Harmony Biosciences Reports Fourth Quarter and Full-Year 2020 Financial Results and Business Updates

March 25, 2021

WAKIX® (pitolisant) Total Revenue of $160 Million for Full-Year 2020; $56 Million for Fourth Quarter 2020

Clinical Utility of WAKIX was Expanded with Additional Approval for Treatment of Cataplexy in Adults with Narcolepsy

Enrollment Continues in Phase 2 Trial of Patients with Prader-Willi Syndrome

On Track to Initiate Two Additional Clinical Trials with Pitolisant in 2021

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

PLYMOUTH MEETING, Pa., March 25, 2021 (GLOBE NEWSWIRE) -- Harmony Biosciences Holdings, Inc. ("Harmony") (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 its financial results and business updates for the fourth quarter and full year ended December 31, 2020.

2020 Financial and Business Highlights:

- Net product revenue of $56.3 million for the fourth quarter ended December 31, 2020; Full-year net product revenue of $159.7 million;
- U.S. Food and Drug Administration (FDA) approved expanded use of WAKIX for the treatment of cataplexy in adults with narcolepsy;
- Enrolled first patient in Phase 2 clinical trial of WAKIX for the treatment of excessive daytime sleepiness (EDS) in patients with Prader-Willi Syndrome (PWS);
- Completed upsized initial public offering of 6.15 million shares at a price of $24.00 per share on August 21, 2020 for gross proceeds of $147.6 million; and
- Added to the Russell 2000® Index and Russell 3000® Index.

"Harmony achieved many milestones during 2020 and has entered 2021 well positioned to advance our strategic objectives," stated John C. Jacobs, President and Chief Executive Officer of Harmony Biosciences. "Key to our success was the closing of our initial public offering in August 2020 and the listing of our common stock on the Nasdaq Global Market. These events elevated Harmony's visibility among investors and provided the financial resources that we believe will allow us to continue to support our commercialization efforts for WAKIX, advance our clinical programs, and pursue the acquisition of additional assets that would be complementary to our existing commercial footprint and core areas of expertise."

Mr. Jacobs added, "With FDA approval of the cataplexy indication for WAKIX and despite the COVID-19 pandemic, WAKIX sales posted double-digit, quarter-over-quarter growth. I am grateful to our employees who met the challenge of achieving these goals during a disruptive global pandemic. Looking ahead, our Phase 2 trial in patients with Prader-Willi Syndrome is actively enrolling patients and our clinical team has made good progress toward the initiation of two additional clinical trials, one in patients with myotonic dystrophy and another in pediatric narcolepsy patients."

Fourth Quarter 2020 Financial Results
For the three-month period ended December 31, 2020, Harmony reported net product revenue of $56.3 million, compared to $6.0 million for the same three-month period in 2019. The increase was primarily due to growing sales of WAKIX, which first became commercially available in November 2019, and the label expansion to include cataplexy in patients with narcolepsy that occurred on October 13, 2020.

For the three-month period ended December 31, 2020, Harmony reported net loss of $0.2 million, or $0.00 per diluted share on a U.S. generally accepted accounting principles (GAAP) basis.

For the three-month period ended December 31, 2020 and 2019, a comparison of total operating expenses is not meaningful and not included in this commentary as WAKIX did not become commercially available for the treatment of EDS in adult patients with narcolepsy until November 2019.

Full Year 2020 Financial Results
For the twelve-month period ended December 31, 2020, net product revenue grew to $159.7 million, compared to $6.0 million during the same twelve-month period in 2019. The increase was primarily due to growing sales of WAKIX following the drug's initial FDA approval in November 2019 as a treatment for EDS in adult patients with narcolepsy and the label expansion in October 2020 to include cataplexy in adult patients with narcolepsy.

