# Harmony Biosciences Reports Strong Q2 2025 Financial Results and Reaffirms 2025 Revenue Guidance; On Track to Announce Fragile X Topline Data From Phase 3 Registrational Trial in Q3 2025

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- *WAKIX® (pitolisant) Franchise Continues Strong Growth with Net Revenue of $200.5M for Q2 2025 (+16% YoY Growth); Increases Average Patients by 400 to Achieve 7,600 Average Patients in Q2 2025*
- *Phase 3 RECONNECT Study in Fragile X Syndrome (FXS) Designed to Confirm Positive Findings from the Phase 2/3 CONNECT Study; Opportunity to Address Unmet Needs of 80,000 Patients with FXS*
- *On Track to Begin First-in-Human Clinical Trial with BP1.15205, a Potential Best-In-Class Orexin-2 Agonist, in 2H 2025*
- *Initiation of Next-Generation Pitolisant HD Phase 3 Registrational Trials in Narcolepsy & Idiopathic Hypersomnia in Q4 2025; Both Indications Targeted for PDUFA in 2028*

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

PLYMOUTH MEETING, Pa.--(BUSINESS WIRE)--Aug. 5, 2025-- Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY) today announced plans to announce topline data from its phase 3 registrational clinical trial of ZYN002 in Fragile X syndrome in Q3 2025. The company also announced 16% year-over-year revenue growth for WAKIX® in Q2 2025, driven by strong patient adds of 400 for the quarter, continuing its trajectory toward blockbuster status in narcolepsy and a potential $1B+ market opportunity. The company continues to build on four consecutive years of revenue growth and profitability. With over $672 million in cash and investments, Harmony has further strengthened its financial position, solidifying its unique profile as a profitable, self-funding biotech company with a robust, late-stage pipeline and strong long-term growth potential.

“The approximately 80,000 U.S. families in the Fragile X community have been waiting far too long for a treatment that addresses the core symptoms of this serious condition. We are on track to announce the Phase 3 readout for ZYN002 in the third quarter, which represents a potentially transformative moment for these patients and for Harmony. With global rights to this product, if successful, we see a meaningful opportunity to address this significant unmet medical need both in the U.S. and around the world,” said Jeffrey M. Dayno, M.D., President and CEO of Harmony Biosciences. “Based on the strength of our commercial business, our continued profitability and commitment to patients, Harmony is building a commercially durable business with a robust pipeline and clear path to delivering long-term value for patients, providers, and shareholders alike.”

**Franchise Highlights**

***Neurobehavioral Franchise***

**ZYN002**

- Topline Data from the Phase 3 registrational trial of ZYN002 in Fragile X syndrome on track for Q3 2025.
    - RECONNECT study is designed to confirm the statistically significant and clinically meaningful findings from the prespecified analysis of the primary outcome in the subgroup of patients with complete methylation from the Phase 2/3 CONNECT study.
        - Over 50% of patients in the CONNECT study demonstrated clinically meaningful improvements in social avoidance and irritability/disruptive behaviors.
    - ZYN002 is an innovative product: 100% purely synthetic, pharmaceutically manufactured cannabidiol devoid of THC, in a patent-protected, permeation-enhanced gel formulation.
    - Unique mode of transdermal delivery (through the skin) that results in stable blood levels to maximize efficacy.
        - This mode of delivery is also patient friendly for those with FXS, who often have difficulty swallowing tablets, enhancing compliance.
    - Over 8 years of long-term safety, tolerability and durability of effectiveness data in patients with FXS.
        - The most common TEAE was mild to moderate application site skin reactions, in less than 7% of patients, which was transient and self-resolving.
- Potential to be the first and only approved treatment for patients with FXS; 80,000 patients in the U.S. and Harmony possesses global rights.
- Prepared to initiate Phase 3 registrational trial in 22q11.2 deletion syndrome (22q), another neurobehavioral disorder with similar symptoms to FXS, in Q4 2025.

***Sleep/Wake Franchise***

**WAKIX in Narcolepsy**

- Net Revenue was $200.5 million for Q2 2025.
- 2025 Net Revenue on track to achieve $820 to $860 million.
- Increase of 400 average patients to achieve 7,600 average patients in Q2 2025.

