand tapping into a large market opportunity (approximately 80,000 patients diagnosed with narcolepsy in the U.S.) and the broad clinical utility of WAKIX across the approximately 9,000 HCPs that we call on (about 5,000 of whom do not participate in an oxybate REMS program). The average number of patients on WAKIX increased by approximately 300 sequentially to approximately 7,100 for the quarter ended December 31, 2024.

GAAP net income for the quarter ended December 31, 2024, was \$49.5 million, or \$0.85 earnings per diluted share, compared to GAAP net income of \$26.6 million, or \$0.45 earnings per diluted share, for the same period in 2023. Non-GAAP adjusted net income was \$63.0 million, or \$1.08 earnings per diluted share, for the quarter ended December 31, 2024, compared to Non-GAAP adjusted net income of \$42.8 million, or \$0.73 per diluted share, for the same period in 2023.

Reconciliations of applicable GAAP financial measures to Non-GAAP financial measures are included at the end of this press release.

Harmony's operating expenses included the following:

- Research and Development expenses were \$34.7 million in the fourth quarter of 2024, as compared to \$30.3 million for the same quarter in 2023, representing a 14% increase;
- Sales and Marketing expenses were \$27.6 million in the fourth quarter of 2024, as compared to \$26.9 million for the same quarter in 2023, representing a 3% increase;
- General and Administrative expenses were \$28.9 million in the fourth quarter of 2024, as compared to \$27.9 million for the same quarter in 2023, representing a 4% increase; and
- Total Operating Expenses were \$91.1 million in the fourth quarter of 2024, as compared to \$85.1 million for the same

quarter in 2023, representing a 7% increase.

Full Year 2024 Financial Results

Net product revenues for the year ended December 31, 2024, were \$714.7 million, compared to \$582.0 million for the same period in 2023. The 23% growth versus the same period in 2023 is primarily attributed to strong commercial sales of WAKIX driven by continued organic demand tapping into a large market opportunity (approximately 80,000 patients diagnosed with narcolepsy in the U.S.) and the broad clinical utility of WAKIX across the approximately 9,000 HCPs that we call on (about 5,000 of whom do not participate in an oxybate REMS program).

GAAP net income for the year ended December 31, 2024, was \$145.5 million, or \$2.51 earnings per diluted share, compared to GAAP net income of \$128.9 million, or \$2.13 earnings per diluted share, for the same period in 2023. Non-GAAP adjusted net income was \$233.9 million, or \$4.04 earnings per diluted share, for the year ended December 31, 2024, compared to Non-GAAP adjusted net income of \$188.4 million, or \$3.12 per diluted share, for the same period in 2023.

Reconciliations of applicable GAAP financial measures to Non-GAAP financial measures are included at the end of this press release.

Harmony's operating expenses included the following:

- Research and Development expenses were \$145.8 million for the year ended December 31, 2024, as compared to \$76.1 million for the prior year, representing an 92% increase, primarily driven by a \$25.5 million upfront licensing fee as part of the 2024 Bioprojet Sublicense Agreement for BP1.15205, an orexin-2 receptor agonist, and a \$17.1 million IPR&D charge related to the acquisition of Epygenix
- Sales and Marketing expenses were \$110.9 million for the year ended December 31, 2024, as compared to \$97.4 million for the prior year, representing a 14% increase;
- General and Administrative expenses were \$110.4 million for the year ended December 31, 2024, as compared to \$95.3 million for the prior year, representing a 16% increase; and
- Total Operating Expenses were \$367.1 million for the year ended December 31, 2024, as compared to \$268.8 million for the prior year, representing a 37% increase.

As of December 31, 2024, Harmony had cash, cash equivalents and investments of \$576.1 million, compared to \$425.6 million as of December 31, 2023.

2025 Net Product Revenue Guidance

Expect full year 2025 net product revenue of \$820 million to \$860 million.

Share Repurchase Program

The remaining amount of common stock authorized for repurchases as of December 31, 2024, was \$150 million.

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

We are hosting our fourth quarter and full year 2024 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 at <https://ir.harmonybiosciences.com/>. To participate in the live call by phone, dial 800-445-7795 (domestic) or 785-424-1699 (international), and reference passcode HRMYQ424.