For the twelve-month period ended December 31, 2020, total operating expenses were $115.0 million compared to $150.3 million for the same twelve-month period in 2019. The decrease was primarily driven by a decrease in R&D expenses related to payment of a $50 million milestone to Bioprojet, partially offset by an increase in sales and marketing and general and administrative expenses related to the commercial launch of WAKIX.

For the twelve-month period ended December 31, 2020, Harmony reported a net loss of $36.9 million, or $2.48 per diluted share on a GAAP basis. For the same period, non-GAAP adjusted net income was $32.5 million, and after deducting $26.9 million of accumulation of yield on preferred stock, non-GAAP adjusted net income available to common stockholders was $5.5 million, or $0.21 per diluted share. Reconciliations of applicable GAAP measures to non-GAAP adjusted information are included at the end of this press release.

As of December 31, 2020, Harmony had cash and cash equivalents of $228.6 million compared to $24.5 million for the same period in 2019.

2020 Select Business Highlights

Initial Public Offering
On August 21, 2020, Harmony completed an upsized initial public offering of 6.15 million primary shares of common stock at $24.00 per share, which began trading on the Nasdaq Global Market under the ticker symbol “HRMY”. The gross proceeds, before deducting any discounts, commissions or expenses, were $147.6 million. Goldman Sachs, Jefferies and Piper Sandler managed the deal.

FDA Approved New Indication for WAKIX
On October 13, 2020, the FDA approved WAKIX for the treatment of cataplexy in adult patients with narcolepsy. This approval expands the label for WAKIX and broadens its clinical utility for healthcare professionals managing adult patients living with narcolepsy. In August 2019, the FDA approved WAKIX as the first treatment for EDS associated with narcolepsy that is not scheduled as a controlled substance by the U.S. Drug Enforcement Administration.

Advances in WAKIX Clinical Programs
On December 15, 2020 Harmony enrolled the first patient in a Phase 2 randomized, double-blind, placebo-controlled trial for EDS in patients with PWS, a rare genetic condition. The trial is designed to evaluate the safety and efficacy of WAKIX for EDS and other symptoms (behavioral, cognitive dysfunction) in patients with PWS. Harmony expects to report top-line results in first half of 2022.

In December 2020, Harmony submitted an Investigational New Drug (IND) application to the FDA to evaluate pitolisant in patients with myotonic dystrophy (DM). The IND opened in January 2021 and Harmony is on-track to initiate a Phase 2 trial in patients with DM the first half of 2021.

Conference Call Today at 8:30 a.m. ET
We are hosting our fourth quarter and full-year 2020 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 5049024. A replay will be accessible until April 1, 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 on-going 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. 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 Société Civile de Recherche (Bioprojet). 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 Biosciences, 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 December 31,	Twelve Months Ended December 31,

	2020	2019	2020	2019
Net product revenues	$ 56,288	$ 5,995	$ 159,742	$ 5,995
Cost of product sold	9,918	1,577	27,738	1,577
Gross profit	46,370	4,418	132,004	4,418
Operating expenses:				
Research and development	7,618	5,276	19,448	69,595
Sales and marketing	17,526	16,841	55,824	44,318
General and administrative	13,466	15,995	39,746	36,409
Total operating expenses	38,610	38,112	115,018	150,322
Operating income (loss)	7,760	(33,694)	16,986	(145,904)
Loss on debt extinguishment	—	—	(22,639)	—
Other expense, net	—	—	(3,071)	—
Interest expense, net	(7,966)	(2,747)	(28,220)	(6,073)
Loss before income taxes	(206)	(36,441)	(36,944)	(151,977)
Income taxes	—	—	—	—
Net loss and comprehensive loss	$ (206)	$ (36,441)	$ (36,944)	$ (151,977)
Accumulation of dividends on preferred stock	—	(9,575)	(26,904)	(35,231)
Net loss available to common stockholders	$ (206)	$ (46,016)	$ (63,848)	$ (187,208)
NET LOSS PER SHARE:				
Basic	$ (0.00)	$ (5.92)	$ (2.48)	$ (24.07)
Diluted	$ (0.00)	$ (5.92)	$ (2.48)	$ (24.07)
Weighted average number of shares of common stock - basic	56,889,460	7,778,453	25,772,419	7,777,441
Weighted average number of shares of common stock - diluted	56,889,460	7,778,453	25,772,419	7,777,441

