Harmony Biosciences Reports Third Quarter 2021 Financial Results and Business Updates

November 9, 2021 12:30 PM EST

WAKIX® *(pitolisant) Net Revenue of $80.7 Million for Third Quarter 2021 Increase of 77% vs. the Same Period in 2020*

Average Number of Patients on WAKIX Increased to ~3,500

Announced Inclusion of WAKIX in American Academy of Sleep Medicine's (AASM) Updated Clinical Practice Guideline

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

PLYMOUTH MEETING, Pa., Nov. 09, 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 with rare neurological diseases, today reported financial results and business updates for the quarter ended September 30, 2021.

"The company continues to execute on optimizing the performance of WAKIX, demonstrated by another solid quarter of sequential revenue growth with an average number of patients on WAKIX of approximately 3,500," stated John C. Jacobs, President and Chief Executive Officer of Harmony. "Inclusion of WAKIX in the recently updated AASM clinical practice guideline is further evidence of its favorable benefit-risk profile. We believe this updated clinical practice guideline has resulted in increased awareness of WAKIX by healthcare professionals who are seeking meaningfully differentiated treatment options for people living with narcolepsy. Our vision remains focused on building Harmony into a leading neurological disease company serving patients suffering from rare diseases, for which there is high unmet medical need. In addition to optimizing WAKIX's performance, our three-pillar growth strategy also includes broadening the clinical utility of WAKIX in additional indications, as well as acquiring new assets."

Third Quarter 2021 Financial Results
Net product revenues for the quarter ended September 30, 2021 were $80.7 million, compared to $45.6 million for the same period in 2020. The 77.0% growth versus the same period in 2020 can be primarily attributed to strong commercial sales of WAKIX driven by organic demand.

For the quarter ended September 30, 2021, GAAP net loss available to shareholders was $9.6 million, or a loss of $0.17 per diluted share driven by a one-time charge of $26.1 million related to the extinguishment of our prior less advantageous debt facility. This compares to a net loss available to shareholders of $4.1 million, or a loss of $0.14 per diluted share, for the same period in 2020. Non-GAAP adjusted net income was $30.4 million, or $0.51 per diluted share, for the quarter ended September 30, 2021, compared to a non-GAAP adjusted net income of $7.7 million, or $0.25 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 the press release.

The components of Harmony's operating expenses include:

- Research and Development expenses were $11.7 million in the third quarter of 2021 as compared with $4.2 million for the same quarter in 2020;
- Sales and Marketing expenses were $16.5 million in the third quarter of 2021 as compared to $12.6 million for the same quarter in 2020, representing a 30.8% increase;
- General and Administrative expenses were $16.9 million in the third quarter of 2021 as compared to $10.5 million for the same quarter in 2020, representing a 60.4% increase; and
- Total Operating Expenses were $45.1 million in the third quarter of 2021 as compared with $27.3 million for the same quarter in 2020, representing a 64.9% increase.

As of September 30, 2021, Harmony had cash and cash equivalents of $189.7 million.

In August 2021, Harmony entered into a strategic financing collaboration with Blackstone to provide up to $330 million in financing which includes $200 million to refinance the Company's existing debt at a lower interest rate, $100 million for drawdown within the next twelve months, and a $30 million equity investment in Harmony common stock.

Clinical Development and Recent Updates

- The American Academy of Sleep Medicine published an updated clinical practice guideline which includes WAKIX as a recommended treatment option for adults living with narcolepsy. The new clinical practice guideline was published in the *Journal of Clinical Sleep Medicine* in a special article titled, "*Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline*." The new guideline updates and replaces the previous AASM guideline published in 2007, and now includes WAKIX as a strong recommendation for the treatment of narcolepsy in adults based on data that showed clinically significant improvement in excessive daytime sleepiness (EDS) and cataplexy in patients treated with WAKIX.
- Enrollment continues in Harmony's Phase 2 proof of concept clinical trial evaluating the safety and efficacy of pitolisant for the treatment of EDS and other symptoms in patients with PWS with top line data anticipated in the first half of 2022.
- Our Phase 2 proof of concept clinical trial to evaluate the safety and efficacy of pitolisant for EDS and other non-muscular symptoms in adult patients with type 1 myotonic dystrophy (DM1) is advancing with additional clinical sites being activated during Q3. Top-line results are anticipated in the second half of 2022.
- In August 2021, Harmony acquired HBS-102 (formerly CSTI-100), a potential first-in-class molecule with a novel mechanism of action.