**Pitolisant HD (high dose)**

- Phase 3 registrational trials in both narcolepsy and IH to initiate in Q4 2025 with target PDUFA dates in 2028.
- Higher dose and optimized pharmacokinetic profile designed for greater efficacy without compromising safety and tolerability profile.
- Phase 3 registrational trial in narcolepsy designed for greater efficacy in excessive daytime sleepiness and cataplexy; includes endpoint on narcolepsy-related fatigue in pursuit of a differentiated label.
- Phase 3 registrational trial in IH to include endpoint on sleep inertia in pursuit of a differentiated label.
- Utility patents filed for pitolisant HD with potential exclusivity to 2044.

**Pitolisant GR (gastro-resistant)**

- Topline data readout from pivotal BE study anticipated in Q4 2025 with potential PDUFA date in 2026.
- Designed to address potential for treatment-related GI side effects as patients with narcolepsy commonly experience GI symptoms related to their underlying disease (up to 90%).
- Provides an ability for patients to start at therapeutic dose range without the need for titration.
- Utility patents filed for pitolisant GR with potential exclusivity to 2044.

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

- First-in-human study to commence in 2H 2025 with clinical data anticipated in 2026.
- Comprehensive and compelling preclinical safety and efficacy data presented at SLEEP 2025.
- Potential to be best-in-class orexin-2 receptor agonist based on a novel chemical scaffold, preclinical potency, selectivity, safety and efficacy data, as well as its potential for once-a-day dosing.

***Rare Epilepsy Franchise***

**EPX-100 (clemizole hydrochloride)**

- One of the most advanced development programs in the 5HT2 (serotonin) agonist class.
- Enrollment ongoing for Phase 3 registrational trial in Dravet syndrome (ARGUS Study) with topline data anticipated in 2026.
- Enrollment ongoing for Phase 3 registrational trial in patients with Lennox-Gastaut syndrome (LIGHTHOUSE Study) with topline data 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.

**Business Development**

- Harmony Biosciences entered into a research collaboration with CiRC Biosciences, a regenerative medicine company developing novel therapies based on cellular reprogramming, focused on developing novel regenerative cellular therapies to replace and restore function in patients with serious, refractory neurological disorders.
- This collaboration is strategically aligned with Harmony's pipeline and focused on treatments for refractory epilepsy and treatment-resistant narcolepsy. It could potentially result in the next generation of innovative, disease-modifying therapies for these neurological diseases using allogeneic, off-the-shelf, readily sourced cGMP-grade cell lines without the use of stem cells, enabling a significant competitive and manufacturing advantage.
- Harmony Biosciences paid $15 million upfront to CiRC in conjunction with this research collaboration agreement. We have an option to acquire an exclusive license for each program (refractory epilepsy and treatment-resistant narcolepsy) after the establishment of preclinical *in vivo* proof of concept, for an aggregate of $10 million in milestone and option fee payments for each program. The agreement includes customary milestones and royalties that we may be obligated to pay in the future based on the continued development and potential commercialization of each of these therapies.

**Strong Patent Position for WAKIX with Third Settlement in ANDA Litigation**

- On June 5th, Harmony announced a settlement agreement with Lupin Limited, one of the largest generic manufacturers, resolving the patent infringement litigation related to Lupin's Abbreviated New Drug Application

(ANDA) for a generic version of WAKIX® (pitolisant hydrochloride).
- As part of the agreement, litigation in the United States District Court for the District of Delaware was dismissed, and Lupin received a license to launch its generic product no earlier than January 2030 (or July 2030 with pediatric exclusivity), or earlier under certain circumstances.
- Harmony remains committed to vigorously defending its intellectual property and continues to litigate its consolidated patent infringement case against several other companies that have filed ANDAs seeking approval for generic versions of WAKIX® (pitolisant hydrochloride).

**Second Quarter 2025 Financial Results**

Harmony Biosciences reported net product revenue of $200.5 million for the quarter ended June 30, 2025, compared to $172.8 million for the same period in 2024, representing 16% year-over-year growth. This performance was primarily driven by strong commercial sales of WAKIX, reflecting both continued organic demand within the large narcolepsy market opportunity (approximately 80,000 diagnosed patients in the U.S.) and the product's broad clinical utility. Our commercial efforts reached approximately 9,000 healthcare providers during the quarter, including about 5,000 who do not participate in an oxybate REMS program, demonstrating successful penetration across both traditional and expanded prescriber bases.

