# Harmony Biosciences Reports Strong Second Quarter 2024 Financial Results and Advances Pitolisant High-Dose Program Toward Expected PDUFA Date in 2028

August 6, 2024 11:30 AM EDT

*WAKIX® (pitolisant) Net Revenue of $172.8 Million for Second Quarter 2024; ~29% Growth Year-over-Year*

*Next Generation Pitolisant High-Dose (HD) Program Advances Based on Pilot Pharmacokinetic (PK) Data with PDUFA Date Expected in 2028 to Extend Pitolisant Franchise Beyond 2040*

*WAKIX Patent Upheld Again - U.S. Patent and Trademark Office (USPTO) Issues Final Denial After Two Attempts to Challenge the WAKIX Patent*

*Received U.S. Food and Drug Administration (FDA) Approval and Launched WAKIX for the Treatment of EDS in Pediatric Patients with Narcolepsy Providing the First and Only Non-Scheduled Treatment Option*

*On Track to Submit Supplemental New Drug Application for Pitolisant in Idiopathic Hypersomnia (IH) in Fourth Quarter 2024*

*Reiterates 2024 Net Product Revenue Guidance of $700 - $720 Million*

*Company to Host Investor Day in New York City on October 1st*

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

PLYMOUTH MEETING, Pa., Aug. 06, 2024 (GLOBE NEWSWIRE) -- Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY), today reported year-over-year net revenue growth of 29 percent for the quarter ended June 30, 2024. In addition, with the goal of addressing ongoing unmet medical needs in the narcolepsy market, the next generation pitolisant-HD development program is advancing and on track towards an expected PDUFA date in 2028.

“We made substantial progress and continue to advance our pitolisant high-dose development program, targeting a PDUFA date in 2028, giving us the opportunity to extend the pitolisant franchise beyond 2040,” said Jeffrey M. Dayno, M.D., President and Chief Executive Officer of Harmony. “In addition, we are executing on our late-stage pipeline across three orphan/rare CNS franchises, which we expect to deliver at least one new product or indication launch every year over the next five years, with multi-billion-dollar revenue potential extending beyond 2040. We also delivered another strong quarter of revenue growth for WAKIX, confirming our confidence in WAKIX being a billion dollar plus market opportunity in narcolepsy alone, while gaining the approval and launching WAKIX in pediatric narcolepsy.”

**Key Franchise Highlights:**

***Sleep/Wake***

- WAKIX Net Revenue of $172.8 million in the second quarter of 2024, representing 29% growth over the same period in 2023.
- The average number of patients on WAKIX increased by approximately 250 patients sequentially to approximately 6,550 for the quarter ended June 30, 2024.
- WAKIX patent upheld again. We announced that the USPTO has issued a final denial of the petition for reexamination, which was filed by a short seller. This denial is non-appealable and reinforces our confidence in the strength of our patents, the validity of the patent portfolio, and our ability to rigorously enforce the intellectual property rights protecting WAKIX.
- Received FDA approval for WAKIX for the treatment of EDS in pediatric patients 6 years and older with narcolepsy on June 21, 2024, and executed commercial launch July 1, 2024.
- On track to submit supplemental new drug application (sNDA) for pitolisant in IH in the fourth quarter of 2024.
- Pitolisant Gastro-Resistant (GR): On track to initiate Dosing Optimization study in the fourth quarter of 2024 and Pivotal Bioequivalence study in the first quarter of 2025. PDUFA date expected in 2026. Provisional patent filed with the potential for patent protection out to 2044.
- Pitolisant HD: Pilot PK data showed meaningful differentiation with at least a ~ 20% increase in relative bioavailability and a decrease in the variability of the PK profile compared to an equivalent WAKIX dose of 35.6 mg, the highest labeled dose. Formulation optimization work continues, and we plan to study up to two times the current highest

