HARMONY BIOSCIENCES PRELIMINARY UNAUDITED FOURTH QUARTER AND FULL YEAR 2023 NET PRODUCT REVENUE INCREASES MORE THAN 30 PERCENT; PROVIDES 2024 NET PRODUCT REVENUE GUIDANCE

Jan 08, 2024 at 8:05 AM EST

WAKIX® (pitolisant) Preliminary Net Revenue of ~$168 Million for Fourth Quarter and ~$582 Million for Full Year 2023; Representing Growth of ~31% and ~33%, Respectively

Average Number of Patients on WAKIX Increased to ~6,150

2024 Net Product Revenue Projected Between $700 -$720 Million

$50 Million Common Stock Repurchase in Fourth Quarter Bringing 2023 Total to $100 Million; Expect to Continue Opportunistic Share Repurchases in 2024

PLYMOUTH MEETING, Pa., Jan. 8, 2024 /PRNewswire/ -- Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY) today reported preliminary, unaudited fourth quarter and full year 2023 net product revenue growth of more than 30 percent.

The company also provided 2024 net product revenue guidance of $700 to $720 million and outlined key priorities in advance of its presentation at the 42nd Annual J.P. Morgan Healthcare Conference on Wednesday, January 10, 2024 at 5:15 p.m. PT / 8:15 p.m. ET.

"In 2023, Harmony advanced our clinical development programs and diversified our portfolio while achieving net revenue of approximately $582 million," said Jeffrey M. Dayno, M.D., Harmony President and CEO. "We enter 2024 poised to generate up to $720 million in net revenue and are well on our way toward a one billion dollar plus opportunity for WAKIX in adult narcolepsy alone. Leveraging our strong cash position, as well as our expertise in clinical development and commercial execution, we will continue to advance our growth strategy by adding new products to build out a robust pipeline."

Fourth Quarter and Full Year 2023 Net Product Revenue (Preliminary and Unaudited)

- Preliminary, unaudited net product revenue for the quarter ended December 31, 2023, was approximately $168 million, compared to $128.3 million for the same period in 2022, representing ~31% growth
- Preliminary, unaudited net product revenue for the full year ended December 31, 2023, was approximately $582 million, compared to $437.9 million for the same period in 2022, representing ~33% growth
- The average number of patients on WAKIX increased by approximately 350 sequentially to approximately 6,150 for the quarter ended December 31, 2023

2024 Key Priorities

- *Continued Strong Growth for WAKIX in Adult Narcolepsy*

Drive commercial strategy to achieve Net Revenue >$700 million

Grow average number of patients on WAKIX to ~7,000

Increase educational outreach to drive continued growth in depth and breadth of prescriber base and patient interest in WAKIX

- *Advance and Expand the Pipeline*

Report pharmacokinetic (PK) data on new pitolisant-based formulations in 1H 2024

Drive patient enrollment in the Phase 3 pivotal RECONNECT trial for Fragile X syndrome

Initiate Phase 3 TEMPO study in Prader-Willi syndrome in Q1 2024

FDA meeting request submitted to discuss Idiopathic Hypersomnia path forward; anticipate meeting in Q1 2024

Complete review of positive Myotonic Dystrophy Type 1 Phase 2 POC data in EDS and fatigue; assess opportunity

- *Disciplined Capital Allocation to Maximize Shareholder Value*

Actively pursue business development opportunities to expand our pipeline and diversify our portfolio

Continued opportunistic execution of share repurchase program

2024 Net Product Revenue Guidance

- Expect full year 2024 net product revenue of $700 million to $720 million

Share Repurchase Program

- Repurchased ~1.8 million shares of common stock for $50 million in fourth quarter 2023
- Repurchased ~3.2 million shares of common stock for $100 million in full year 2023
- Remaining share repurchase program authorization of $150 million. Expect to continue opportunistic repurchase of shares.

The financial information included in this press release is preliminary, unaudited, and subject to change. It does not present all the information necessary for an understanding of the company's financial results for the fourth quarter or full year 2023.

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 at least 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 tract 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 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 Statements
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 future capabilities following the acquisition of Zynerba. 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 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 of the 2022 LCA with Bioprojet; our ability to recognize the intended benefits of our acquisition of Zynerba Pharmaceuticals; 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; statements related to our intended share repurchases and repurchase timeframe 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 21, 2023, 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.

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