Harmony Biosciences Reports First Quarter 2021 Results and Business Updates

May 11, 2021

WAKIX® *(pitolisant) Total Revenue of $59.7 Million for First Quarter 2021*

Achieves Profitability with $7.4 Million Net Income

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

PLYMOUTH MEETING, Pa., May 11, 2021 (GLOBE NEWSWIRE) -- Harmony Biosciences Holdings, Inc. ("Harmony" or the "Company") (Nasdaq: HRMY), a pharmaceutical company dedicated to developing and commercializing innovative therapies for patients living with rare neurological disorders who have unmet medical needs, today reported financial results and business updates for the first quarter ended March 31, 2021.

"We are off to a very strong start in 2021 with the continued demand for WAKIX® driving strong first quarter net revenues," stated John C. Jacobs, President and Chief Executive Officer of Harmony. "We saw growth in the average number of patients on WAKIX and net revenue, putting us in the position of profitability this quarter, for the first time in our company history, demonstrating our resilience and performance through the lingering pandemic and anticipated seasonal payer dynamics in Q1.

As a first-in-class medication with a novel mechanism of action and differentiated product profile, WAKIX remains the only FDA approved product for excessive daytime sleepiness or cataplexy in adult patients with narcolepsy that is not scheduled as a controlled substance, filling a significant unmet medical need for patients living with narcolepsy. With a strong cash position and positive cash flow, we are well positioned to continue supporting our commercialization efforts for WAKIX, advance and expand our clinical programs, and to consider the acquisition of complementary assets to build out our product pipeline."

First Quarter 2021 Highlights:

- Net product revenue of $59.7 million for the quarter ended March 31, 2021;
- Significant growth in WAKIX sales, supported by the addition of the cataplexy indication, which strengthens the overall benefit/risk profile;
- Increased average number of patients on WAKIX and number of unique healthcare professionals who have prescribed WAKIX since launch;
- Net income positive for the first quarter of 2021; and
- Cash and cash equivalents of $141.2 million.

First Quarter 2021 Financial Results

Net product revenues for the quarter ended March 31, 2021 were $59.7 million, compared to $19.8 million for the same period in 2020. The increase was driven by strong commercial sales of WAKIX since product launch for excessive daytime sleepiness (EDS) in adult patients with narcolepsy coupled with the addition of the cataplexy indication in October 2020, which expanded the label for WAKIX.

For the quarter ended March 31, 2021 GAAP net income was $7.4 million, or $0.13 per diluted share, compared to a net loss of $38.6 million or $6.30 per diluted share for the same period in 2020. For the first quarter of 2021, non-GAAP adjusted net income was $22.4 million, or $0.38 per diluted share, compared to an adjusted net loss of $6.2 million or $2.14 per diluted share for the same period in 2020.

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 $4.7 million in Q1 2021 as compared with $3.4 million for the same quarter in 2020, representing a 36.4% increase;
- Sales and Marketing expenses were $15.5 million in Q1 2021 as compared to $13.3 million for the same quarter in 2020, representing a 17.0% increase;
- General and Administrative expenses were $14.5 million in Q1 2021 as compared to $9.3 million for the same quarter in 2020, representing a 56.6% increase; and
- Operating expenses were $34.7 million in the first quarter of 2021 as compared with $26.0 million for the same quarter in 2020, representing a 33.7% increase.

As of March 31, 2021 Harmony had cash and cash equivalents of $141.2 million compared to cash and cash equivalents of $228.6 million, respectively, at year-end 2020. The decrease in cash is primarily attributed to the $100 million milestone payment owed under our License Agreement with Bioprojet that was paid in connection with the cataplexy indication.

Clinical Development Update

- Enrollment continues in Harmony's Phase 2 clinical trial evaluating the safety and efficacy of pitolisant for the treatment of EDS and other symptoms in patients with Prader-Willi Syndrome (PWS) and is on track to achieve top line data in the first

half of 2022.

- Harmony is on-track to initiate a Phase 2 trial in patients with Myotonic Dystrophy Type 1 (DM1) in the first half of 2021.
- Harmony's strategic partner, Bioprojet, is evaluating pitolisant in pediatric patients ages 6 to 18 years with narcolepsy in a Phase 3 trial. Bioprojet and Harmony have decided to wait for the data from Bioprojet's trial to read out in order to decide on next steps in pursuit of both a pediatric narcolepsy indication and pediatric exclusivity. Harmony anticipates providing an update on the path forward in the coming months.
- WAKIX time-to-onset of clinical response and cardiovascular safety data were presented at the 2021 American Academy of Neurology (AAN) annual meeting in April.
- Data on the efficacy of WAKIX in patients with a high burden of narcolepsy symptoms (both EDS and cataplexy) were recently published in the journal *Sleep Medicine*.

Conference Call Today at 8:30 a.m. ET
We are hosting our first quarter 2021 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 page of our website at https://ir.harmonybiosciences.com/. To participate in the live call by phone, dial (833) 614-1471 (domestic) or +1 (914) 987-7209 (international), and reference passcode 2269379. A replay will be accessible until May 18, 2021 by dialing (855) 859-2056 (domestic) or +1 (404) 537-3406 (international).