labeled dose of WAKIX, where we expect to demonstrate a further increase in relative bioavailability and decrease in variability in the PK profile. An optimized PK profile, along with a higher dose, GR coating and targeting unique symptoms (e.g., fatigue in narcolepsy, in addition to EDS and cataplexy) is expected to provide a differentiated product profile and label compared to WAKIX. PDUFA date expected in 2028. Provisional patent filed with the potential for patent protection out to 2044.
- Patient enrollment is ongoing in Phase 3 TEMPO study in patients with Prader-Willi syndrome (PWS).
- TPM-1116, a highly potent and selective oral orexin-2 receptor agonist that will be evaluated for the treatment of narcolepsy and other sleep-wake disorders. IND enabling studies are ongoing and we expect to file an IND in mid-2025 and initiate first-in-human studies in the second half of 2025.
- Completed pre-clinical POC study for HBS-102 in PWS with encouraging initial results; final study report and results to be shared later this year.

***Neurobehavioral***

- On track for topline data from the Phase 3 RECONNECT registrational trial of ZYN002 in Fragile X syndrome (FXS) in mid-2025.
- Phase 3 preparation ongoing for ZYN002 in 22q11.2 deletion syndrome (22q).

***Rare Epilepsy***

- EPX-100 is a potent, oral, centrally acting serotonin (5HT2) agonist, currently in a pivotal registrational trial (ARGUS) for Dravet syndrome (DS) with topline data expected in 2026.
- Phase 3 trial for Lennox-Gastaut syndrome (LGS), expected to initiate later this year.
- EPX-200 is a potent, oral, centrally acting and selective 5HT2C agonist, and is currently in IND-enabling stage.

**Second Quarter 2024 Financial Results**

Net product revenues for the quarter ended June 30, 2024, were $172.8 million, compared to $134.2 million for the same period in 2023. The 29% 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 US) 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 250 sequentially to approximately 6,550 for the quarter ended June 30, 2024.

GAAP net income for the quarter ended June 30, 2024, was $11.6 million, or $0.20 earnings per diluted share, compared to GAAP net income of $34.3 million, or $0.56 earnings per diluted share, for the same period in 2023. The decrease in GAAP net income was primarily driven by a $25.5 million upfront licensing fee paid as part of the 2024 Bioprojet Sublicensing Agreement for TPM-1116 and a $17.1 million IPR&D charge related to the acquisition of Epygenix. Non-GAAP adjusted net income was $60.6 million, or $1.05 earnings per diluted share, for the quarter ended June 30, 2024, compared to Non-GAAP adjusted net income of $45.9 million, or $0.76 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 include the following:

- Research and Development expenses were $63.6 million in the second quarter of 2024, as compared to $15.0 million for the same quarter in 2023, representing a 325% increase, primarily driven by a $25.5 million upfront licensing fee as part of the 2024 Bioprojet Sublicense Agreement and a $17.1 million IPR&D charge related to the acquisition of Epygenix;
- Sales and Marketing expenses were $28.5 million in the second quarter of 2024, as compared to $24.5 million for the same quarter in 2023, representing a 16% increase;
- General and Administrative expenses were $27.2 million in the second quarter of 2024, as compared to $22.8 million for the same quarter in 2023, representing a 19% increase; and
- Total Operating Expenses were $119.3 million in the second quarter of 2024, as compared to $62.3 million for the same quarter in 2023, representing a 92% increase.

As of June 30, 2024, Harmony had cash, cash equivalents and investments of $434.1 million, compared to $425.6 million as of December 31, 2023.

**Reiterates 2024 Net Product Revenue Guidance**

Expect full year 2024 net product revenue of $700 million to $720 million.

**Share Repurchase Program**

The remaining amount of common stock authorized for repurchases as of June 30, 2024, was $150 million.

**Investor Day on October 1st**

The company will host an investor day in New York City on October 1st. Additional event details to follow.

**Conference Call Today at 8:30 a.m. ET**
We are hosting our second quarter 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) 225-9448 (domestic) or +1 (203) 518-9708 (international), and reference passcode HRMYQ224.

**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 or cataplexy in adult patients with narcolepsy and has been commercially available in the U.S. since Q4 2019. 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 (see full prescribing information). WAKIX is 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.

