



Harmony Biosciences Reports Fourth Quarter and Full Year 2023 Financial Results and Business Updates

Feb 22, 2024 at 7:30 AM EST

WAKIX® (pitolisant) Net Revenue of \$168.4 Million for Fourth Quarter and \$582.0 Million for Full Year 2023; Representing Growth of ~31% and ~33%, Respectively

U.S. Food and Drug Administration (FDA) Granted Priority Review for WAKIX in Pediatric Narcolepsy; PDUFA Date of June 21, 2024

Meeting with FDA to Discuss Idiopathic Hypersomnia Development Program Scheduled for March 2024

FDA Granted Orphan Drug Designation to Pitolisant for the Treatment of Prader-Willi Syndrome; On Track to Initiate Phase 3 TEMPO Study in First Quarter 2024

2024 Net Product Revenue Projected Between \$700 - \$720 Million

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

PLYMOUTH MEETING, Pa., Feb. 22, 2024 (GLOBE NEWSWIRE) -- Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY), today reported net revenue growth of more than 30% for the fourth quarter and full year ended December 31, 2023.

“Harmony delivered another year of outstanding performance in 2023, with continued strong growth for WAKIX, demonstrating its durability going into year five on the market,” stated Jeffrey M. Dayno, M.D., President and Chief Executive Officer of Harmony. “In addition to our strong commercial execution, we advanced all our clinical development programs for pitolisant, moved the Next-Generation formulations of pitolisant into the clinic, expanded our pipeline and diversified our portfolio with the acquisition of Zynherba and the ongoing Phase 3 trial in Fragile X syndrome. Harmony continues to be a growth story and we look forward to continued strong execution in 2024.”

Key Business Updates

- FDA granted priority review of supplemental new drug application (sNDA) for WAKIX in pediatric narcolepsy; PDUFA date of June 21, 2024
- Meeting with the FDA to discuss Idiopathic Hypersomnia (IH) development program scheduled for March 2024
- FDA granted Orphan Drug designation to pitolisant for the treatment of Prader-Willi syndrome (PWS); on track to initiate the Phase 3 TEMPO study in patients with PWS in the first quarter of 2024
- Reported positive Phase 2 proof-of-concept (POC) data in EDS and fatigue in Myotonic Dystrophy Type 1 (DM1) in the fourth quarter of 2023
- On track to report pharmacokinetic (PK) data on next-gen pitolisant-based formulations in the first half of 2024
- Expect to complete patient enrollment in the Phase 3 pivotal RECONNECT trial for Fragile X syndrome (FXS) in the first quarter of 2025 with topline data expected in mid-2025
- On track to report pre-clinical POC data for HBS-102 in PWS in the first half of 2024
- Repurchased approximately 3.2 million shares of common stock for \$100 million in full-year 2023 and expect to continue the opportunistic repurchase of shares under the remaining share repurchase program authorization of \$150 million.

Fourth Quarter 2023 Financial Results

Net product revenue for the quarter ended December 31, 2023 was \$168.4 million, compared to \$128.3 million for the same period in 2022. The 31% growth versus the same period in 2022 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). The average number of patients on WAKIX increased by approximately 350 sequentially to approximately 6,150 for the quarter ended December 31, 2023.

GAAP net income for the quarter ended December 31, 2023, was \$26.6 million, or \$0.45 per diluted share, compared to GAAP net income of \$48.5 million, or \$0.79 per diluted share, for the same period in 2022. Non-GAAP adjusted net income was \$42.8 million, or \$0.73 per diluted share, for the quarter ended December 31, 2023, compared to Non-GAAP adjusted net income of \$61.9 million, or \$1.01 per diluted share, for the same period in 2022.

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 \$30.3 million in the fourth quarter of 2023, as compared to \$10.1 million for the same quarter in 2022, representing a 200% increase. Expenses in the fourth quarter of 2023 included one-time Zynherba transaction related costs of \$6.0 million;
- Sales and Marketing expenses were \$26.9 million in the fourth quarter of 2023, as compared to \$21.1 million for the same quarter in 2022, representing a 28% increase;

- General and Administrative expenses were \$27.9 million in the fourth quarter of 2023, as compared to \$22.6 million for the same quarter in 2022, representing a 23% increase. Expenses in the fourth quarter of 2023 included one-time Zynerba transaction related costs of \$3.8 million; and
- Total Operating Expenses were \$85.1 million in the fourth quarter of 2023, as compared to \$53.8 million for the same quarter in 2022, representing a 58% increase. Total Operating Expenses in the fourth quarter of 2023 included one-time Zynerba transaction related costs of \$9.8 million.

