Harmony Biosciences Reports Third Quarter 2022 Financial Results and Business Updates

November 1, 2022

WAKIX® (pitolisant) Net Revenue of $117.2 Million for Third Quarter 2022 Increase of ~45% vs. the Same Period in 2021

Average Number of Patients on WAKIX Increased to ~4,600

Prader-Willi Syndrome (PWS) Phase 2 Proof-Of-Concept Study Topline Data Showed Positive Signal in Treating Excessive Daytime Sleepiness

Good Momentum in Phase 3 Idiopathic Hypersomnia (IH) INTUNE Study

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

PLYMOUTH MEETING, Pa., Nov. 01, 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 quarter ended September 30, 2022.

"We delivered another strong quarter of performance, reflecting the underlying demand for WAKIX and the significant unmet need that persists in the narcolepsy market," stated John C. Jacobs, President and Chief Executive Officer of Harmony.

"In addition, we are encouraged by the positive signal seen on the primary outcome of excessive daytime sleepiness from our Phase 2 proof-of-concept study in Prader Willi syndrome and the progress we are making in our clinical programs, as we continue executing on our three-pillar growth strategy."

Third Quarter 2022 Financial Results

Net product revenues for the quarter ended September 30, 2022 were $117.2 million, compared to $80.7 million for the same period in 2021. The 45.2% growth versus the same period in 2021 is primarily attributed to strong commercial sales of WAKIX driven by continued organic demand. The average number of patients on WAKIX increased to approximately 4,600 for the quarter ended September 30, 2022.

GAAP net income for the quarter ended September 30, 2022, was $87.9 million, or $1.44 per diluted share, compared to a GAAP net loss of $9.6 million, or ($0.17) per diluted share, for the same period in 2021. The increase in GAAP net income was primarily driven by the release of the valuation allowance on our deferred tax assets, which resulted in a $74.5 million income tax benefit for the quarter ended September 30, 2022, partially offset by a $30.0 million initial licensing fee as part of the 2022 Licensing and Commercialization Agreement with Bioprojet (the "2022 LCA"). Non-GAAP adjusted net income was $58.1 million, or $0.95 per diluted share, for the quarter ended September 30, 2022, compared to Non-GAAP adjusted net income of $23.4 million, or $0.41 per diluted share, for the same period in 2021.

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

Harmony's operating expenses include the following:

- Research and Development expenses were $40.5 million in the third quarter of 2022, as compared to $11.7 million for the same quarter in 2021, representing a 245.4% increase, driven by a $30.0 million initial licensing fee as part of the 2022 LCA;
- Sales and Marketing expenses were $20.5 million in the third quarter of 2022, as compared to $16.5 million for the same quarter in 2021, representing a 24.2% increase;
- General and Administrative expenses were $21.3 million in the third quarter of 2022, as compared to $16.9 million for the same quarter in 2021, representing a 26.5% increase; and
- Total Operating Expenses were $82.3 million in the third quarter of 2022, as compared to $45.1 million for the same quarter in 2021, representing a 82.7% increase.

As of September 30, 2022, Harmony had cash, cash equivalents and investment securities of $316.0 million.

Recent Updates

- Closed the 2022 LCA, focused on developing innovative therapeutics based on pitolisant, and expanding Harmony's opportunity in narcolepsy, and potentially other indications mutually agreed upon by the parties.
- Announced topline data from the PWS Phase 2 proof-of-concept study which showed a positive signal on improvement in the primary outcome related to excessive daytime sleepiness.
- Good momentum in patient enrollment in the Phase 3 registrational trial in adult patients with IH (INTUNE Study), with over 70% of the planned clinical trial sites activated.
- Enrollment continues in the Myotonic Dystrophy (DM1) study. Anticipate topline data from this Phase 2 proof-of-concept trial in 2023.
- Submitted a request for a Pediatric Written Request to the U.S. Food and Drug Administration (FDA) in pursuit of obtaining

pediatric exclusivity for WAKIX.
- Initiated pre-clinical proof-of-concept study in PWS for HBS-102.

Conference Call Today at 8:30 a.m. ET
We are hosting our third 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 (800) 225-9448 (domestic) or +1 (203) 518-9708 (international), and reference passcode HRMYQ322.