On a GAAP basis, net income for the quarter was $39.8 million, or $0.68 per diluted share, compared to $11.6 million, or $0.20 per diluted share, in Q2 2024. Non-GAAP adjusted net income, which we believe better reflects our core business performance, was $53.8 million ($0.92 per diluted share) for the second quarter of 2025 versus $24.5 million ($0.43 per diluted share) for the comparable 2024 period. This represents a 116% increase in adjusted profitability, highlighting our ability to grow both top-line revenue and bottom-line results while maintaining investments in our late-stage pipeline programs.

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

Harmony’s operating expenses include the following:

- Research and Development expenses were $50.2 million in the second quarter of 2025, as compared to $63.6 million for the same quarter in 2024, representing a 21.1% decrease; primarily driven by a total of $42.6 million in IPR&D charges in Q2 2024 related to the Bioprojet sublicensing agreement for an orexin-2 agonist compound and acquisition of Epygenix, partially offset by a $15.0 million IPR&D charge related to the upfront fee from the 2025 CiRC Agreement that occurred this quarter;
- Sales and Marketing expenses were $30.1 million in the second quarter of 2025, as compared to $28.5 million for the same quarter in 2024, representing a 5.5% increase;
- General and Administrative expenses were $33.9 million in the second quarter of 2025, as compared to $27.2 million for the same quarter in 2024, representing a 24.6% increase; and
- Total Operating Expenses were $114.2 million in the second quarter of 2025, as compared to $119.3 million for the same quarter in 2024, representing a 4.3% decrease.

As of June 30, 2025, Harmony had cash, cash equivalents and investments of $672.3 million, compared to $576.1 million as of December 31, 2024.

**2025 Net Product Revenue Guidance**

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

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

We are hosting our second quarter 2025 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 833-316-2483 (domestic) or 785-838-9284 (international), and reference passcode HRMYQ225.

**Non-GAAP Financial Measures**

In addition to our GAAP results, we present certain Non-GAAP measures 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 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 ($H_3$) receptor antagonist/inverse agonist. The mechanism of action of WAKIX is unclear; however, its efficacy could be mediated through its activity at $H_3$ 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 2025 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, including ZYN002 and EPX-100; 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 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**

**(In thousands, except share and per share data)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Net product revenue | $ 200,489 | $ 172,814 | $ 385,222 | $ 327,429 |
| Cost of product sold | 38,153 | 32,144 | 70,147 | 59,628 |
| Gross profit | 162,336 | 140,670 | 315,075 | 267,801 |
| Operating expenses: | | | | |
| Research and development | 50,159 | 63,583 | 84,699 | 85,772 |
| Sales and marketing | 30,073 | 28,507 | 60,784 | 55,740 |
| General and administrative | 33,924 | 27,224 | 65,167 | 52,900 |
| Total operating expenses | 114,156 | 119,314 | 210,650 | 194,412 |
| Operating income | 48,180 | 21,356 | 104,425 | 73,389 |
| Other expense, net | (193) | 37 | (469) | (104) |
| Interest expense | (3,646) | (4,404) | (7,482) | (8,939) |
| Interest income | 5,296 | 4,705 | 10,340 | 9,133 |
| Income before income taxes | 49,637 | 21,694 | 106,814 | 73,479 |
| Income tax expense | (9,861) | (10,103) | (21,478) | (23,554) |
| Net income | $ 39,776 | $ 11,591 | $ 85,336 | $ 49,925 |
| Unrealized income (loss) on investments | (6) | (63) | 173 | (236) |
| Comprehensive income | $ 39,770 | $ 11,528 | $ 85,509 | $ 49,689 |
| EARNINGS PER SHARE: | | | | |
| Basic | $ 0.69 | $ 0.20 | $ 1.49 | $ 0.88 |
| Diluted | $ 0.68 | $ 0.20 | $ 1.46 | $ 0.87 |
| Weighted average number of shares of common stock - basic | 57,469,775 | 56,802,357 | 57,390,298 | 56,786,873 |
| Weighted average number of shares of common stock - diluted | 58,427,134 | 57,541,696 | 58,468,717 | 57,571,570 |