Full Year 2023 Financial Results

Net product revenue for the year ended December 31, 2023 was \$582.0 million, compared to \$437.9 million for 2022. The 33% growth versus the same period in 2022 is primarily attributed to strong commercial sales of WAKIX driven by continued organic demand tapping into a large market opportunity.

GAAP net income for the year ended December 31, 2023, was \$128.9 million, or \$2.13 per diluted share, compared to GAAP net income of \$181.5 million, or \$2.97 per diluted share, for 2022. The decrease in GAAP net income was primarily driven by the release of the valuation allowance on our deferred tax assets, which resulted in a \$74.5 million income tax benefit for the year ended December 31, 2022. Non-GAAP adjusted net income was \$188.4 million, or \$3.12 per diluted share, for the year ended December 31, 2023, compared to Non-GAAP adjusted net income of \$183.5 million, or \$3.00 per diluted share, for 2022.

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 \$76.1 million for the year ended December 31, 2023, as compared to \$70.9 million for the prior year, representing a 7% increase. Expenses in 2023 included one-time Zynerba transaction related costs of \$6.0 million;
- Sales and Marketing expenses were \$97.4 million for the year ended December 31, 2023, as compared to \$79.3 million for the prior year, representing a 23% increase;
- General and Administrative expenses were \$95.3 million for the year ended December 31, 2023, as compared to \$84.0 million for the prior year, representing a 13% increase. Expenses in 2023 included one-time Zynerba transaction related costs of \$3.8 million; and
- Total Operating Expenses were \$268.8 million for the year ended December 31, 2023, as compared to \$234.2 million for the prior year, representing a 15% increase. Total Operating Expenses in 2023 included one-time Zynerba transaction related costs of \$9.8 million.

As of December 31, 2023, Harmony had cash, cash equivalents and investment securities of \$425.6 million, compared to \$345.7 million on December 31, 2022.

2024 Net Product Revenue Guidance

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

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

We are hosting our fourth quarter and full year 2023 financial results conference call and webcast today 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) 579-2543 (domestic) or +1 (785) 424-1789 (international), and reference passcode HRMYQ423.

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 (H₃) receptor antagonist/inverse agonist. The mechanism of action of WAKIX is unclear; however, its efficacy could be mediated through its activity at H₃ receptors, thereby increasing the synthesis and release of histamine, a wake promoting neurotransmitter. WAKIX was designed and developed by Bioprojet (France). Harmony has an exclusive license from Bioprojet to develop, manufacture and commercialize pitolisant in the United States.

Indications and Usage

WAKIX is indicated for the treatment of excessive daytime sleepiness or cataplexy in adult patients 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 ($\geq 5\%$ and twice placebo) for WAKIX were insomnia (6%), nausea (6%), and anxiety (5%). Other adverse reactions that occurred at $\geq 2\%$ and more frequently than in patients treated with placebo included headache, upper respiratory 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 Myotonic Dystrophy Type 1

Myotonic dystrophy Type 1 (DM1) is the most common form of adult-onset muscular dystrophy. It is a genetic disorder inherited in an autosomal-dominant pattern. Latest estimates suggest a prevalence of about one per 2,100 people with the genetic defect for DM1. This equates to about 150,000 people in the U.S. with the genetic defect for DM1. Estimates suggest there are 40,000 people currently diagnosed with DM1 in the U.S., with up to 90% of them reporting EDS and fatigue and over 60% of them experiencing cognitive dysfunction.

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 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 HBS-102

HBS-102, an investigational compound, is a melanin-concentrating hormone (MCH) receptor 1 (MCHR1) antagonist that targets MCH neurons in the brain. It has the potential to be a first-in-class molecule with a novel mechanism of action that could offer a new approach to the treatment of a variety of rare neurological diseases.

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 product WAKIX and our future capabilities following the acquisition of Zynerba. 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 WAKIX, 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 development activities with Bioprojet, and plans to explore the therapeutic potential of pitolisant in additional indications; our ongoing and planned clinical trials; 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 of our product candidates, including those we are developing with Bioprojet; our failure to achieve the potential benefits of the 2022 LCA with Bioprojet; our ability to recognize the intended benefits of our acquisition of Zynerba Pharmaceuticals; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; our ability to identify 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.

