Harmony Biosciences Reports First Quarter 2022 Financial Results and Business Updates

May 3, 2022

WAKIX® *(pitolisant) Net Revenue of $85.3 Million for First Quarter 2022 Increase of 43% vs. the Same Period in 2021*

WAKIX Surpasses $500 Million in Cumulative Net Revenue Since Launch

Initiated Phase 3 Clinical Trial in Patients with Idiopathic Hypersomnia

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

PLYMOUTH MEETING, Pa., May 03, 2022 (GLOBE NEWSWIRE) -- Harmony Biosciences Holdings, Inc. ("Harmony" or the "Company") (Nasdaq: HRMY), a pharmaceutical company focused on delivering innovative therapies that improve the health of people living with rare neurological diseases, today reported financial results and business updates for the quarter ended March 31, 2022.

"In Q1, we continued to execute on our three-pillar growth strategy, with another quarter of significant progress. WAKIX® underlying business fundamentals remained strong, despite anticipated seasonal payor dynamics. March 2022 represented our strongest month of performance in top line prescription demand and new patient starts in over a year, and we also reached an important milestone, surpassing $500 million in cumulative net revenue for WAKIX since launch, demonstrating the differentiated product profile and unmet need in the narcolepsy market," stated John C. Jacobs, President and Chief Executive Officer of Harmony.

"With the initiation of our Phase 3 study in patients with Idiopathic Hypersomnia, we are continuing to advance our clinical development programs, with the goal of expanding the clinical utility of WAKIX. Finally, we remain focused on acquiring new assets as we work towards our goal of evolving Harmony into a leading rare neurology company with the plan of building a broad portfolio of innovative products."

First Quarter 2022 Financial Results

Net product revenues for the quarter ended March 31, 2022 were $85.3 million, compared to $59.7 million for the same period in 2021. The 43.0% growth versus the same period in 2021 can be primarily attributed to strong commercial sales of WAKIX driven by continued organic demand. The average number of patients on WAKIX increased to approximately 3,900.

GAAP net income for the quarter ended March 31, 2022 was $21.5 million, or $0.35 per diluted share. This compares to GAAP net income of $7.4 million, or $0.13 per diluted share, for the same period in 2021. Non-GAAP adjusted net income was $31.1 million, or $0.51 per diluted share, for the quarter ended March 31, 2022, compared to a Non-GAAP adjusted net income of $16.0 million, or $0.27 per diluted share, for the same period in 2021.

Reconciliations of applicable GAAP measures to Non-GAAP adjusted information are included at the end of this press release.

The components of Harmony's operating expenses include:

- Research and Development expenses were $7.6 million in the first quarter of 2022, as compared to $4.7 million for the same quarter in 2021, representing a 62.0% increase;
- Sales and Marketing expenses were $17.6 million in the first quarter of 2022, as compared to $15.5 million for the same quarter in 2021, representing a 13.4% increase;
- General and Administrative expenses were $17.9 million in the first quarter of 2022, as compared to $14.5 million for the same quarter in 2021, representing a 22.9% increase; and
- Total Operating Expenses were $43.0 million in the first quarter of 2022, as compared to $34.7 million for the same quarter in 2021, representing a 23.9% increase.

As of March 31, 2022, Harmony had cash and cash equivalents of $224.5 million, compared to $234.3 million at year end December 31, 2021. The decrease in cash was driven by payment of the final milestone due to our partner, Bioprojet, of $40.0 million which was triggered upon surpassing $500 million in cumulative WAKIX net revenue since launch, partially offset by continued cash generation.

Clinical Development Update

- Initiated a Phase 3 clinical trial to evaluate the efficacy and safety of pitolisant in adult patients with Idiopathic Hypersomnia (IH).
- Enrollment continues in the Prader-Willi Syndrome (PWS) and Myotonic Dystrophy (DM1) studies. We anticipate topline data from the Phase 2 proof-of-concept trial in PWS in the second half of 2022 and DM1 topline data in 2023.
- For HBS-102, our early-stage asset, we are on track to begin a preclinical proof of concept study in PWS later in 2022.

Conference Call Today at 8:30 a.m. ET
We are hosting our first quarter 2022 financial results conference call and webcast today, beginning 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 (866) 342-8591 (domestic) or +1 (203) 518-9713 (international), and reference passcode HRMYQ122.

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. The company uses 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 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 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 disciples 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 Statement
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 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 agreement with Bioprojet; the availability of favorable insurance coverage and reimbursement for WAKIX; the impact of the COVID-19 pandemic, including any current and future variants; 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 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; 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 28, 2022, 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 March 31,	
	2022	2021
Net product revenues	$ 85,313	$ 59,674
Cost of product sold	14,716	10,409
Gross profit	70,597	49,265
Operating expenses:		
Research and development	7,578	4,679
Sales and marketing	17,583	15,506
General and administrative	17,880	14,547

Total operating expenses	43,041	34,732
Operating income	27,556	14,533
Other income (expense), net	(2)	(20)
Interest expense, net	(4,169)	(7,127)
Income before income taxes	23,385	7,386
Income tax expense	(1,900)	—
Net income and comprehensive income	$ 21,485	$ 7,386
EARNINGS PER SHARE:		
Basic	$ 0.36	$ 0.13
Diluted	$ 0.35	$ 0.13
Weighted average number of shares of common stock - basic	58,908,526	56,891,451
Weighted average number of shares of common stock - diluted	60,586,875	58,805,285

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

	March 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 224,499	$ 234,309
Trade receivables, net	38,133	34,843
Inventory, net	4,597	4,432
Prepaid expenses	9,618	7,637
Other current assets	3,410	3,218
Total current assets	280,257	284,439
NONCURRENT ASSETS:		
Property and equipment, net	748	820
Restricted cash	750	750
Intangible assets, net	178,837	143,919
Other noncurrent assets	3,413	3,515
Total noncurrent assets	183,748	149,004
TOTAL ASSETS	$ 464,005	$ 433,443
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 6,904	$ 1,001
Accrued compensation	4,976	9,165
Accrued expenses	39,380	40,249
Current portion of long term debt	2,000	2,000
Other current liabilities	3,268	1,360
Total current liabilities	56,528	53,775
NONCURRENT LIABILITIES:		
Long term debt, net	189,896	189,984
Other noncurrent liabilities	3,078	3,177
Total noncurrent liabilities	192,974	193,161
TOTAL LIABILITIES	249,502	246,936
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at March 31, 2022 and December 31, 2021, respectively; 59,030,148 shares and 58,825,769 issued and outstanding at March 31, 2022 and December 31, 2021, respectively	1	1
Additional paid in capital	646,615	640,104
Accumulated deficit	(432,113)	(453,598)
TOTAL STOCKHOLDERS' EQUITY	214,503	186,507
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 464,005	$ 433,443

HARMONY BIOSCIENCES HOLDINGS, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS

(In thousands except share and per share data)

	Three Months Ended March 31,	
	2022	2021
GAAP Net income	**$ 21,485**	**$ 7,386**
Non-GAAP Adjustments:		
Non-cash Interest expense (1)	412	664
Depreciation	117	100
Amortization (2)	5,082	4,579
Stock-based compensation expense	4,896	3,251
Income tax effect related to non-GAAP adjustments (3)	(854)	-
Non-GAAP adjusted net income	$ 31,138	$ 15,980
GAAP net income per diluted share	**$ 0.35**	**$ 0.13**
Non-GAAP adjusted net income per diluted share	$ 0.51	$ 0.27
Weighted average number of shares of common stock used in non-GAAP diluted per share	60,586,875	58,805,285

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**.**

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