Harmony Biosciences Reports Fourth Quarter and Full Year 2021 Financial Results and Business Updates

February 28, 2022

WAKIX® (pitolisant) Net Revenue Increased 62% Year-over-Year to $91.2 Million for Fourth Quarter 2021 and 91% to $305.4 Million for Full Year

Achieved First Full Year of Profitability and Net income was $22.7 Million for the Fourth Quarter 2021

Average Number of Patients on WAKIX Increased to ~3,800

On Track to Initiate the Phase 3 Clinical Trial in Patients with Idiopathic Hypersomnia First Half of This Year

Year-End 2021 Cash and Cash Equivalents of Approximately $234 Million

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

PLYMOUTH MEETING, Pa., Feb. 28, 2022 (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 fourth quarter and full year ended December 31, 2021.

"Our performance in 2021 demonstrated the team's commitment and ability to execute on our three-pillar growth strategy designed to support long-term, sustainable value creation. The sequential quarter-over-quarter revenue growth we have achieved since launching WAKIX is supported by the positive feedback from both healthcare providers and patients who are gaining experience with WAKIX," stated John C. Jacobs, President and Chief Executive Officer of Harmony. "In 2022, we expect ongoing growth of WAKIX due to continued strong underlying demand. We are also excited to initiate our Phase 3 registrational trial in Idiopathic Hypersomnia in the first half of this year. Finally, our dedicated business development team remains focused on acquiring new assets to expand our portfolio beyond WAKIX."

Fourth Quarter 2021 Financial Results

Net product revenues for the quarter ended December 31, 2021 were $91.2 million compared to $56.3 million for the same period in 2020. The 62.0% growth versus the same period in 2020 can be primarily attributed to strong commercial sales of WAKIX driven by continued organic demand.

GAAP net income available to shareholders for the quarter ended December 31, 2021, was $22.7 million, or $0.38 per diluted share. This compares to a net loss available to shareholders of $0.2 million, or a loss of $0.00 per diluted share, for the same period in 2020. Non-GAAP adjusted net income was $37.8 million, or $0.63 per diluted share, for the quarter ended December 31, 2021, compared to a non-GAAP adjusted net income of $15.1 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 this press release.

The components of Harmony's operating expenses include:

- Research and Development expenses were $7.5 million in the fourth quarter of 2021 as compared to $7.6 million for the same quarter in 2020, representing a 1.3% decrease;
- Sales and Marketing expenses were $19.1 million in the fourth quarter of 2021 as compared to $17.5 million for the same quarter in 2020, representing a 9.0% increase;
- General and Administrative expenses were $18.2 million in the fourth quarter of 2021 as compared to $13.5 million for the same quarter in 2020, representing a 35.2% increase; and
- Total Operating Expenses were $44.8 million in the fourth quarter of 2021 as compared with $38.6 million for the same quarter in 2020, representing a 15.9% increase.

Full Year 2021 Financial Results

Net product revenues for the year ended December 31, 2021 were $305.4 million compared to $159.7 million for 2020. The 91.2% growth versus 2020 can be primarily attributed to strong commercial sales of WAKIX driven by organic demand.

GAAP net income available to shareholders for the year ended December 31, 2021 was $34.6 million, or $0.38 per diluted share. This compares to a net loss available to shareholders of $63.8 million, or a loss of $2.48 per diluted share, for the prior year. Non-GAAP adjusted net income was $122.5 million, or $2.07 per diluted share, for the year ended December 31, 2021, compared to a non-GAAP adjusted net income of $5.5 million, or $0.21 per diluted share, for the prior year.

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 $30.4 million for the year ended December 31, 2021 as compared with $19.4 million for the prior year, representing a 56.1% increase;

- Sales and Marketing expenses were $68.1 million for the year ended December 31, 2021 as compared to $55.8 million for the prior year, representing a 22.0% increase;
- General and Administrative expenses were $63.9 million for the year ended December 31, 2021 as compared to $39.7 million for the prior year, representing a 60.8% increase; and
- Total Operating Expenses were $162.4 million for the year ended December 31, 2021 as compared with $115 million for the prior year, representing a 41.2% increase.

As of December 31, 2021, Harmony had cash and cash equivalents of $234.3 million.

Clinical Development and Recent Updates

- The U.S. Food and Drug Administration ("FDA") accepted an Investigational New Drug application for pitolisant for the treatment of Idiopathic Hypersomnia ("IH"). Harmony is on track to initiate a Phase 3 clinical trial to evaluate the safety and efficacy of pitolisant in adult patients with IH in the first half of 2022.
- In light of the ongoing COVID-19 pandemic, and recent emergence of the Omicron variant, the Company is updating the timing of its other life cycle management programs for pitolisant. We now anticipate topline data from the Phase 2 proof-of-concept trial in Prader-Willi Syndrome in the second half of 2022 and Myotonic Dystrophy topline data in 2023.
- With regard to pediatric narcolepsy, our partner Bioprojet has completed its Phase 3 trial. We will look to the data as a key input to help inform our strategy related to pediatric exclusivity and a potential pediatric narcolepsy indication.
- For HBS-102, our early-stage asset, we are exploring potential clinical targets within the realm of rare neurological diseases and plan to begin preclinical proof of concept studies on one or two of those potential targets in the second half of 2022.
- Two post-hoc analyses highlighting clinically relevant data for pitolisant, which further elucidate the efficacy profile of WAKIX, were published during Q4 2021 in CNS Drugs. One is titled, "*Time to Onset of Response to Pitolisant for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Patients with Narcolepsy: An Analysis of Randomized Placebo-Controlled Trials,"* and the other is "*Clinical Impact of Pitolisant on Excessive Daytime Sleepiness and Cataplexy in Adults with Narcolepsy: An Analysis of Randomized Placebo-Controlled Trials."*

Conference Call Today at 8:30 a.m. ET
We are hosting our fourth quarter and full-year 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 relations 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 7277008. A replay will be accessible until March 7, 2022 by dialing (855) 859-2056 (domestic) or +1 (404) 537-3406 (international).

