Harmony Biosciences Reports Third Quarter 2020 Financial Results and Business Updates

November 12, 2020

WAKIX® (pitolisant) Total Revenue of $45.6 Million for Third Quarter of 2020

Differentiated Product Profile Aligns with Unmet Medical Need

On Track to Initiate Phase 2 Trial in Patients with Prader-Willi Syndrome by Year End

Conference Call and Webcast to be held today at 8:30 a.m. Eastern Time

PLYMOUTH MEETING, Penn. and CHICAGO, Nov. 12, 2020 (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 financial results for the quarter ended September 30, 2020, and provided recent business updates.

"Harmony experienced another productive quarter with continued WAKIX revenue growth and meaningful advancement of our key clinical programs," commented John C. Jacobs, Harmony's President and Chief Executive Officer. "WAKIX sales continued to increase on a quarterly basis through the COVID-19 pandemic, reflecting the unmet medical need for a first-in-class medication with a novel mechanism of action. The recent approval of the cataplexy indication for WAKIX expanded the label in narcolepsy which, along with WAKIX being the only FDA approved product for narcolepsy that is not scheduled as a controlled substance, provides additional commercial opportunity. With a robust cash position stemming from our recent IPO, we have the financial resources to continue supporting our commercialization efforts for WAKIX, advance our clinical programs, and to pursue the acquisition of additional assets that would be complimentary to our existing commercial footprint and core areas of expertise."

Third Quarter 2020 Financial Highlights:

- Net product revenue was $45.6 million for the third quarter ended September 30, 2020.
- Research and development expenses were $4.2 million for the third quarter of 2020 compared with $4.3 million for the third quarter of 2019.
- Sales and marketing expenses were $12.6 million for the third quarter of 2020 compared with $12.9 million for the third quarter of 2019.
- General and administrative expenses were $10.5 million for the third quarter of 2020 compared with $12.6 million for the third quarter of 2019.
- Net income was $1.9 million for the third quarter of 2020 compared with a net loss of $31.9 million for the third quarter of 2019.
- Cash and cash equivalents as of September 30, 2020 was $221.7 million.

Harmony Founder and Chairman, and Paragon Biosciences Chairman and CEO, Jeff Aronin, commented, "From the time we founded Harmony, to its FDA approval of WAKIX, and recent approval of a second indication, the team has worked relentlessly to build a company that has contributed to scientific innovation in neurological disorders. We are pleased with Harmony's continued progress to address unmet medical needs, including the benefits that WAKIX has provided for people living with narcolepsy."

Recent Program Highlights and Updates:

WAKIX® (pitolisant) in Narcolepsy

- On October 13, 2020, the U.S. Food and Drug Administration (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. WAKIX is the first and only treatment approved by the FDA for people with excessive daytime sleepiness (EDS) or cataplexy associated with narcolepsy that is not scheduled as a controlled substance by the U.S. Drug Enforcement Administration (DEA).

Pitolisant in Patients with Prader-Willi Syndrome (PWS) and Myotonic Dystrophy (DM)

- PWS and DM are rare, genetic multi-system diseases for which there are no approved treatments for many of the symptoms, resulting in significant unmet medical needs.
  • For PWS, clinical sites are being activated to conduct a Phase 2 randomized, double-blind, placebo-controlled trial to assess the safety and efficacy of pitolisant in patients with PWS, with the primary endpoint being EDS. We are on-track to initiate this trial this year.
  • For DM, we are on-track to submit an IND by year end with the plan to initiate a Phase 2 clinical trial in the first half of 2021.

Recent Business Updates:

- On August 21, 2020 we successfully completed our upsized IPO of 6,151,162 shares of common stock at a public offering price of $24.00 per share, including an exercise in full of the underwriters' option to purchase additional shares. The gross proceeds from the offering, before deducting underwriting discounts and commissions and other offering expenses, were $147.6 million.
- In November, we expanded the depth and breadth of our Board of Directors with the addition of Mark Graf and Eric Motley.

Conference Call Today at 8:30 a.m. ET
We are hosting our third quarter 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 7489154. A replay will be accessible until November 19, 2020 by dialing (855) 859-2056 (domestic) or +1 (404) 537-3406 (international).

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. Although, the mechanism of action of WAKIX is unclear, 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 and Chicago, IL. 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 the company'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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 12, 2020, 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.
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,	
	2020	2019	2020	2019
Net product revenues	$ 45,609	$ —	$ 103,454	$ —
Cost of product sold	7,890	—	17,820	—
Gross profit	37,719	—	85,634	—
Operating expenses:				
Research and development	4,230	4,336	11,829	62,319
Sales and marketing	12,601	12,908	38,297	27,477
General and administrative	10,508	12,560	26,280	22,415
Total operating expenses	27,339	29,804	76,406	112,211
Operating income (loss)	10,380	(29,804)	9,228	(112,211)
Loss on debt extinguishment	—	—	(22,639)	—
Other expense, net	(1,525)	—	(3,071)	—
Interest expense, net	(6,946)	(2,095)	(20,254)	(3,326)
Income (loss) before income taxes	1,909	(31,899)	(36,736)	(115,537)
Income taxes	—	—	—	—
Net income (loss) and comprehensive loss	$ 1,909	$ (31,899)	$ (36,736)	$ (115,537)
Accumulation of dividends on preferred stock	(6,013)	(9,027)	(26,904)	(25,656)
Net loss available to common stockholders	$ (4,104)	$ (40,926)	$ (63,640)	$ (141,193)
NET LOSS PER SHARE:				
Basic	$ (0.14)	$ (5.26)	$ (4.15)	$ (18.15)
Diluted	$ (0.14)	$ (5.26)	$ (4.15)	$ (18.15)
Weighted average number of shares of common stock - basic	30,212,959	7,777,100	15,324,362	7,777,100
Weighted average number of shares of common stock - diluted	30,212,959	7,777,100	15,324,362	7,777,100

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

	September 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 221,740	$ 24,457
Trade receivables, net	16,326	4,255
Inventory, net	2,311	1,088
Prepaid expenses	4,240	1,436
Other current assets	5,625	261
Total current assets	250,242	31,497
NONCURRENT ASSETS:		
Property and equipment, net	1,038	1,330
Restricted cash	750	750
Intangible asset, net	66,625	72,185
Other noncurrent assets	1,418	941
Total noncurrent assets	69,831	75,206
TOTAL ASSETS	$ 320,073	$ 106,703
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Trade payables	$ 9,347	$ 6,360
Accrued compensation	5,243	7,917
Accrued expenses	17,200	5,500
Other current liabilities	—	115
Total current liabilities	31,790	19,892
NONCURRENT LIABILITIES:		
Deferred rent	305	287
Long term debt, net	192,858	97,946
Other noncurrent liabilities	571	163
Total noncurrent liabilities	193,734	98,396
TOTAL LIABILITIES	225,524	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 September 30, 2020 and December 31, 2019, respectively; 0 shares and 285,000,000 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	348,203
Series B convertible preferred stock - $1.25 stated value; 0 shares and 8,030,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares and 8,000,000 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	12,023
Series C convertible preferred stock - $1.96 stated value; 0 shares and 25,600,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares and 25,510,205 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	51,051
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock - $0.00001 par value; 10,000,000 shares and 0 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 shares issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock - $0.00001 par value; 500,000,000 shares and 423,630,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 56,888,625 shares and 7,787,470 issued and outstanding at September 30, 2020 and December 31, 2019, respectively	1	—
Additional paid in capital	582,535	—
Accumulated deficit	(487,987)	(422,862)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	94,549	(422,862)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 320,073	$ 106,703

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