Non-GAAP Financial Measures

In addition to our GAAP results, we present certain Non-GAAP metrics including Non-GAAP adjusted net income and Non-GAAP adjusted net income per share, which we believe provides important supplemental information to management and investors regarding our performance. These measurements are not a substitute for GAAP measurements, and the manner in which we calculate Non-GAAP adjusted net income and Non-GAAP adjusted net income per share may not be identical to the manner in which other companies calculate adjusted net income and adjusted net income per share. We use these Non-GAAP measurements as an aid in monitoring our financial performance from quarter-to-quarter and year-to-year and for benchmarking against comparable companies.

Non-GAAP financial measures should not be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with our consolidated financial statements prepared in accordance with GAAP; have no standardized meaning prescribed by GAAP; and are not prepared under any comprehensive set of accounting rules or principles. In addition, from time to time in the future there may be other items that we may exclude for purposes of our Non-GAAP financial measures; and we may in the future cease to exclude items that we have historically excluded for purposes of our Non-GAAP financial measures.

About WAKIX® (pitolisant) Tablets

WAKIX, a first-in-class medication, is approved by the U.S. Food and Drug Administration for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy and for the treatment of EDS in pediatric patients 6 years of age

and older with narcolepsy. It was granted orphan drug designation for the treatment of narcolepsy in 2010, and breakthrough therapy designation for the treatment of cataplexy in 2018. WAKIX is a selective histamine 3 (H₃) receptor antagonist/inverse agonist. The mechanism of action of WAKIX is unclear; however, its efficacy could be mediated through its activity at H₃ receptors, thereby increasing the synthesis and release of histamine, a wake promoting neurotransmitter. WAKIX was designed and developed by Bioprojet (France). Harmony has an exclusive license from Bioprojet to develop, manufacture and commercialize pitolisant in the United States.

Indications and Usage

WAKIX is indicated for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy and for the treatment of excessive daytime sleepiness (EDS) in pediatric patients 6 years of age and older with narcolepsy.

Important Safety Information

Contraindications

WAKIX is contraindicated in patients with known hypersensitivity to pitolisant or any component of the formulation. Anaphylaxis has been reported. WAKIX is also contraindicated in patients with severe hepatic impairment.

Warnings and Precautions

WAKIX prolongs the QT interval; avoid use of WAKIX in patients with known QT prolongation or in combination with other drugs known to prolong the QT interval. Avoid use in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and the presence of congenital prolongation of the QT interval.

The risk of QT prolongation may be greater in patients with hepatic or renal impairment due to higher concentrations of pitolisant; monitor these patients for increased QTc. Dosage modification is recommended in patients with moderate hepatic impairment and moderate or severe renal impairment. WAKIX is contraindicated in patients with severe hepatic impairment and not recommended in patients with end-stage renal disease (ESRD).

Adverse Reactions

In the placebo-controlled clinical trials conducted in patients with narcolepsy with or without cataplexy, the most common adverse reactions (≥5% and at least twice placebo) for WAKIX were insomnia (6%), nausea (6%), and anxiety (5%). Other adverse reactions that occurred at ≥2% and more frequently than in patients treated with placebo included headache, upper respiratory tract infection, musculoskeletal pain, heart rate increased, hallucinations, irritability, abdominal pain, sleep disturbance, decreased appetite, cataplexy, dry mouth, and rash.

In the placebo-controlled phase of the clinical trial conducted in pediatric patients 6 years and older with narcolepsy with or without cataplexy, the most common adverse reactions (≥5% and greater than placebo) for WAKIX were headache (19%) and insomnia (7%). The overall adverse reaction profile of WAKIX in the pediatric clinical trial was similar to that seen in the adult clinical trial program.

Drug Interactions

Concomitant administration of WAKIX with strong CYP2D6 inhibitors increases pitolisant exposure by 2.2-fold. Reduce the dose of WAKIX by half.

Concomitant use of WAKIX with strong CYP3A4 inducers decreases exposure of pitolisant by 50%. Dosage adjustments may be required.

H1 receptor antagonists that cross the blood-brain barrier may reduce the effectiveness of WAKIX. Patients should avoid centrally acting H1 receptor antagonists.

