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, 2020

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 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

As previously reported, on July 28, 2017, Harmony Biosciences Holdings, Inc. (the "Company") entered into a license and commercialization agreement (as such agreement has been amended from time to time, the "License Agreement") with Bioprojet Société Civile de Recherche ("Bioprojet"), which granted the Company an exclusive, sublicensable license to commercialize, in the United States and its territories, commonwealths, and protectorates, including Puerto Rico, a product containing pitolisant currently known as WAKIX for narcolepsy, obstructive sleep apnea, idiopathic hypersomnia, Parkinson's disease, and any other indication agreed upon by the parties, which currently include Prader-Willi Syndrome and Muscular Dystrophy (the "Field"), as well as rights to related patent rights, know-how, trademarks, trade dress, regulatory filings and approvals (the "Bioprojet Assets"). Bioprojet also granted to the Company a co-exclusive (with Bioprojet), sublicensable license to Bioprojet Assets to clinically develop and register the pitolisant product in the Field in the United States. Bioprojet retained the right to manufacture the product in the United States, and to develop outside the United States and commercialize other products that contain pitolisant as an active ingredient anywhere in the world. Bioprojet also granted to the Company an exclusive license to use certain trademarks and trade names in connection with the commercialization of the product under the Bioprojet License Agreement. In exchange for these rights under the License Agreement, the Company agreed to pay to Bioprojet certain milestone and royalty payments.

On October 13, 2020, the Company received notice that the U.S. Food and Drug Administration ("FDA") approved the Company's new drug application ("NDA") for the Company's product WAKIX for the treatment of cataplexy in adult patients with narcolepsy. Pursuant to the License Agreement, upon FDA approval of a cataplexy indication for WAKIX (the "Trigger Date"), the Company is obligated to make a payment to Bioprojet of $2.0 million within 15 days of the Trigger Date and a milestone payment to Bioprojet of $100.0 million within 90 days of the Trigger Date. Accordingly, the Company plans to make both payments to Bioprojet on or before their respective due dates.

Descriptions of the other material terms of the License Agreement are hereby incorporated by reference to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on August 13, 2020 (the "Registration Statement"). The description of the License Agreement contained herein does not purport to be complete, and is qualified in its entirety by reference to the complete text of the License Agreement filed as Exhibit 10.1 to the Company's Registration Statement.

Item 7.01. Regulation FD.

On October 14, 2020, the Company issued a press release entitled "Harmony Biosciences Receives FDA Approval for Expanded Use of WAKIX (pitolisant) for the Treatment of Cataplexy in Adult Patients with Narcolepsy," a copy of which is furnished as Exhibit 99.1 hereto.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 (the "Securities Act"), except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d)Exhibits.

Exhibit No.	Description
99.1*	Press release issued by the Company dated October 14, 2020.

* 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 14, 2020

By: /s/ John C. Jacobs
John C. Jacobs
President and Chief Executive Officer

Exhibit 99.1

HARMONY BIOSCIENCES RECEIVES FDA APPROVAL FOR EXPANDED USE OF WAKIX® (PITOLISANT) FOR THE TREATMENT OF CATAPLEXY IN ADULT PATIENTS WITH NARCOLEPSY

WAKIX is the first and only non-scheduled treatment approved for excessive daytime sleepiness or cataplexy in adult patients with narcolepsy

PLYMOUTH MEETING, PA and CHICAGO, IL, October 14, 2020 — 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 announced the U.S. Food and Drug Administration (FDA) has approved WAKIX® (pitolisant) for the treatment of cataplexy in adult patients with narcolepsy. WAKIX is the first and only treatment approved by the FDA for people with excessive daytime sleepiness or cataplexy associated with narcolepsy that is not scheduled as a controlled substance by the U.S. Drug Enforcement Administration. WAKIX received FDA approval for the treatment of excessive daytime sleepiness in adult patients with narcolepsy in August 2019.

“All people living with narcolepsy have excessive daytime sleepiness and up to two-thirds of them also experience cataplexy, which is one of the most debilitating symptoms of this chronic, rare neurological disorder,” said Harmony’s Chief Medical Officer, Jeffrey Dayno, M.D. “Today’s FDA approval of the cataplexy indication for WAKIX, coupled with it being the first and only non-scheduled treatment option approved for adult patients with narcolepsy to treat both excessive daytime sleepiness or cataplexy, provides an opportunity for WAKIX to offer broad clinical utility to healthcare professionals managing adult patients living with narcolepsy.”