INCOME (LOSS)
(In thousands, except share and per share data)

	Three Months Ended		Year Ended	
	December 31,	December 31,	December 31,	December 31,
	2023	2022	2023	2022
Net product revenue	\$ 168,412	\$ 128,308	\$ 582,022	\$ 437,855
Cost of product sold	43,152	26,885	121,236	83,481
Gross profit	125,260	101,423	460,786	354,374
Operating expenses:				
Research and development	30,306	10,092	76,063	70,886
Sales and marketing	26,886	21,075	97,404	79,285
General and administrative	27,872	22,643	95,289	84,017
Total operating expenses	85,064	53,810	268,756	234,188
Operating income	40,196	47,613	192,030	120,186
Loss on debt extinguishment	—	—	(9,766)	—
Other expense (income), net	193	73	159	169
Interest expense	(4,796)	(5,444)	(23,757)	(18,795)
Interest income	4,096	1,861	14,730	3,126
Income before income taxes	39,689	44,103	173,396	104,686
Income tax benefit (expense)	(13,082)	4,406	(44,543)	76,782
Net income	\$ 26,607	\$ 48,509	\$ 128,853	\$ 181,468
EARNINGS PER SHARE:				
Basic	\$ 0.46	\$ 0.82	\$ 2.17	\$ 3.07
Diluted	\$ 0.45	\$ 0.79	\$ 2.13	\$ 2.97
Weighted average number of shares of common stock - basic	58,320,400	59,478,933	59,469,648	59,173,121
Weighted average number of shares of common stock - diluted	58,853,292	61,620,712	60,372,397	61,097,045

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

	December 31,	December 31,
	2023	2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 311,660	\$ 243,784
Investments, short-term	41,800	79,331
Trade receivables, net	74,140	54,740
Inventory, net	5,363	4,297
Prepaid expenses	12,570	9,347
Other current assets	5,537	8,786
Total current assets	451,070	400,285
NONCURRENT ASSETS:		
Property and equipment, net	371	573
Restricted cash	270	750
Investments, long-term	72,169	22,568
Intangible assets, net	137,108	160,953
Deferred tax asset	144,162	85,943
Other noncurrent assets	6,298	2,798
Total noncurrent assets	360,378	273,585
TOTAL ASSETS	\$ 811,448	\$ 673,870
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 17,730	\$ 3,786
Accrued compensation	23,747	11,532
Accrued expenses	99,494	59,942
Current portion of long-term debt	15,000	2,000
Other current liabilities	7,810	1,624
Total current liabilities	163,781	78,884

NONCURRENT LIABILITIES:			
Long-term debt, net		178,566	189,647
Other noncurrent liabilities		2,109	2,501
Total noncurrent liabilities		180,675	192,148
TOTAL LIABILITIES		344,456	271,032
COMMITMENTS AND CONTINGENCIES (Note 13)			
STOCKHOLDERS' EQUITY:			
Common stock—\$0.00001 par value; 500,000,000 shares authorized at December 31, 2023 and December 31, 2022, respectively; - shares 56,769,081 and 59,615,731 issued and outstanding at December 31, 2023 and December 31, 2022, respectively		1	1
Additional paid in capital		610,266	675,118
Accumulated other comprehensive (loss) income		2	(151)
Accumulated deficit		(143,277)	(272,130)
TOTAL STOCKHOLDERS' EQUITY		466,992	402,838
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	811,448	\$ 673,870

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

	Three Months Ended		Year Ended	
	December 31,	December 31,	December 31,	December 31,
	2023	2022	2023	2022
GAAP net income	\$ 26,607	\$ 48,509	\$ 128,853	\$ 181,468
Non-GAAP Adjustments:				
Non-cash interest expense (1)	185	422	3,246	1,663
Depreciation	164	107	514	419
Amortization (2)	5,961	5,961	23,845	22,966
Stock-based compensation expense	8,894	7,671	31,205	26,905
Transaction related costs (3)	9,804	-	9,804	-
Loss on debt extinguishment	-	-	9,766	-
Licensing fees and milestone payments (4)	-	-	750	30,000
Valuation allowance release	-	-	-	(74,474)
Income tax effect related to non-GAAP adjustments (5)	(8,789)	(731)	(19,624)	(5,409)
Non-GAAP adjusted net income	\$ 42,826	\$ 61,939	\$ 188,359	\$ 183,538
GAAP reported net income per diluted share	\$ 0.45	\$ 0.79	\$ 2.13	\$ 2.97
Non-GAAP adjusted net income per diluted share	\$ 0.73	\$ 1.01	\$ 3.12	\$ 3.00
Weighted average number of shares of common stock used in non-GAAP diluted per share	58,853,292	61,620,712	60,372,397	61,097,045

(1) Includes amortization of deferred finance charges.

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

(3) Includes costs associated with the acquisition of Zynherba in October 2023. There were \$2.3M of IPR&D charges and \$3.7M of severance recorded in research and development expenses and \$3.8M of severance recorded in general and administrative expenses.

(4) Includes a \$0.8M milestone payment related to HBS-102 preclinical milestone in March 2023 and \$30M licensing fee incurred upon closing the 2022 Licensing and Commercialization Agreement with Bioprojet in August 2022.

(5) Calculated using the reported effective tax rate for the periods presented less impact of valuation allowance release and discrete items.

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