WAKIX is a borderline/weak inducer of CYP3A4. WAKIX may reduce the effectiveness of sensitive CYP3A4 substrates, including hormonal contraceptives. Patients using hormonal contraception should be advised to use an alternative non-hormonal contraceptive method during treatment with WAKIX and for at least 21 days after discontinuing treatment.

Use in Specific Populations

There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to WAKIX during pregnancy. Patients should be encouraged to enroll in the WAKIX pregnancy registry if they become pregnant. To enroll or obtain information from the registry, patients can call 1-800-833-7460.

The safety and effectiveness of WAKIX have not been established for treatment of excessive daytime sleepiness in pediatric patients less than 6 years of age with narcolepsy.

The safety and effectiveness of WAKIX have not been established for treatment of cataplexy in pediatric patients with narcolepsy.

WAKIX is extensively metabolized by the liver. WAKIX is contraindicated in patients with severe hepatic impairment. Dosage adjustment is required in patients with moderate hepatic impairment.

WAKIX is not recommended in patients with end-stage renal disease. Dosage adjustment of WAKIX is recommended in patients with eGFR <60 mL/minute/1.73 m².

Dosage reduction is recommended in patients known to be poor CYP2D6 metabolizers; these patients have higher concentrations of WAKIX than normal CYP2D6 metabolizers.

Please see the [Full Prescribing Information](#) for WAKIX for more information.

To report suspected adverse reactions, contact Harmony Biosciences at 1-800-833-7460 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About Narcolepsy

Narcolepsy is a rare, chronic, debilitating neurological disease of sleep-wake state instability that impacts approximately 170,000 Americans and is primarily characterized by excessive daytime sleepiness (EDS) and cataplexy – its two cardinal symptoms – along with other manifestations of REM sleep dysregulation (hallucinations and sleep paralysis), which intrude into wakefulness. EDS is the inability to stay awake and alert during the day and is the symptom that is present in all people living with narcolepsy. In most patients, narcolepsy is caused by the loss of hypocretin/orexin, a neuropeptide in the brain that supports sleep-wake state stability. This disease affects men and women equally, with typical symptom onset in adolescence or young adulthood; however, it can take up to a decade to be properly diagnosed.

About Idiopathic Hypersomnia

Idiopathic Hypersomnia (IH) is a rare and chronic neurological disease that is characterized by excessive daytime sleepiness (EDS) despite sufficient or even long sleep time. EDS in IH cannot be alleviated by naps, longer sleep or more efficient sleep. People living with IH experience significant EDS along with the symptoms of sleep inertia (prolonged difficulty waking up from sleep) and 'brain fog' (impaired cognition, attention, and alertness). The cause of IH is unknown, but it is likely due to alterations in areas of the brain that stabilize states of sleep and wakefulness. IH is one of the central disorders of hypersomnolence and, like narcolepsy, is a debilitating sleep disorder that can result in significant disruption in daily functioning.

About ZYN002

ZYN002 is the first-and-only pharmaceutically manufactured synthetic cannabidiol devoid of THC and formulated as a patent-protected permeation-enhanced gel for transdermal delivery through the skin and into the circulatory system. The product is manufactured through a synthetic process in a cGMP facility and is not extracted from the cannabis plant. ZYN002 does not contain THC, the compound that causes the euphoric effect of cannabis, and has the potential to be a nonscheduled product if approved. Cannabidiol, the active ingredient in ZYN002, has been granted orphan drug designation by the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of FXS and for the treatment of 22q. Additionally, ZYN002 has received FDA Fast Track designation for the treatment of behavioral symptoms in patients with FXS.

About Fragile X Syndrome

Fragile X syndrome (FXS) is a rare genetic disorder that is the leading known cause of both inherited intellectual disability and autism spectrum disorder. The disorder negatively affects synaptic function, plasticity and neuronal connections, and results in a spectrum of intellectual disabilities and behavioral symptoms, such as social avoidance and irritability. While the exact prevalence is unknown, upwards of 80,000 patients in the U.S. and 121,000 patients in the European Union and the UK are believed to have FXS, based on FXS prevalence estimates of approximately 1 in 4,000 to 7,000 in males and approximately 1 in 8,000 to 11,000 in females. There is a significant unmet medical need in patients living with FXS as there are currently no FDA-approved treatments for this disorder.

