Harmony Biosciences Reports Second Quarter 2023 Financial Results and Business Updates

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WAKIX® (pitolisant) Net Revenue Increased ~25% Year-over-Year to $134.2 Million for Second Quarter 2023

Average Number of Patients on WAKIX Increased by ~350 Sequentially to ~5,450 for Second Quarter 2023

Exited Second Quarter 2023 With ~5,600 Patients on WAKIX

Completed Enrollment in Phase 3 Idiopathic Hypersomnia (IH) INTUNE Study; On-track for Topline Data in Fourth Quarter 2023

Plans to Initiate Prader-Willi Syndrome (PWS) Phase 3 Study in Fourth Quarter 2023

Board of Directors Authorized $125 Million Share Repurchase Program

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

PLYMOUTH MEETING, Pa., Aug. 01, 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 June 30, 2023.

“This quarter represented the highest top line prescription demand since our first full quarter of launch in 2020 and the strongest quarter of new patient starts in our history,” said Jeffrey M. Dayno, M.D., President and Chief Executive Officer at Harmony. “This sustained momentum in our core business, driven by robust underlying demand, reinforces our confidence in WAKIX being a $1 billion plus opportunity in narcolepsy alone.”

“Our share repurchase program reflects our ongoing confidence in the strength of our core business as well as our conviction in the long-term growth potential for Harmony. Looking ahead, we made significant progress in all of our current life cycle management programs setting us up for a catalyst rich remainder of the year.”

Second Quarter 2023 Financial Results

Net product revenues for the quarter ended June 30, 2023 were $134.2 million, compared to $107.0 million for the same period in 2022. The 25% 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), partially offset by specialty pharmacy buying patterns resulting in lower trade inventory levels at the end of the quarter. The average number of patients on WAKIX increased by approximately 350 sequentially to approximately 5,450 patients for the quarter ended June 30, 2023. We exited the quarter ended June 30, 2023, with approximately 5,600 patients on WAKIX.

GAAP net income for the quarter ended June 30, 2023, was $34.3 million, or $0.56 earnings per diluted share, compared to GAAP net income of $23.5 million, or $0.39 earnings per diluted share, for the same period in 2022. Non-GAAP adjusted net income was $45.9 million, or $0.76 earnings per diluted share, for the quarter ended June 30, 2023, compared to Non-GAAP adjusted net income of $34.7 million, or $0.57 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 $15.0 million in the second quarter of 2023, as compared to $12.7 million for the same quarter in 2022, representing a 18% increase;
- Sales and Marketing expenses were $24.5 million in the second quarter of 2023, as compared to $20.2 million for the same quarter in 2022, representing a 22% increase;
- General and Administrative expenses were $22.8 million in the second quarter of 2023, as compared to $22.2 million for the same quarter in 2022, representing a 3% increase; and
- Total Operating Expenses were $62.3 million in the second quarter of 2023, as compared to $55.0 million for the same quarter in 2022, representing a 13% increase.

As of June 30, 2023, Harmony had cash, cash equivalents and investment securities of $429.6 million, compared to $345.7 million as of December 31, 2022.

Company Updates

- Completed enrollment of Phase 3 registrational trial (INTUNE Study) in adult patients with IH, nine months ahead of plan, and on-track for topline data in the fourth quarter of 2023.
- Positive End-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA"). We plan to initiate a Phase 3 study in patients with PWS in the fourth quarter of 2023.
- On-track for topline data from the Myotonic Dystrophy ("DM1") Phase 2 proof-of-concept signal detection trial in the fourth quarter of 2023.
- Regarding a pediatric narcolepsy indication, we are working with Bioprojet on the submission to FDA of a supplemental new drug application ("sNDA") for pediatric narcolepsy. We expect to submit the sNDA in the fourth quarter of 2023.
- We are actively pursuing pediatric exclusivity for WAKIX and have made progress with FDA in aligning on the requirements.
- Our Board of Directors authorized a $125 million share repurchase program.
- We entered into a new $185 million term loan facility, further strengthening the balance sheet and reducing annual interest expense by approximately $6 million. Net proceeds from the new term loan facility and cash on hand were used to repay existing debt.

