Harmony Biosciences Reports Strong Third Quarter 2023 Financial Results

Oct 31, 2023 at 7:30 AM EDT

Continued Strong Growth with WAKIX® (pitolisant) Net Revenue of $160.3 Million for Third Quarter 2023; Increased ~37% Year-over-Year

Average Number of Patients on WAKIX Increased by ~350 Sequentially to ~5,800 for Third Quarter 2023

Remain Committed and Continue to Pursue Idiopathic Hypersomnia Indication; Next Step to Meet with FDA Informed by Review of Full Data Set

Expanded and Diversified Pipeline with Acquisition of Zynerba Pharmaceuticals; Zygel™ in Pivotal Phase 3 Trial for Fragile X syndrome

Repurchased ~1.4 Million Shares of Common Stock for $50 Million in Third Quarter 2023; Board of Directors Authorized New $200 Million Share Repurchase Program

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

PLYMOUTH MEETING, Pa., Oct. 31, 2023 (GLOBE NEWSWIRE) -- Harmony Biosciences Holdings, Inc. (“Harmony” or the “Company”) (Nasdaq: HRMY), a pharmaceutical company dedicated to developing and commercializing innovative therapies for patients with rare neurological diseases, today reported financial results and business updates for the quarter ended September 30, 2023.

“We continue to demonstrate very strong growth in our commercial business, with WAKIX in narcolepsy delivering the strongest revenue quarter in Harmony's history,” stated Jeffrey M. Dayno, M.D., President and Chief Executive Officer of Harmony. “In addition, we advanced our pitolisant pipeline programs, and expanded our pipeline with the addition of Zygel through the closing of the Zynerba acquisition.”

“Given our continued confidence in the underlying strength of the business and our conviction in the growth potential for the company, we are announcing a new share repurchase program of $200 million.”

Third Quarter 2023 Financial Results

Net product revenues for the quarter ended September 30, 2023 were $160.3 million, compared to $117.2 million for the same period in 2022. The 37% 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 United States). The average number of patients on WAKIX increased by approximately 350 sequentially to approximately 5,800 for the quarter ended September 30, 2023.

GAAP net income for the quarter ended September 30, 2023 was $38.5 million, or $0.63 earnings per diluted share, compared to GAAP net income of $87.9 million, or $1.44 earnings per diluted share, for the same period in 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 quarter ended September 30, 2022, partially offset by a $30.0 million initial licensing fee as part of the 2022 Licensing and Commercialization Agreement with Bioprojet (the “2022 LCA”). For the quarter ended September 30, 2023, we also incurred a $9.8 million loss on debt extinguishment. Non-GAAP adjusted net income was $58.8 million, or $0.97 earnings per diluted share, for the quarter ended September 30, 2023, compared to Non-GAAP adjusted net income of $58.1 million, or $0.95 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 $17.5 million in the third quarter of 2023, as compared to $40.5 million for the same quarter in 2022, representing a 57% decrease, driven by a $30.0 million licensing fee as part of the 2022 LCA incurred during the third quarter of 2022;
- Sales and Marketing expenses were $23.4 million in the third quarter of 2023, as compared to $20.5 million for the same quarter in 2022, representing a 14% increase;
- General and Administrative expenses were $22.5 million in the third quarter of 2023, as compared to $21.3 million for the same quarter in 2022, representing a 6% increase; and
- Total Operating Expenses were $63.5 million in the third quarter of 2023, as compared to $82.3 million for the same quarter in 2022, representing a 23% decrease.

As of September 30, 2023, Harmony had cash, cash equivalents and investment securities of $438.4 million, compared to $345.7 million as of December 31, 2022.

Company Updates

- Reported topline results from the Phase 3 INTUNE study in adult patients with idiopathic hypersomnia (IH). While the primary endpoint did not reach statistical significance during the randomized withdrawal phase, a robust clinical effect was demonstrated in the open label phase of the study. Based on the totality of the data, the company remains committed and continues to pursue an indication for pitolisant in IH. Next step is to meet with the FDA informed by the review of the full data set.

- Received FDA alignment on the protocol for the Phase 3 TEMPO study in patients with Prader-Willi syndrome (PWS) which will satisfy the requirements for both the registrational trial and now pediatric exclusivity as well. We expect to initiate the study in the first quarter of 2024.
- On track for topline data from the Myotonic Dystrophy (DM1) Phase 2 proof-of-concept signal detection trial in the fourth quarter of 2023.
- On track to submit a supplemental new drug application (sNDA) for a pediatric narcolepsy indication to the FDA in the fourth quarter of 2023.
- Advancing new pitolisant based formulations into the clinic in the fourth quarter of 2023. Anticipate data in the first half of 2024.
- Expanded and diversified our pipeline with the acquisition of Zynerba Pharmaceuticals. Zygel is in a Pivotal Phase 3 trial for Fragile X syndrome (FXS).
- During the third quarter of 2023, the company repurchased 1,439,792 shares of common stock at an aggregate cost of $50 million, as part of the prior $125 million share repurchase program, which we closed.
- Our Board of Directors authorized a new $200 million share repurchase program.

Conference Call Today at 8:30 a.m. ET
We are hosting our third quarter 2023 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 +1 (203) 518-9765 (international), and reference passcode HRMYQ323.