Non-GAAP Financial Measures
In addition to our GAAP results, we present certain non-GAAP metrics including adjusted net income and 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 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 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
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, 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 (LOSS)
(In thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Net product revenues	$ 91,213	$ 56,288	$ 305,440	$ 159,742
Cost of product sold	17,817	9,918	55,518	27,738
Gross profit	73,396	46,370	249,922	132,004
Operating expenses:				
Research and development	7,451	7,618	30,367	19,448
Sales and marketing	19,109	17,526	68,118	55,824
General and administrative	18,205	13,466	63,909	39,746
Total operating expenses	44,765	38,610	162,394	115,018
Operating income	28,631	7,760	87,528	16,986
Loss on debt extinguishment	—	—	(26,146)	(22,639)
Other income (expense), net	31	—	16	(3,071)
Interest expense, net	(4,187)	(7,966)	(23,970)	(28,220)
Income (loss) before income taxes	24,475	(206)	37,428	(36,944)
Income tax expense	(1,761)	—	(2,831)	—
Net income (loss) and comprehensive income (loss)	$ 22,714	$ (206)	$ 34,597	$ (36,944)
Accumulation of dividends on preferred stock	—	—	—	(26,904)
Net income (loss) available to common stockholders	$ 22,714	$ (206)	$ 34,597	$ (63,848)
EARNINGS (LOSS) PER SHARE:				
Basic	$ 0.39	$ (0.00)	$ 0.60	$ (2.48)
Diluted	$ 0.38	$ (0.00)	$ 0.58	$ (2.48)
Weighted average number of shares of common stock - basic	58,550,657	56,889,460	57,531,540	25,772,419
Weighted average number of shares of common stock - diluted	60,314,395	56,889,460	59,205,213	25,772,419

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

	December 31, 2021	December 31, 2020
ASSETS		

CURRENT ASSETS:		
Cash and cash equivalents	$ 234,309	$ 228,631
Trade receivables, net	34,843	22,176
Inventory, net	4,432	3,823
Prepaid expenses	7,637	6,959
Other current assets	3,218	1,302
Total current assets	284,439	262,891
NONCURRENT ASSETS:		
Property and equipment, net	820	938
Restricted cash	750	750
Intangible assets, net	143,919	162,343
Other noncurrent assets	3,515	152
Total noncurrent assets	149,004	164,183
TOTAL ASSETS	$ 433,443	$ 427,074
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 1,001	$ 2,556
Accrued compensation	9,165	8,942
Accrued expenses	40,249	122,727
Current portion of long term debt	2,000	—
Other current liabilities	1,360	314
Total current liabilities	53,775	134,539
NONCURRENT LIABILITIES:		
Long term debt, net	189,984	194,250
Other noncurrent liabilities	3,177	1,105
Total noncurrent liabilities	193,161	195,355
TOTAL LIABILITIES	246,936	329,894
COMMITMENTS AND CONTINGENCIES (Note 9)		
STOCKHOLDERS' EQUITY:		
Preferred stock - $0.00001 par value; 10,000,000 shares and 00 shares authorized at December 31, 2021 and December 31, 2020, respectively; 00 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	—	—
Common stock—$0.00001 par value; 500,000,000 shares authorized at December 31, 2021 and December 31, 2020, respectively; 58,825,769 shares and 56,890,569 issued and outstanding at December 31, 2021 and December 31, 2020, respectively	1	1
Additional paid in capital	640,104	585,374
Accumulated deficit	(453,598)	(488,195)
TOTAL STOCKHOLDERS' EQUITY	186,507	97,180
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 433,443	$ 427,074

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Net (loss) income	**$ 22,714**	**$ (206)**	**$ 34,597**	**$ (36,944)**
Non-GAAP Adjustments:				
Interest expense	4,187	7,966	23,970	28,220
Taxes	1,761	—	2,831	—
Depreciation	117	100	416	394
Amortization	4,643	4,283	18,424	9,843
EBITDA	33,422	12,143	80,238	1,513
Additional Non-GAAP Adjustments:				
Stock-based compensation expense	4,383	2,924	16,105	5,190
Loss on debt extinguishment	—	—	26,146	22,639
Warrant expense	—	—	—	3,109
Non-GAAP adjusted net income	$ 37,805	$ 15,067	$ 122,489	$ 32,451

Accumulation of yield on preferred stock	—	—	—	(26,904)
Non-GAAP adjusted net income available to common stockholders	37,805	15,067	122,489	5,547
GAAP reported net income (loss) per diluted share	**$ 0.38**	**$ (0.00)**	**0.58**	**$ (2.48)**
Non-GAAP adjusted net income per diluted share	$ 0.63	$ 0.25	2.07	$ 0.21
Weighted average number of shares of common stock used in non-GAAP diluted per share	60,314,395	59,128,981	59,205,213	26,982,978

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