HARMONY BIOSCIENCES REPORTS STRONG THIRD QUARTER 2024 FINANCIAL RESULTS AND HIGHLIGHTS CATALYST-RICH, LATE-STAGE PIPELINE POISED TO DELIVER ONE OR MORE NEW LAUNCHES EVERY YEAR OVER NEXT FIVE YEARS

October 29, 2024 11:30 AM EDT

WAKIX (pitolisant) Net Revenue of $186.0 Million for Third Quarter 2024; Surpassed $2B in Cumulative Net Revenue in Less Than Five Years

On Track to Submit sNDA for Pitolisant in Idiopathic Hypersomnia (IH) in Q4 2024 Based on Updated Strong and Sustained Efficacy Data from Long-Term Extension Study

Next-Gen Pitolisant-GR and Pitolisant-HD Programs Advance; IND for Potential Best-In-Class, Novel Orexin-2 Agonist On Track for mid-2025, Extending Leadership in Sleep/Wake Beyond 2040s

Highlights Most Advanced Development Program and Proven Serotonergic (5-HT_2) Mechanism of Action For EPX-100 in Rare Epilepsies; Pivotal Phase 3 Trial in Dravet Syndrome Ongoing; Phase 3 Registrational Trial in Lennox-Gastaut Syndrome to Initiate Before Year End

Next Major Clinical Catalyst: Topline Data From ZYN-002 Pivotal Phase 3 RECONNECT Trial in Fragile X Syndrome on Track For mid-2025

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

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

PLYMOUTH MEETING, Pa., Oct. 29, 2024 /PRNewswire/ -- Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY), today reported a record $186.0 million in net revenue for the quarter ending on September 30, 2024, surpassing $2 billion in cumulative net revenues since the launch of WAKIX® in adult narcolepsy in November of 2019. In addition, the company recently hosted an Investor Day on October 1, during which it highlighted its transformation into an innovative, catalyst-rich, self-funding biotech company with a robust late-stage pipeline.

"Going into Q4, Harmony has great momentum. During our Investor Day, we shared new data in support of our confidence and excitement about the company's growth trajectory as we advance our robust, catalyst-rich, late-stage pipeline and expand into additional rare CNS therapeutic areas. We are building on our success in sleep/wake with a strategy focused on continuous innovation, patient impact, and long-term value creation for our shareholders, and, if successful, our current pipeline is poised to deliver over $3 billion in net revenue going forward," said Jeffrey M. Dayno, M.D., President and Chief Executive Officer of Harmony Biosciences. "We have been building a leading CNS biotech company and are committed to addressing unmet medical

needs for people living with CNS disorders that have few or no treatment options and, when we deliver on this promise to patients, we have the potential to deliver significant value to our shareholders as well."

Key Franchise Highlights:

Sleep/Wake: Extending Leadership Position

WAKIX:

- Net Sales for the quarter were $186.0M; with these quarterly sales, WAKIX surpassed $2B in cumulative net revenue in less than five years on the market
- The average number of patients on WAKIX increased by approximately 250 patients sequentially to approximately 6,800 for the quarter ended September 30, 2024

Pitolisant in Idiopathic Hypersomnia (IH):

- New data from the Long-Term Extension study demonstrate robust and sustained efficacy of pitolisant in patients with idiopathic hypersomnia

  Mean improvement in Epworth Sleepiness Scale (ESS) was ~9 points from baseline out beyond one year, with the majority of patients in the normal range as measured by the ESS

  Sustained efficacy was also observed on the Idiopathic Hypersomnia Severity Scale (IHSS) and Sleep Inertia Questionnaire (SIQ) beyond one year

- Data supports strong benefit/risk proposition; on track to submit sNDA in Q4 2024

Pitolisant-HD (high dose) program:

- Pitolisant-HD is an enhanced formulation of pitolisant designed with the following attributes:

  A higher dose with an optimized pharmacokinetic profile to drive greater efficacy in EDS and cataplexy

  Targeting a unique indication for fatigue in narcolepsy

  A gastro-resistant coating with no need for a titration dose

- Preliminary safety data up to 5x the current highest labeled dose of WAKIX are consistent with the established safety profile of WAKIX and establish safety margins for the pitolisant-HD development program
- Pitolisant-HD on track for PDUFA in 2028 with the goal to extend the pitolisant franchise to mid-2040s
- Provisional patents filed until 2044 with the opportunity to grow the pitolisant franchise by pursuing additional indications