**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 (see full prescribing information).

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. Therefore, reduced effectiveness of sensitive CYP3A4 substrates may occur when used concomitantly with WAKIX. The effectiveness of hormonal contraceptives may be reduced when used with WAKIX and effectiveness may be reduced for 21 days after discontinuation of therapy.

**Use in Specific Populations**
WAKIX may reduce the effectiveness of 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.

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 in patients less than 18 years of age.

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 moderate or severe renal impairment.

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 Prader-Willi syndrome**
PWS is an orphan/rare, genetic neurological disorder with many of the symptoms resulting from hypothalamic dysfunction. The hypothalamus is the part of the brain that controls both sleep-wake state stability and signals that mediate the balance between hunger and satiety, resulting in two of the main symptoms in patients with PWS; EDS and hyperphagia (an intense persistent sensation of hunger accompanied by food preoccupations, an extreme drive to consume food, food-related behavior problems, and a lack of normal satiety). Other features include low muscle tone, short stature, behavioral problems, and cognitive impairment. Approximately 15,000 to 20,000 people in the U.S. live with PWS, and over half of them experience EDS and the majority of them have behavioral disturbances.

**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 22q11.2 Deletion Syndrome**
22q11.2 deletion syndrome (22q) is a disorder caused by a small missing piece of the 22nd chromosome. The deletion occurs near the middle of the chromosome at a location designated q11.2. It is considered a mid-line condition, with physical symptoms including characteristic palate abnormalities, heart defects, immune dysfunction, and esophageal/ GI issues, as well as debilitating neuropsychiatric and behavioral symptoms, including anxiety, social withdrawal, ADHD, cognitive impairment and autism spectrum disorder. It is estimated that 22q occurs in one in 4,000 live births, suggesting that there are approximately 80,000 people living with 22q in the U.S. and 129,000 in the European Union and the UK. Patients with 22q deletion syndrome are managed by multidisciplinary care providers, and there are currently no FDA approved treatments for this disorder.

**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.[1] 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**
At Harmony Biosciences, we specialize in developing and delivering treatments for rare neurological diseases that others often overlook. We believe that where empathy and innovation meet, a better life can begin for people living with neurological diseases. Established by Paragon Biosciences, LLC, in 2017 and headquartered in Plymouth Meeting, PA, our team of experts from a wide variety of disciplines and experiences is driven by our shared conviction that innovative science translates into therapeutic possibilities for our patients, who are at the heart of everything we do. 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 22, 2024, 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**
**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, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Net product revenue | $ 172,814 | $ 134,216 | $ 327,429 | $ 253,342 |
| Cost of product sold | 32,144 | 25,008 | 59,628 | 45,788 |
| Gross profit | 140,670 | 109,208 | 267,801 | 207,554 |
| Operating expenses: | | | | |
| Research and development | 63,583 | 14,969 | 85,772 | 28,258 |
| Sales and marketing | 28,507 | 24,528 | 55,740 | 47,100 |
| General and administrative | 27,224 | 22,809 | 52,900 | 44,871 |
| Total operating expenses | 119,314 | 62,306 | 194,412 | 120,229 |
| Operating income | 21,356 | 46,902 | 73,389 | 87,325 |
| Other (expense) income, net | 37 | (31) | (104) | (29) |
| Interest expense | (4,404) | (6,218) | (8,939) | (11,949) |
| Interest income | 4,705 | 3,442 | 9,133 | 6,528 |
| Income before income taxes | 21,694 | 44,095 | 73,479 | 81,875 |
| Income tax expense | (10,103) | (9,795) | (23,554) | (18,090) |
| Net income | $ 11,591 | $ 34,300 | $ 49,925 | $ 63,785 |
| Unrealized (loss) income on investments | (63) | (491) | (236) | (371) |
| Comprehensive income | $ 11,528 | $ 33,809 | $ 49,689 | $ 63,414 |
| EARNINGS PER SHARE: | | | | |
| Basic | $ 0.20 | $ 0.57 | $ 0.88 | $ 1.07 |
| Diluted | $ 0.20 | $ 0.56 | $ 0.87 | $ 1.05 |
| Weighted average number of shares of common stock - basic | 56,802,357 | 59,974,123 | 56,786,873 | 59,853,808 |
| Weighted average number of shares of common stock - diluted | 57,541,696 | 60,743,953 | 57,571,570 | 60,997,410 |