Conference Call Today at 8:30 a.m. ET
We are hosting our second quarter 2023 financial results conference call and webcast today at 8:30 a.m. Eastern Time. The live and replayed 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 HRMYQ223.

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 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. 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 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net product revenues	$ 134,216	$ 107,028	$ 253,342	$ 192,341
Cost of product sold	25,008	18,921	45,788	33,637
Gross profit	109,208	88,107	207,554	158,704
Operating expenses:				
Research and development	14,969	12,668	28,258	20,246
Sales and marketing	24,528	20,160	47,100	37,743
General and administrative	22,809	22,163	44,871	40,043
Total operating expenses	62,306	54,991	120,229	98,032
Operating income	46,902	33,116	87,325	60,672
Other (expense) income, net	(31)	42	(29)	40
Interest expense, net	(2,776)	(3,927)	(5,421)	(8,096)
Income before income taxes	44,095	29,231	81,875	52,616
Income tax expense	(9,795)	(5,700)	(18,090)	(7,600)
Net income	$ 34,300	$ 23,531	$ 63,785	$ 45,016
Unrealized loss on investments	(491)	(29)	(371)	(29)
Comprehensive income	$ 33,809	$ 23,502	$ 63,414	$ 44,987
EARNINGS PER SHARE:				
Basic	$ 0.57	$ 0.40	$ 1.07	$ 0.76
Diluted	$ 0.56	$ 0.39	$ 1.05	$ 0.74

Weighted average number of shares of common stock - basic	59,974,123	59,063,358	59,853,808	58,986,370
Weighted average number of shares of common stock - diluted	60,743,953	60,922,672	60,997,410	60,759,026

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

	June 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 317,415	$ 243,784
Investments, short-term	53,568	79,331
Trade receivables, net	63,812	54,740
Inventory, net	4,854	4,297
Prepaid expenses	9,442	9,347
Other current assets	6,550	8,786
Total current assets	455,641	400,285
NONCURRENT ASSETS:		
Property and equipment, net	572	573
Restricted cash	250	750
Investments, long-term	58,651	22,568
Intangible assets, net	149,031	160,953
Deferred tax asset	93,578	85,943
Other noncurrent assets	2,460	2,798
Total noncurrent assets	304,542	273,585
TOTAL ASSETS	$ 760,183	$ 673,870
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 6,563	$ 3,786
Accrued compensation	7,972	11,532
Accrued expenses	63,563	59,942
Current portion of long-term debt	11,000	2,000
Other current liabilities	3,947	1,624
Total current liabilities	93,045	78,884
NONCURRENT LIABILITIES:		
Long-term debt, net	180,487	189,647
Other noncurrent liabilities	1,479	2,501
Total noncurrent liabilities	181,966	192,148
TOTAL LIABILITIES	275,011	271,032
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at June 30, 2023 and December 31, 2022, respectively; 59,999,658 shares and 59,615,731 issued and outstanding at June 30, 2023 and December 31, 2022, respectively	1	1
Additional paid in capital	694,038	675,118
Accumulated other comprehensive (loss) income	(522)	(151)
Accumulated deficit	(208,345)	(272,130)
TOTAL STOCKHOLDERS' EQUITY	485,172	402,838
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 760,183	$ 673,870

RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS
(In thousands except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
GAAP net income	**$ 34,300**	**$ 23,531**	**$ 63,785**	**$ 45,016**
Non-GAAP Adjustments:				
Non-cash interest expense (1)	424	411	840	823
Depreciation	103	94	206	211
Amortization (2)	5,961	5,961	11,922	11,043
Stock-based compensation expense	7,793	7,371	14,354	12,267
Income tax effect related to non-GAAP adjustments (3)	(2,712)	(2,662)	(5,112)	(3,516)
Non-GAAP adjusted net income	$ 45,869	$ 34,706	$ 85,995	$ 65,844
GAAP reported net income per diluted share	**$ 0.56**	**$ 0.39**	**1.05**	**$ 0.74**
Non-GAAP adjusted net income per diluted share	$ 0.76	$ 0.57	1.41	$ 1.08
Weighted average number of shares of common stock used in non-GAAP diluted per share	60,743,953	60,922,672	60,997,410	60,759,026

(1) Includes amortization of deferred finance charges

(2) Includes amortization of intangible asset related to WAKIX

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

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