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

| | June 30, 2025 | December 31 2024 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 546,050 | $ 453,001 |
| Investments, short-term | 19,224 | 14,185 |
| Trade receivables, net | 92,981 | 83,033 |
| Inventory, net | 6,100 | 7,198 |
| Prepaid expenses | 18,363 | 13,714 |
| Other current assets | 8,636 | 8,121 |
| Total current assets | 691,354 | 579,252 |
| NONCURRENT ASSETS: | | |
| Property and equipment, net | 1,376 | 1,257 |
| Restricted cash | 270 | 270 |
| Investments, long-term | 107,008 | 108,874 |
| Intangible assets, net | 101,341 | 113,263 |
| Deferred tax asset | 201,194 | 190,398 |
| Other noncurrent assets | 5,465 | 5,886 |
| Total noncurrent assets | 416,654 | 419,948 |
| TOTAL ASSETS | $ 1,108,008 | $ 999,200 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Trade payables | $ 28,301 | $ 13,744 |

| | | |
|---|---|---|
| Accrued compensation | 11,735 | 18,776 |
| Accrued expenses | 118,293 | 120,640 |
| Current portion of long-term debt | 18,750 | 16,250 |
| Other current liabilities | 3,056 | 5,672 |
| Total current liabilities | 180,135 | 175,082 |
| NONCURRENT LIABILITIES: | | |
| Long-term debt, net | 153,345 | 163,016 |
| Other noncurrent liabilities | 1,448 | 1,947 |
| Total noncurrent liabilities | 154,793 | 164,963 |
| TOTAL LIABILITIES | 334,928 | 340,045 |
| COMMITMENTS AND CONTINGENCIES (Note 13) | | |
| STOCKHOLDERS' EQUITY: | | |
| Common stock—$0.00001 par value; 500,000,000 shares authorized at June 30, 2025 and December 31, 2024, respectively; 57,537,869 and 57,144,887 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively | 1 | 1 |
| Additional paid in capital | 685,288 | 656,872 |
| Accumulated other comprehensive income | 239 | 66 |
| Retained earnings | 87,552 | 2,216 |
| TOTAL STOCKHOLDERS' EQUITY | 773,080 | 659,155 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | $ 1,108,008 | $ 999,200 |

**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 | | Six Months Ended | |
|---|---|---|---|---|
| | June 30, 2025 | June 30, 2024 | June 30, 2025 | June 30, 2024 |
| **GAAP net income** (1) | **$ 39,776** | **$ 11,591** | **$ 85,336** | **$ 49,925** |
| Non-GAAP Adjustments: | | | | |
| Non-cash interest expense (2) | 163 | 176 | 329 | 356 |
| Depreciation | 6 | 91 | 13 | 254 |
| Amortization (3) | 5,961 | 5,961 | 11,922 | 11,922 |
| Stock-based compensation expense | 11,394 | 10,963 | 23,844 | 21,397 |
| Income tax effect related to non-GAAP adjustments (4) | (3,481) | (4,282) | (7,261) | (8,632) |
| Non-GAAP adjusted net income (1) | $ 53,819 | $ 24,500 | $ 114,183 | $ 75,222 |
| **GAAP reported net income per diluted share** | **$ 0.68** | **$ 0.20** | **$ 1.46** | **$ 0.87** |
| Non-GAAP adjusted net income per diluted share | $ 0.92 | $ 0.43 | $ 1.95 | $ 1.31 |
| Weighted average number of shares of common stock used in non-GAAP diluted per share | 58,427,134 | 57,541,696 | 58,468,717 | 57,571,570 |

(1) Includes a $15,000 million IPR&D charge related to an upfront fee incurred upon closing the CiRC research collaboration agreement for the three and six months ended June 30, 2025. Includes a $25,500 charge related to an upfront license fee incurred upon closing the 2024 Bioprojet Sublicense Agreement and a $17,095 IPR&D charge related to the acquisition of Epygenix for the three and six months ended June 30, 2024.

(2) Includes amortization of deferred finance charges.

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

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

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