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

| | June 30, 2024 | December 31, 2023 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 317,296 | $ 311,660 |

| | | |
|---|---|---|
| Investments, short-term | 29,614 | 41,800 |
| Trade receivables, net | 83,157 | 74,140 |
| Inventory, net | 5,643 | 5,363 |
| Prepaid expenses | 16,127 | 12,570 |
| Other current assets | 6,507 | 5,537 |
| Total current assets | 458,344 | 451,070 |
| NONCURRENT ASSETS: | | |
| Property and equipment, net | 754 | 371 |
| Restricted cash | 270 | 270 |
| Investments, long-term | 87,178 | 72,169 |
| Intangible assets, net | 125,186 | 137,108 |
| Deferred tax asset | 180,186 | 144,162 |
| Other noncurrent assets | 6,465 | 6,298 |
| Total noncurrent assets | 400,039 | 360,378 |
| TOTAL ASSETS | $ 858,383 | $ 811,448 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Trade payables | $ 22,683 | $ 17,730 |
| Accrued compensation | 9,641 | 23,747 |
| Accrued expenses | 91,644 | 99,494 |
| Current portion of long-term debt | 15,000 | 15,000 |
| Other current liabilities | 7,614 | 7,810 |
| Total current liabilities | 146,582 | 163,781 |
| NONCURRENT LIABILITIES: | | |
| Long-term debt, net | 171,422 | 178,566 |
| Other noncurrent liabilities | 1,796 | 2,109 |
| Total noncurrent liabilities | 173,218 | 180,675 |
| TOTAL LIABILITIES | 319,800 | 344,456 |
| COMMITMENTS AND CONTINGENCIES (Note 13) | | |
| STOCKHOLDERS' EQUITY: | | |
| Common stock—$0.00001 par value; 500,000,000 shares authorized at June 30, 2024 and December 31, 2023, respectively; 56,833,771 and 56,769,081 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively | 1 | 1 |
| Additional paid in capital | 632,168 | 610,266 |
| Accumulated other comprehensive (loss) income | (234) | 2 |
| Accumulated deficit | (93,352) | (143,277) |
| TOTAL STOCKHOLDERS' EQUITY | 538,583 | 466,992 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | $ 858,383 | $ 811,448 |

**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, 2024 | June 30, 2023 | June 30, 2024 | June 30, 2023 |
| **GAAP net income** | **$ 11,591** | **$ 34,300** | **$ 49,925** | **$ 63,785** |
| Non-GAAP Adjustments: | | | | |
| Non-cash interest expense (1) | 176 | 424 | 356 | 840 |
| Depreciation | 91 | 103 | 254 | 206 |
| Amortization (2) | 5,961 | 5,961 | 11,922 | 11,922 |
| Stock-based compensation expense | 10,963 | 7,793 | 21,397 | 14,354 |
| Licensing fee and milestone payments (3) | 25,500 | - | 25,500 | 750 |
| Transaction related costs (4) | 17,095 | - | 17,095 | - |
| Income tax effect related to non-GAAP adjustments (5) | (10,769) | (2,712) | (15,119) | (5,252) |
| Non-GAAP adjusted net income | $ 60,608 | $ 45,869 | $ 111,330 | $ 86,605 |

| | | | | |
|---|---|---|---|---|
| **GAAP reported net income per diluted share** | **$ 0.20** | **$ 0.56** | **$ 0.87** | **$ 1.05** |
| Non-GAAP adjusted net income per diluted share | $ 1.05 | $ 0.76 | $ 1.93 | $ 1.42 |
| Weighted average number of shares of common stock used in non-GAAP diluted per share | 57,541,696 | 60,743,953 | 57,571,570 | 60,997,410 |

(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 and milestone payment related to HBS102 in March 2023.
(4) Includes IPR&D charge related to the acquisition of Epygenix.
(5) Calculated using the reported effective tax rate for the periods presented less impact of discrete items.

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Source: Harmony Biosciences