FXS is caused by a mutation in FMR1, a gene which modulates a number of systems, including the endocannabinoid system, and most critically, codes for a protein called FMRP. The FMR1 mutation manifests as multiple repeats of a DNA segment, known as the CGG triplet repeat, resulting in deficiency or lack of FMRP. FMRP helps regulate the production of other proteins and plays a role in the development of synapses, which are critical for relaying nerve impulses, and in regulating synaptic plasticity. In people with full mutation of the FMR1 gene, the CGG segment is repeated more than 200 times, and in most cases causes the gene to not function. Methylation of the FMR1 gene also plays a role in determining functionality of the gene. In approximately 60% of patients with FXS, who have complete methylation of the FMR1 gene, no FMRP is produced, resulting in dysregulation of the systems modulated by FMRP.

About Clemizole Hydrochloride (EPX-100)

EPX-100, clemizole hydrochloride, is under development for the treatment of Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS). EPX-100 acts by targeting central 5-hydroxytryptamine receptors to modulate serotonin signaling. The drug candidate is administered orally twice a day in a liquid formulation and has been developed based on a proprietary phenotype-based zebrafish drug screening platform. DS is caused by a loss of function mutation in the SCN1A gene, and scn1

mutant zebrafish replicate the genetic etiology and phenotype observed in the majority of DS patients. The scn1Lab mutant zebrafish model that expresses voltage gated sodium channels has been used for high-throughput screening of compounds that modulate Nav1.1 in the central nervous system.

About Dravet Syndrome

Dravet syndrome (DS) is a severe and progressive epileptic encephalopathy that begins in infancy and causes significant impact on patient functioning. DS begins in the first year of life and is characterized by high seizure frequency and severity, intellectual disability, and a risk of sudden unexpected death in epilepsy. Approximately 85% of Dravet syndrome cases are caused by de novo loss-of-function (LOF) mutations in a voltage-gated sodium channel gene, SCN1A1. DS has an estimated incidence rate of 1:15,700.

About Lennox-Gastaut Syndrome

Lennox-Gastaut syndrome (LGS) is a rare and drug-resistant epileptic encephalopathy characterized by onset in children between 3-5 years of age. The underlying cause of LGS is unknown and can be related to a wide range of factors including genetic differences and structural differences in the brain. As a result, patients experience multiple seizure types, including atonic seizures, and developmental, cognitive, and behavioral issues. LGS affects approximately 48,000 patients in the U.S.

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 2024 net product revenue, expectations for the growth and value of WAKIX, plans to submit an sNDA for pitolisant in idiopathic hypersomnia; 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; 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 the significant costs and required management time as a result of operating as a public company. 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 25, 2025, 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 SUBSIDIARY CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(In thousands, except share and per share data)

Three Months Ended

Year Ended

	<u>December 31, 2024</u>	<u>December 31, 2023</u>	<u>December 31, 2024</u>	<u>December 31, 2023</u>
Net product revenue	\$ 201,267	\$ 168,412	\$ 714,734	\$ 582,022
Cost of product sold	54,409	43,152	156,815	121,236
Gross profit	<u>146,858</u>	<u>125,260</u>	<u>557,919</u>	<u>460,786</u>
Operating expenses:				
Research and development	34,666	30,306	145,825	76,063
Sales and marketing	27,600	26,886	110,916	97,404
General and administrative	28,865	27,872	110,352	95,289
Total operating expenses	<u>91,131</u>	<u>85,064</u>	<u>367,093</u>	<u>268,756</u>
Operating income	55,727	40,196	190,826	192,030
Loss on debt extinguishment	—	—	—	(9,766)
Other expense (income), net	160	193	(68)	159
Interest expense	(4,209)	(4,796)	(17,496)	(23,757)
Interest income	4,477	4,096	18,542	14,730
Income before income taxes	<u>56,155</u>	<u>39,689</u>	<u>191,804</u>	<u>173,396</u>
Income tax benefit (expense)	<u>(6,680)</u>	<u>(13,082)</u>	<u>(46,311)</u>	<u>(44,543)</u>
Net income	<u>\$ 49,475</u>	<u>\$ 26,607</u>	<u>\$ 145,493</u>	<u>\$ 128,853</u>
EARNINGS PER SHARE:				
Basic	\$ 0.87	\$ 0.46	\$ 2.56	\$ 2.17
Diluted	\$ 0.85	\$ 0.45	\$ 2.51	\$ 2.13
Weighted average number of shares of common stock - basic	57,097,092	58,320,400	56,885,455	59,469,648
Weighted average number of shares of common stock - diluted	58,218,052	58,853,292	57,869,915	60,372,397