Non-GAAP Financial Measures
In addition to our GAAP results, we provide certain non-GAAP metrics including adjusted net income and adjusted net income per share. We believe that the presentation of these measures 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 adjusted net income and 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. Company management uses these non-GAAP measurements as an aid in monitoring our ongoing financial performance from quarter-to-quarter and year-to-year on a regular basis and for benchmarking against comparable companies.

These non-GAAP financial measures are not meant to 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 its non-GAAP financial measures; and we may in the future cease to exclude items that it has historically excluded for purposes of its 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 (EDS) 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 FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

About Harmony Biosciences
Harmony Biosciences is a commercial stage pharmaceutical company headquartered in Plymouth Meeting, PA. The Company was established by Paragon Biosciences, LLC, and is focused on providing novel treatment options for people living with rare neurological disorders who have unmet medical needs. For more information on Harmony, please visit the company's website: 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; 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; and 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; 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 March 25, 2021, 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.
CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Net product revenues	$ 59,674	$ 19,840
Cost of product sold	10,409	3,474
Gross profit	49,265	16,366
Operating expenses:		
Research and development	4,679	3,431
Sales and marketing	15,506	13,254
General and administrative	14,547	9,290
Total operating expenses	34,732	25,975
Operating income (loss)	14,533	(9,609)

Loss on debt extinguishment	—	(22,639)
Other expense, net	(20)	—
Interest expense, net	(7,127)	(6,372)
Income (loss) before income taxes	7,386	(38,620)
Income taxes	—	—
Net income (loss) and comprehensive income (loss)	$ 7,386	$ (38,620)
Accumulation of dividends on preferred stock	—	(10,445)
Net income (loss) available to common stockholders	$ 7,386	$ (49,065)
EARNINGS (LOSS) PER SHARE:		
Basic	$ 0.13	$ (6.30)
Diluted	$ 0.13	$ (6.30)
Weighted average number of shares of common stock - basic	56,891,451	7,790,667
Weighted average number of shares of common stock - diluted	58,805,285	7,790,667

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

	March 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 141,169	$ 228,631
Trade receivables, net	23,615	22,176
Inventory, net	4,405	3,823
Prepaid expenses	7,089	6,959
Other current assets	1,466	1,302
Total current assets	177,744	262,891
NONCURRENT ASSETS:		
Property and equipment, net	842	938
Restricted cash	750	750
Intangible assets, net	157,764	162,343
Other noncurrent assets	152	152
Total noncurrent assets	159,508	164,183
TOTAL ASSETS	$ 337,252	$ 427,074
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 4,391	$ 2,556
Accrued compensation	4,523	8,942
Accrued expenses	24,261	122,727
Other current liabilities	262	314
Total current liabilities	33,437	134,539
NONCURRENT LIABILITIES:		
Deferred rent	192	212
Long term debt, net	194,913	194,250
Other noncurrent liabilities	831	893
Total noncurrent liabilities	195,936	195,355
TOTAL LIABILITIES	229,373	329,894
COMMITMENTS AND CONTINGENCIES (Note 9)		
STOCKHOLDERS' EQUITY:		
Preferred stock - $0.00001 par value; 10,000,000 shares and 0 shares authorized at March 31, 2021 and December 31, 2020, respectively; 0 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	—	—
Common stock—$0.00001 par value; 500,000,000 shares authorized at March 31, 2021 and December 31, 2020, respectively; 56,892,406 shares and 56,890,569 issued and outstanding at March 31, 2021 and December 31, 2020, respectively	1	1
Additional paid in capital	588,687	585,374
Accumulated deficit	(480,809)	(488,195)
TOTAL STOCKHOLDERS' EQUITY	107,879	97,180
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 337,252	$ 427,074

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

	For the Three Months Ended March 31,	
	2021	**2020**
Net income (loss)	**$ 7,386**	**$ (38,620)**
Non-GAAP Adjustments:		
Interest expense	7,127	6,372
Taxes	—	—
Depreciation	100	97
Amortization	4,579	1,786
EBITDA	19,192	(30,365)
Additional Non-GAAP Adjustments:		
Stock-based compensation expense	3,251	368
Loss on debt extinguishment	—	22,639
Warrant expense	—	1,146
Non-GAAP adjusted net income (loss)	$ 22,443	$ (6,212)
Accumulation of yield on preferred stock	—	(10,445)
Non-GAAP adjusted net income (loss) available to common stockholders	22,443	(16,657)
GAAP reported net income (loss) per diluted share	**$ 0.13**	**$ (6.30)**
Non-GAAP adjusted net income (loss) per diluted share	$ 0.38	$ (2.14)
Weighted average number of shares of common stock used in non-GAAP diluted per share	58,805,285	7,790,667

Harmony Biosciences Investor Contact:
Lisa Caperelli
610-608-0215
lcaperelli@harmonybiosciences.com

Harmony Biosciences Media Contact:
Nancy Leone
215-891-6046
nleone@harmonybiosciences.com

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