UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): October 13, 2023

HARMONY BIOSCIENCES HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39450**	**82-2279923**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

630 W. Germantown Pike, Suite 215
Plymouth Meeting, PA 19462
(Address of principal executive offices) (Zip Code)

(484) 539-9800
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	**HRMY**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On October 13 2023, Harmony Biosciences Holdings, Inc. (the “Company”) issued a press release announcing topline data from its Phase 3 INTUNE study evaluating the safety and efficacy of pitolisant in adult patients with idiopathic hypersomnia.

The full text of the press release issued in connection with this announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1*	Press release issued by the Company dated October 13, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* This Exhibit is furnished herewith and will not be deemed “filed” for purposes of Section 18 of the Exchange Act or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act except to the extent that Harmony Biosciences Holdings, Inc. specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HARMONY BIOSCIENCES HOLDINGS, INC.

Date: October 13, 2023

By: /s/ Christian Ulrich
Christian Ulrich
SVP & General Counsel

HARMONY BIOSCIENCES ANNOUNCES TOPLINE DATA FROM PHASE 3 INTUNE STUDY EVALUATING PITOLISANT IN PATIENTS WITH IDIOPATHIC HYPERSOMNIA

Pitolisant demonstrated clinically meaningful benefit in patients completing the initial open label phase

Although primary outcome for excessive daytime sleepiness (EDS) between pitolisant and placebo did not reach statistical significance in the randomized withdrawal phase, further data analysis is ongoing to inform next steps

Positive trends favoring pitolisant were observed in other prespecified endpoints including Idiopathic Hypersomnia Severity Scale (IHSS) and Sleep Inertia Questionnaire (SIQ)

Safety and tolerability profile in adult patients with idiopathic hypersomnia was consistent with established safety profile of pitolisant

The totality of evidence from INTUNE study and the Orphan Drug Designation for pitolisant provides optimism for next steps with FDA

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

PLYMOUTH MEETING, PA., October 13, 2023 — 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 announced topline results from the INTUNE study in patients with idiopathic hypersomnia (IH).

Kumar Budur, M.D., Chief Medical Officer at Harmony Biosciences said, “We are very encouraged by the magnitude of the response seen in the initial open-label treatment period, where 83% of patients completing this phase responded with an average 9.4 point improvement in the Epworth Sleepiness Scale (ESS). Equally encouraging is the number of patients, almost 90%, electing to continue into the long-term extension study, allowing us to generate additional safety and efficacy data in this patient population. Positive trends in other important outcomes like sleep inertia add to the totality of evidence that pitolisant has a clinical benefit for patients with IH.”

The INTUNE study was a Phase 3 placebo-controlled, double-blind, randomized withdrawal study. Approximately 83% of patients who completed the 8-week open-label treatment period with pitolisant were responders (as defined by a decrease on the ESS of ≥3 points) and experienced a robust clinical response, with an average ESS change from baseline of – 9.4 points. A positive trend favoring pitolisant was observed during the 4-week double-blind randomized withdrawal period, however no statistically significant difference was observed between pitolisant and placebo groups on ESS, the primary endpoint. Positive trends favoring pitolisant were also observed across additional prespecified endpoints including the IHSS, which approached statistical significance, as well as on the SIQ. Further data analyses are being conducted. Approximately 88% of patients in the study continued into a 12-month long-term extension study, which is ongoing. The safety and tolerability profile of pitolisant in adult patients with idiopathic hypersomnia was consistent with the established safety profile and no new safety signals were observed.

Dr. Budur added, “We are grateful to the patients, family members and clinicians who participated in the INTUNE study. We remain committed to the IH patient community and understand their strong desire for a non-scheduled treatment option for IH. Following a thorough review of the full data set, we will work closely with the FDA to discuss next steps and a path forward for pitolisant in IH.”

Pitolisant is marketed as WAKIX® in the U.S. for the treatment of EDS or cataplexy in adult patients with narcolepsy. Pitolisant is not approved for IH and is currently being evaluated as an investigational agent in adult patients with IH.

Conference Call Today at 8:30 a.m. ET
We are hosting a conference call and webcast today at 8:30 a.m. Eastern Time to discuss the topline data from the Phase 3 INTUNE study. The live and replay 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) 245-3047 (domestic) or +1 (203) 518-9765 (international), and reference passcode HRMY1013.

About the INTUNE Study
The INTUNE study is a placebo-controlled, double-blind, randomized withdrawal Phase 3 registrational trial conducted in adult patients with IH at 52 clinical trial sites across the U.S. A total of 213 patients were enrolled and dosed in the study, of which 139 were randomized. The primary objective was to evaluate the safety and efficacy of pitolisant compared with placebo in treating EDS. The secondary objectives were to assess the impact of pitolisant on other important symptoms of IH, such as sleep inertia, daytime functioning, and cognitive performance. The INTUNE study had two periods: (1) an 8-week open-label period consisting of 3 weeks of dose titration, 3 weeks of dose optimization and 2 weeks of stable dose; followed by (2) a 4-week double-blind randomized withdrawal (DBRW) period. During the open-label

period, all patients were treated with pitolisant. Treatment responders entered the DBRW phase where half of them continued to receive stable dose pitolisant whereas the other half received placebo. All efficacy assessments were administered during the DBRW phase and analyzed to compare the difference between the pitolisant group and the placebo group from the end of stable dose period to the end of the 4-week DBRW phase.

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. 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. Approximately 80,000 people in the U.S. are believed to be affected by IH, with 40,000 currently having been diagnosed. IH is a condition with high unmet medical need.

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 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 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 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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