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 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 (≥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 165,000 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 Zygel ™
Zygel is the first and only pharmaceutically manufactured, synthetic cannabidiol, non-euphoric cannabinoid, formulated as a patent-protected permeation-enhanced gel for transdermal delivery through the skin and into the circulatory system. Zygel is manufactured through a synthetic process in a cGMP facility and is not extracted from the cannabis plant. Therefore, it is devoid of THC, which is what causes the euphoric effect of cannabis, and has the potential to be a nonscheduled product if approved.

Cannabidiol, the active ingredient in Zygel, has been granted orphan drug designation by the FDA and the EMA for the treatment of FXS and for the treatment of 22q11.2 deletion syndrome (22q). Additionally, Zygel 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, affecting 1 in 3,600 to 4,000 males and 1 in 4,000 to 6,000 females. 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. There are approximately 80,000 people in the U.S. and approximately 121,000 people in the European Union and UK living with FXS. 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 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 21, 2023, and our other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net product revenues	$ 160,268	$ 117,206	$ 413,610	$ 309,547
Cost of product sold	32,296	22,959	78,084	56,596
Gross profit	127,972	94,247	335,526	252,951
Operating expenses:				
Research and development	17,499	40,548	45,757	60,794
Sales and marketing	23,418	20,467	70,518	58,210
General and administrative	22,546	21,331	67,417	61,374
Total operating expenses	63,463	82,346	183,692	180,378
Operating income	64,509	11,901	151,834	72,573
Loss on debt extinguishment	(9,766)	—	(9,766)	—
Other (expense) income, net	(5)	56	(34)	96
Interest expense, net	(2,906)	(3,990)	(8,327)	(12,086)
Income before income taxes	51,832	7,967	133,707	60,583
Income tax (expense) benefit	(13,371)	79,976	(31,461)	72,376
Net income	$ 38,461	$ 87,943	$ 102,246	$ 132,959
Unrealized income (loss) on investments	6	(149)	(365)	(178)
Comprehensive income	$ 38,467	$ 87,794	$ 101,881	$ 132,781
EARNINGS PER SHARE:				
Basic	$ 0.64	$ 1.48	$ 1.71	$ 2.25
Diluted	$ 0.63	$ 1.44	$ 1.68	$ 2.18
Weighted average number of shares of common stock - basic	59,863,102	59,234,720	59,856,941	59,070,063

Weighted average number of shares of common stock - diluted	60,681,676	61,207,625	60,892,992	60,921,482

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

	September 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 324,603	$ 243,784
Investments, short-term	46,071	79,331
Trade receivables, net	67,264	54,740
Inventory, net	5,087	4,297
Prepaid expenses	14,269	9,347
Other current assets	5,704	8,786
Total current assets	462,998	400,285
NONCURRENT ASSETS:		
Property and equipment, net	428	573
Restricted cash	250	750
Investments, long-term	67,700	22,568
Intangible assets, net	143,069	160,953
Deferred tax asset	100,485	85,943
Other noncurrent assets	2,836	2,798
Total noncurrent assets	314,768	273,585
TOTAL ASSETS	$ 777,766	$ 673,870
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 6,539	$ 3,786
Accrued compensation	10,322	11,532
Accrued expenses	72,761	59,942
Current portion of long-term debt	15,000	2,000
Other current liabilities	7,786	1,624
Total current liabilities	112,408	78,884
NONCURRENT LIABILITIES:		
Long-term debt, net	182,131	189,647
Other noncurrent liabilities	1,895	2,501
Total noncurrent liabilities	184,026	192,148
TOTAL LIABILITIES	296,434	271,032
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at September 30, 2023 and December 31, 2022, respectively; 58,571,944 shares and 59,615,731 issued and outstanding at September 30, 2023 and December 31, 2022, respectively	1	1
Additional paid in capital	651,731	675,118
Accumulated other comprehensive (loss) income	(516)	(151)
Accumulated deficit	(169,884)	(272,130)
TOTAL STOCKHOLDERS' EQUITY	481,332	402,838
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 777,766	$ 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		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
GAAP net income	**$ 38,461**	**$ 87,943**	**$ 102,246**	**$ 132,959**

Non-GAAP Adjustments:				
Non-cash interest expense (1)	2,221	418	3,061	1,241
Depreciation	144	101	350	312
Amortization (2)	5,962	5,962	17,884	17,005
Stock-based compensation expense	7,957	6,967	22,311	19,234
Licensing fee (3)	-	30,000	-	30,000
Loss on debt extinguishment	9,766	-	9,766	-
Valuation allowance release	-	(74,474)	-	(74,474)
Income tax effect related to non-GAAP adjustments (4)	(5,723)	1,175	(10,835)	(2,341)
Non-GAAP adjusted net income	$ 58,788	$ 58,092	$ 144,783	$ 123,936
GAAP reported net income per diluted share	**$ 0.63**	**$ 1.44**	**$ 1.68**	**$ 2.18**
Non-GAAP adjusted net income per diluted share	$ 0.97	$ 0.95	$ 2.38	$ 2.03
Weighted average number of shares of common stock used in non-GAAP diluted per share	60,681,676	61,207,625	60,892,992	60,921,482

(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 2022 Licensing and Commercialization Agreement with Bioprojet.
(4) Calculated using the reported effective tax rate for the periods presented less impact of discrete items

Harmony Biosciences Investor Contact:
Luis Sanay, CFA
445-235-8386
lsanay@harmonybiosciences.com

Harmony Biosciences Media Contact:
Cate McCanless
202-641-6086
cmccanless@harmonybiosciences.com

Source: Harmony Biosciences