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

	<u>December 31, 2024</u>	<u>December 31, 2023</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 453,001	\$ 311,660
Investments, short-term	14,185	41,800
Trade receivables, net	83,033	74,140
Inventory, net	7,198	5,363
Prepaid expenses	13,714	12,570
Other current assets	8,121	5,537
Total current assets	<u>579,252</u>	<u>451,070</u>
NONCURRENT ASSETS:		
Property and equipment, net	1,257	371
Restricted cash	270	270
Investments, long-term	108,874	72,169
Intangible assets, net	113,263	137,108
Deferred tax asset	190,398	144,162
Other noncurrent assets	5,886	6,298
Total noncurrent assets	<u>419,948</u>	<u>360,378</u>
TOTAL ASSETS	<u>\$ 999,200</u>	<u>\$ 811,448</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 13,744	\$ 17,730

Accrued compensation	18,776	23,747
Accrued expenses	120,640	99,494
Current portion of long-term debt	16,250	15,000
Other current liabilities	5,672	7,810
Total current liabilities	<u>175,082</u>	<u>163,781</u>
NONCURRENT LIABILITIES:		
Long-term debt, net	163,016	178,566
Other noncurrent liabilities	1,947	2,109
Total noncurrent liabilities	<u>164,963</u>	<u>180,675</u>
TOTAL LIABILITIES	<u>340,045</u>	<u>344,456</u>
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY:		
Common stock—\$0.00001 par value; 500,000,000 shares authorized at December 31, 2024 and December 31, 2023, respectively; 57,144,887 and 56,769,081 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	1	1
Additional paid in capital	656,872	610,266
Accumulated other comprehensive (loss) income	66	2
Retained earnings (accumulated deficit)	2,216	(143,277)
TOTAL STOCKHOLDERS' EQUITY	<u>659,155</u>	<u>466,992</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 999,200</u>	<u>\$ 811,448</u>

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARIES
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS
(In thousands except share and per share data)

	Three Months Ended		Year Ended	
	December 31, 2024	December 31, 2023	December 31, 2024	December 31, 2023
GAAP net income	\$ 49,475	\$ 26,607	\$ 145,493	\$ 128,853
Non-GAAP Adjustments:				
Non-cash interest expense (1)	169	185	700	3,246
Depreciation	6	164	267	514
Amortization (2)	5,962	5,961	23,845	23,845
Stock-based compensation expense	9,856	8,894	42,701	31,205
Licensing fee and milestone payments (3)	-	-	26,500	750
Loss on debt extinguishment (4)	-	-	-	9,766
Transaction related costs (5)	-	9,804	17,095	9,804
Income tax effect related to non-GAAP adjustments (6)	(2,442)	(8,789)	(22,657)	(19,624)
Non-GAAP adjusted net income	<u>\$ 63,026</u>	<u>\$ 42,826</u>	<u>\$ 233,944</u>	<u>\$ 188,359</u>
GAAP reported net income per diluted share	\$ 0.85	\$ 0.45	\$ 2.51	\$ 2.13
Non-GAAP adjusted net income per diluted share	\$ 1.08	\$ 0.73	\$ 4.04	\$ 3.12
Weighted average number of shares of common stock used in non-GAAP diluted per share	58,218,052	58,853,292	57,869,915	60,372,397

(1) Includes amortization of deferred finance charges.

(2) Includes amortization of intangible asset related to WAKIX.

(3) Amount represents upfront licensing fee incurred upon closing the 2024 Bioprojet Sublicense Agreement, milestone payment related to HBS-102 in September 2024 and milestone payment related to HBS-102 in March 2023.

(4) Includes loss on extinguishment of the Blackstone Credit Agreement.

(5) Includes IPR&D charge related to the acquisitions of Epygenix in April 2024 and Zynerba in October 2023.

(6) Calculated using the reported effective tax rate for the periods presented less impact of discrete items.

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