Pitolisant-GR (gastro-resistant) program:

- Pitolisant-GR is a gastro-resistant formulation of pitolisant designed to minimize GI tolerability issues in patients with narcolepsy; approximately 90% of patients with narcolepsy experience GI symptoms partly related to the underlying disease mechanism
- On track to initiate pivotal bioequivalence study and dosing optimization study (to remove the titration dose) in Q1 2025
- PDUFA on track for 2026 with IP to the mid-2040s

Orexin-2 agonist program:

- BP1.15205 (formerly TPM-1116) potential to be best-in-class orexin-2 receptor agonist

  Based on a novel chemical scaffold

  Demonstrated greater potency compared to all publicly disclosed data on orexin-2 agonists; allows for dosing flexibility to target all central disorders of hypersomnolence. The potency was consistent across species along with an excellent selectivity of greater than 600x which translates to over 140-fold margin over orexin-1 receptors at the anticipated maximum human dose

  In addition, BP1.15205 demonstrated over 1000-fold selectively over 150 other targets of interest

  Preclinical PK data consistent with once-a-day dosing

Rare Epilepsy: Most Advanced Development Program in the 5-HT_2 agonist class

EPX-100 (clemizole hydrochloride):

- MoA: Proven serotonergic (5-HT_2) mechanism of action in Developmental Epileptic Encephalopathies (DEEs) confirmed via a validated and highly predictive preclinical model (zebra fish model)
- Most advanced development program for the DEEs:

  EPX-100 in Phase 3 registration trial, ARGUS study, in patients with Dravet syndrome (DS); on track for topline data in 2026
- EPX-100 Phase 3 registration trial for Lennox-Gastaut syndrome (LGS) on track to initiate later this year
- Preliminary Safety and Tolerability data suggests favorable profile compared to select approved drugs for rare epilepsies (with no need for routine laboratory or cardiac monitoring)
- Received Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) by the FDA for DS and LGS

EPX-200 (lorcaserin hydrochloride):

- MoA: Potent, selective $5HT_{2C}$ agonist with proven mechanism of action in DEEs confirmed via non-clinical and clinical data
- Currently in IND-enabling stage
- Received ODD for DS, and ODD / RPDD for LGS by the FDA; and ODD for DS by the European Medicines Agency

Neurobehavioral: Next Major Clinical Catalyst

ZYN-002

- Pivotal Phase 3 RECONNECT trial in Fragile X syndrome ongoing; topline data on track for mid-2025
- Anticipate initiation of pivotal Phase 3 trial in 22q11.2 deletion syndrome (22q) in 2025

Third Quarter 2024 Financial Results

Net product revenues for the quarter ended September 30, 2024, were $186.0 million, compared to $160.3 million for the same period in 2023. The 16% 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 250 sequentially to approximately 6,800 for the quarter ended September 30, 2024.

GAAP net income for the quarter ended September 30, 2024, was $46.1 million, or $0.79 earnings per diluted share, compared to GAAP net income of $38.5 million, or $0.63 earnings per diluted share, for the same period in 2023. Non-GAAP adjusted net income was $59.6 million, or $1.03 earnings per diluted share, for the quarter ended September 30, 2024, compared to Non-GAAP adjusted net income of $58.8 million, or $0.97 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 $25.4 million in the third quarter of 2024, as compared to $17.5 million for the same quarter in 2023, representing a 45% increase;
- Sales and Marketing expenses were $27.6 million in the third quarter of 2024, as compared to $23.4 million for the same quarter in 2023, representing a 18% increase;
- General and Administrative expenses were $28.6 million in the third quarter of 2024, as compared to $22.5 million for the same quarter in 2023, representing a 27% increase; and
- Total Operating Expenses were $81.6 million in the third quarter of 2024, as compared to $63.5 million for the same quarter in 2023, representing a 29% increase.

As of September 30, 2024, Harmony had cash, cash equivalents and investments of $504.7 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 September 30, 2024, was $150 million.

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

We are hosting our third 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) 245-3047 (domestic) or (203) 518-9765 (international), and reference passcode HRMYQ324.

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 (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 recommended 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 m^2.

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 ZYN-002
ZYN-002 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. ZYN-002 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 ZYN-002, 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, ZYN-002 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. 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 Lorcaserin (EPX-200)
EPX-200, liquid formulation of lorcaserin is under development for the treatment of DEEs (Developmental Epileptic Encephalopathies). EPX-200 is a selective 5-HT2C receptor agonist. The drug candidate is developed based on a proprietary phenotype-based zebrafish drug screening platform and clinical data in patients with DEEs1,2.