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

	December 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 228,631	$ 24,457
Trade receivables, net	22,176	4,255
Inventory, net	3,823	1,088
Prepaid expenses	6,959	1,436
Other current assets	1,302	261
Total current assets	262,891	31,497
NONCURRENT ASSETS:		
Property and equipment, net	938	1,330
Restricted cash	750	750
Intangible asset, net	162,343	72,185
Other noncurrent assets	152	941
Total noncurrent assets	164,183	75,206
TOTAL ASSETS	$ 427,074	$ 106,703
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Trade payables	$ 2,556	$ 6,360
Accrued compensation	8,942	7,917
Accrued expenses	122,727	5,500
Other current liabilities	314	115
Total current liabilities	134,539	19,892
NONCURRENT LIABILITIES:		
Deferred rent	212	287
Long term debt, net	194,250	97,946
Other noncurrent liabilities	893	163
Total noncurrent liabilities	195,355	98,396
TOTAL LIABILITIES	329,894	118,288

COMMITMENTS AND CONTINGENCIES (Note 9)		
CONVERTIBLE PREFERRED STOCK		
Convertible preferred stock, net of placement costs		
Series A convertible preferred stock - $1.00 stated value; 0 shares and 286,000,000 shares authorized at December 31, 2020 and 2019, respectively; 0 shares and 285,000,000 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	348,203
Series B convertible preferred stock - $1.25 stated value; 0 shares and 8,030,000 shares authorized at December 31, 2020 and 2019, respectively; 0 shares and 8,000,000 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	12,023
Series C convertible preferred stock - $1.96 stated value; 0 shares and 25,600,000 shares authorized at December 31, 2020 and 2019, respectively; 0 shares and 25,510,205 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	51,051
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock - $0.00001 par value; 10,000,000 shares and 0 shares authorized at December 31, 2020 and 2019, respectively; 0 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	—
Common stock—$0.00001 par value; 500,000,000 shares and 423,630,000 shares authorized at December 31, 2020 and 2019, respectively; 56,890,569 shares and 7,787,470 issued and outstanding at December 31, 2020 and 2019, respectively	1	—
Additional paid in capital	585,374	—
Accumulated deficit	(488,195)	(422,862)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	97,180	(422,862)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 427,074	$ 106,703

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
GAAP reported loss	**$ (207)**	**$ (36,439)**	**$ (36,944)**	**$ (151,977)**
Non-GAAP adjustments:				
Interest expense	7,967	2,747	28,220	6,073
Taxes	—	—	—	—
Depreciation	100	95	394	395
Amortization	4,283	1,850	9,843	2,815
EBITDA	12,143	(31,747)	1,513	(142,694)
Additional non-GAAP adjustments:				
Stock-based compensation expense	2,924	8,805	5,190	9,909
Loss on debt extinguishment	—	—	22,639	—
Warrant expense	—	—	3,109	—
Non-GAAP adjusted net income (loss)	15,067	(22,942)	32,451	(132,785)
Accumulation of dividends on preferred stock	—	(9,575)	(26,904)	(35,231)
Non-GAAP net income (loss) available to common stockholders	$ 15,067	$ (32,517)	$ 5,547	$ (168,016)
GAAP reported net loss per diluted share	**$ (0.00)**	**$ (5.92)**	**$ (2.48)**	**$ (24.07)**
Non-GAAP adjusted net income (loss) per diluted share	$ 0.25	$ (4.18)	$ 0.21	$ (21.60)
Weighted average number of shares of common stock used in non-GAAP diluted per share	59,128,981	7,778,453	26,982,978	7,777,441

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Source: Harmony Biosciences