“This approval underscores our ongoing commitment to support people who are living with narcolepsy,” said John C. Jacobs, Harmony’s President and Chief Executive Officer. “At Harmony, we always keep patients at the heart of all we do and with this approval, we are inspired to continue our mission to develop novel treatment options for those living with rare, neurological disorders who have unmet medical needs.”

“From the very beginning, our passion at Bioprojet has been to bring WAKIX to people living with the daily challenges that are associated with impaired wakefulness and the risk of cataplexy attacks. This approval highlights the recognition by the FDA of a new therapeutic option in the treatment of the two major symptoms of narcolepsy by a drug with a novel mechanism of action,” said Professor Jean-Charles Schwartz, PhD. Professor Schwartz is the discoverer of histaminergic neurotransmission in the brain and the histamine-3 receptor, which is the target receptor of WAKIX. He is also the co-founder, with Jeanne-Marie Lecomte, of Bioprojet.

WAKIX, a first-in-class medication, is a selective histamine 3 (H_3) receptor antagonist/inverse agonist that works through a novel mechanism of action to increase the synthesis and release of histamine, a wake-promoting neurotransmitter in the brain. WAKIX is administered orally, once daily in the morning upon wakening.

FDA approval of WAKIX for the treatment of cataplexy in adult patients with narcolepsy is based on the results from two randomized, controlled trials (HARMONY CTP and HARMONY 1) from the clinical development program for WAKIX. After a complete response letter (CRL) for the cataplexy indication was issued by the FDA in August 2019, Harmony met with the Agency in December 2019 to discuss the deficiencies cited in the CRL. After that meeting, the FDA agreed to review the reanalysis of the HARMONY 1 data that were submitted during the NDA review, after which the Agency acknowledged that those analyses confirmed that a statistically significant reduction in the rate of cataplexy for WAKIX compared to placebo was demonstrated, which supported the positive results from the HARMONY CTP trial. Subsequently, the FDA recommended that Harmony submit a resubmission to the CRL, which Harmony submitted in August 2020 and has led to today's FDA approval of the cataplexy indication for WAKIX.

Cataplexy is characterized by sudden, temporary loss of muscle tone and is often triggered by strong emotions, such as excitement or laughter. Cataplexy can be subtle, such as drooping of eyelids, or severe, such as knee buckling or total body collapse. Cataplexy may often go unrecognized because of the subtle nature of the symptoms in some patients, variability of how cataplexy is expressed, and/or lack of patient complaints or physician recognition of the symptoms as manifestations of cataplexy. Up to two-thirds of all patients with narcolepsy have cataplexy, which can have a significant impact on a person's daily functioning.

About WAKIX® (pitolisant) Tablets

WAKIX, a first-in-class medication, was approved by the U.S. Food and Drug Administration in August 2019 for the treatment of excessive daytime sleepiness 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. 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.

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 Narcolepsy

Narcolepsy is a rare, chronic, debilitating neurological disorder of sleep-wake state instability that impacts up to 165,000 Americans and is primarily characterized by excessive daytime sleepiness (EDS) and cataplexy along with other manifestations of REM sleep dysregulation, 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. Cataplexy is characterized by sudden temporary loss of muscle tone and is often triggered by strong emotions, such as excitement or laughter. In most patients, narcolepsy is caused by the loss of hypocretin, a neuropeptide in the brain that supports sleep-wake state stability. This disorder 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 Harmony Biosciences

Harmony Biosciences is a pharmaceutical company headquartered in Plymouth Meeting, PA and Chicago, IL. The company was established by Paragon Biosciences, LLC, with a vision to provide novel treatment options for people living with rare, neurological disorders who have unmet medical needs.

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 final prospectus in connection with our initial public offering dated August 18, 2020 filed with the Securities and Exchange Commission (the "SEC") on August 19, 2020 pursuant to Rule 424(b) under the Securities Act of 1933, as amended, 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 Media Contact:

Nancy Leone
215-891-6046
nleone@harmonybiosciences.com

Harmony Biosciences Investor Contact:

Lisa Caperelli
484-539-9736
lcaperelli@harmonybiosciences.com