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 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
UNAUDITED CONDENSED CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net product revenue	$ 186,038	$ 160,268	$ 513,467	$ 413,610
Cost of product sold	42,778	32,296	102,406	78,084
Gross profit	143,260	127,972	411,061	335,526
Operating expenses:				
Research and development	25,387	17,499	111,159	45,757
Sales and marketing	27,576	23,418	83,316	70,518
General and administrative	28,587	22,546	81,487	67,417
Total operating expenses	81,550	63,463	275,962	183,692
Operating income	61,710	64,509	135,099	151,834
Loss on debt extinguishment	—	(9,766)	—	(9,766)
Other (expense) income, net	(124)	(5)	(228)	(34)
Interest expense	(4,348)	(7,012)	(13,287)	(18,961)
Interest income	4,932	4,106	14,065	10,634
Income before income taxes	62,170	51,832	135,649	133,707
Income tax expense	(16,077)	(13,371)	(39,631)	(31,461)
Net income	$ 46,093	$ 38,461	$ 96,018	$ 102,246
Unrealized (loss) income on investments	733	6	497	(365)
Comprehensive income	$ 46,826	$ 38,467	$ 96,515	$ 101,881
EARNINGS PER SHARE:				
Basic	$ 0.81	$ 0.64	$ 1.69	$ 1.71
Diluted	$ 0.79	$ 0.63	$ 1.66	$ 1.68
Weighted average number of shares of common stock - basic	56,870,234	59,863,102	56,815,167	59,856,941
Weighted average number of shares of common stock - diluted	58,103,963	60,681,676	57,754,016	60,892,992

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

	September 30,	December 31,

	2024	2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 387,367	$ 311,660
Investments, short-term	23,109	41,800
Trade receivables, net	81,502	74,140
Inventory, net	6,915	5,363
Prepaid expenses	16,057	12,570
Other current assets	7,455	5,537
Total current assets	522,405	451,070
NONCURRENT ASSETS:		
Property and equipment, net	750	371
Restricted cash	270	270
Investments, long-term	94,222	72,169
Intangible assets, net	119,225	137,108
Deferred tax asset	185,016	144,162
Other noncurrent assets	6,247	6,298
Total noncurrent assets	405,730	360,378
TOTAL ASSETS	$ 928,135	$ 811,448
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 10,532	$ 17,730
Accrued compensation	14,224	23,747
Accrued expenses	109,673	99,494
Current portion of long-term debt	15,000	15,000
Other current liabilities	11,850	7,810
Total current liabilities	161,279	163,781
NONCURRENT LIABILITIES:		
Long-term debt, net	167,847	178,566
Other noncurrent liabilities	2,205	2,109
Total noncurrent liabilities	170,052	180,675
TOTAL LIABILITIES	331,331	344,456
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at September 30, 2024 and December 31, 2023, respectively; 57,030,897 and 56,769,081 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	1	1
Additional paid in capital	643,563	610,266
Accumulated other comprehensive (loss) income	499	2
Accumulated deficit	(47,259)	(143,277)
TOTAL STOCKHOLDERS' EQUITY	596,804	466,992
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 928,135	$ 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		Nine Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
GAAP net income	**$ 46,093**	**$ 38,461**	**$ 96,018**	**$ 102,246**
Non-GAAP Adjustments:				
Non-cash interest expense (1)	175	2,221	531	3,061
Depreciation	7	144	261	350
Amortization (2)	5,961	5,962	17,883	17,884

Stock-based compensation expense	11,448	7,957	32,845	22,311
Licensing fee and milestone payments (3)	1,000	-	26,500	750
Loss on debt extinguishment (4)	-	9,766	-	9,766
Transaction related costs (5)	-	-	17,095	-
Income tax effect related to non-GAAP adjustments (6)	(5,096)	(5,723)	(20,215)	(10,987)
Non-GAAP adjusted net income	$ 59,596	$ 58,788	$ 170,926	$ 145,381
GAAP reported net income per diluted share	**$ 0.79**	**$ 0.63**	**$ 1.66**	**$ 1.68**
Non-GAAP adjusted net income per diluted share	$ 1.03	$ 0.97	$ 2.96	$ 2.39
Weighted average number of shares of common stock used in non-GAAP diluted per share	58,103,963	60,681,676	57,754,016	60,892,992

(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 acquisition of Epygenix.

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

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