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 disciplines 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 and our 2022 LCA with Bioprojet. 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 development activities with Bioprojet and plans to explore the therapeutic potential of pitolisant in additional indications; our ongoing and planned clinical trials; 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 of our product candidates, including those we are developing with Bioprojet; our failure to achieve the potential benefits under our 2022 LCA with Bioprojet; 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	Nine Months Ended

	September 30, 2022	September 30, 2021	September 30, 2022	September 30 2021
Net product revenues	$ 117,206	$ 80,732	$ 309,547	$ 214,227
Cost of product sold	22,959	14,604	56,596	37,701
Gross profit	94,247	66,128	252,951	176,526
Operating expenses:				
Research and development	40,548	11,739	60,794	22,916
Sales and marketing	20,467	16,480	58,210	49,009
General and administrative	21,331	16,856	61,374	45,704
Total operating expenses	82,346	45,075	180,378	117,629
Operating income	11,901	21,053	72,573	58,897
Loss on debt extinguishment	—	(26,146)	—	(26,146)
Other expense (income), net	56	—	96	(15)
Interest expense, net	(3,990)	(5,429)	(12,086)	(19,783)
Income (loss) before income taxes	7,967	(10,522)	60,583	12,953
Income tax benefit (expense)	79,976	902	72,376	(1,070)
Net income	$ 87,943	$ (9,620)	$ 132,959	$ 11,883
Unrealized loss on investments	(149)	—	(178)	—
Comprehensive income	$ 87,794	$ (9,620)	$ 132,781	$ 11,883
EARNINGS PER SHARE:				
Basic	$ 1.48	$ (0.17)	$ 2.25	$ 0.21
Diluted	$ 1.44	$ (0.17)	$ 2.18	$ 0.20
Weighted average number of shares of common stock - basic	59,234,720	57,722,163	59,070,063	57,188,101
Weighted average number of shares of common stock - diluted	61,207,625	57,722,163	60,921,482	58,776,158

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

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 261,343	$ 234,309
Investments, short-term	46,420	—
Trade receivables, net	55,065	34,843
Inventory, net	3,900	4,432
Prepaid expenses	11,246	7,637
Other current assets	4,108	3,218
Total current assets	382,082	284,439
NONCURRENT ASSETS:		
Property and equipment, net	680	820
Restricted cash	750	750
Investments, long-term	8,280	—
Intangible assets, net	166,914	143,919
Deferred tax asset	81,679	—
Other noncurrent assets	3,079	3,515
Total noncurrent assets	261,382	149,004
TOTAL ASSETS	$ 643,464	$ 433,443
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 10,049	$ 1,001
Accrued compensation	8,331	9,165
Accrued expenses	85,606	40,249
Current portion of long-term debt	2,000	2,000
Other current liabilities	1,371	1,360
Total current liabilities	107,357	53,775
NONCURRENT LIABILITIES:		
Long-term debt, net	189,725	189,984

Other noncurrent liabilities	2,498	3,177
Total noncurrent liabilities	192,223	193,161
TOTAL LIABILITIES	299,580	246,936
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at September 30, 2022 and December 31, 2021, respectively; 59,304,408 shares and 58,825,769 issued and outstanding at September 30, 2022 and December 31, 2021, respectively	1	1
Additional paid in capital	664,700	640,104
Accumulated other comprehensive income (loss)	(178)	—
Accumulated deficit	(320,639)	(453,598)
TOTAL STOCKHOLDERS' EQUITY	343,884	186,507
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 643,464	$ 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		Nine Months Ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
GAAP net income	**$ 87,943**	**$ (9,620)**	**$ 132,959**	**$ 11,883**
Non-GAAP Adjustments:				
Non-cash interest expense (1)	418	459	1,241	1,820
Depreciation	101	99	312	299
Amortization (2)	5,962	4,573	17,005	13,781
Stock-based compensation expense	6,967	4,664	19,234	11,722
Licensing fee (3)	30,000	-	30,000	-
Loss on debt extinguishment	-	26,146	-	26,146
Valuation allowance release	(74,474)	-	(74,474)	-
Income tax effect related to non-GAAP adjustments (4)	1,175	(2,943)	(2,341)	(4,442)
Non-GAAP adjusted net income	$ 58,092	$ 23,378	$ 123,936	$ 61,209
GAAP reported net income per diluted share	**$ 1.44**	**$ (0.17)**	**$ 2.18**	**$ 0.20**
Non-GAAP adjusted net income per diluted share	$ 0.95	$ 0.41	$ 2.03	$ 1.04
Weighted average number of shares of common stock used in non-GAAP diluted per share	61,207,625	57,722,163	60,921,482	58,776,158

(1) Includes amortization of deferred finance charges

(2) Includes amortization of intangible asset related to WAKIX.

(3) Amount represents initial licensing fee incurred upon closing the 2022 Licensing and Commercialization Agreement with Bioprojet.

(4) Calculated using the reported effective tax rate for the periods presented.

Harmony Biosciences Investor Contact:
Luis Sanay, CFA
445-235-8386
lsanay@harmonybiosciences.com

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

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