Conference Call Today at 8:30 a.m. ET
We are hosting our third 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 4387084. A replay will be accessible until November 16, 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 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 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
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. AND SUBSIDIARY
UNAUDITED CONDENSED CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net product revenues	$ 80,732	$ 45,609	$ 214,227	$ 103,454
Cost of product sold	14,604	7,890	37,701	17,820
Gross profit	66,128	37,719	176,526	85,634
Operating expenses:				
Research and development	11,739	4,230	22,916	11,829
Sales and marketing	16,480	12,601	49,009	38,297
General and administrative	16,856	10,508	45,704	26,280
Total operating expenses	45,075	27,339	117,629	76,406
Operating income	21,053	10,380	58,897	9,228
Loss on debt extinguishment	(26,146)	—	(26,146)	(22,639)
Other income (expense), net	—	(1,525)	(15)	(3,071)
Interest expense, net	(5,429)	(6,946)	(19,783)	(20,254)
(Loss) income before income taxes	(10,522)	1,909	12,953	(36,736)
Income tax benefit (expense)	902	—	(1,070)	—
Net (loss) income and comprehensive (loss) income	$ (9,620)	$ 1,909	$ 11,883	$ (36,736)
Accumulation of dividends on preferred stock	—	(6,013)	—	(26,904)
Net (loss) income available to common stockholders	$ (9,620)	$ (4,104)	$ 11,883	$ (63,640)
(LOSS) EARNINGS PER SHARE:				
Basic	$ (0.17)	$ (0.14)	$ 0.21	$ (4.15)
Diluted	$ (0.17)	$ (0.14)	$ 0.20	$ (4.15)
Weighted average number of shares of common stock - basic	57,722,163	30,212,959	57,188,101	15,324,362
Weighted average number of shares of common stock - diluted	57,722,163	30,212,959	58,776,158	15,324,362

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

	September 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 189,704	$ 228,631

Trade receivables, net	33,206	22,176
Inventory, net	4,805	3,823
Prepaid expenses	9,793	6,959
Other current assets	3,183	1,302
Total current assets	240,691	262,891
NONCURRENT ASSETS:		
Property and equipment, net	937	938
Restricted cash	750	750
Intangible assets, net	148,562	162,343
Other noncurrent assets	152	152
Total noncurrent assets	150,401	164,183
TOTAL ASSETS	$ 391,092	$ 427,074
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 4,179	$ 2,556
Accrued compensation	6,785	8,942
Accrued expenses	34,223	122,727
Current portion of long term debt	2,000	—
Other current liabilities	436	314
Total current liabilities	47,623	134,539
NONCURRENT LIABILITIES:		
Long term debt, net	190,069	194,250
Other noncurrent liabilities	1,382	1,105
Total noncurrent liabilities	191,451	195,355
TOTAL LIABILITIES	239,074	329,894
COMMITMENTS AND CONTINGENCIES (Note 9)		
STOCKHOLDERS' EQUITY:		
Preferred stock - $0.00001 par value; 10,000,000 shares and 00 shares authorized at September 30, 2021 and December 31, 2020, respectively; 00 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Common stock—$0.00001 par value; 500,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 58,414,546 shares and 56,890,569 issued and outstanding at September 30, 2021 and December 31, 2020, respectively	1	1
Additional paid in capital	628,329	585,374
Accumulated deficit	(476,312)	(488,195)
TOTAL STOCKHOLDERS' EQUITY	152,018	97,180
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 391,092	$ 427,074

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net (loss) income	**$ (9,620)**	**$ 1,909**	**$ 11,883**	**$ (36,736)**
Non-GAAP Adjustments:				
Interest expense	5,429	6,946	19,783	20,254
Taxes	(902)	—	1,070	—
Depreciation	99	100	299	294
Amortization	4,573	1,867	13,781	5,560
EBITDA	(421)	10,822	46,816	(10,628)
Additional Non-GAAP Adjustments:				

Stock-based compensation expense	4,664	1,330	11,722	2,266
Loss on debt extinguishment	26,146	—	26,146	22,639
Warrant expense	—	1,525	—	3,109
Non-GAAP adjusted net income (loss)	$ 30,389	$ 13,677	$ 84,684	$ 17,386
Accumulation of yield on preferred stock	—	(6,013)	—	(26,904)
Non-GAAP adjusted net income (loss) available to common stockholders	30,389	7,664	84,684	(9,518)
GAAP reported net income (loss) per diluted share	**$ (0.17)**	**$ (0.14)**	**0.20**	**$ (4.15)**
Non-GAAP adjusted net income (loss) per diluted share	$ 0.51	$ 0.25	1.44	$ (0.62)
Weighted average number of shares of common stock used in non-GAAP diluted per share (1)	59,270,603	30,212,959	58,776,158	15,324,362

Harmony Biosciences Investor Contact:
Patti Bank
415-513-1284
ir@harmonybiosciences.com

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

Source: Harmony Biosciences