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): November 12, 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 2.02. Results of Operations and Financial Condition.

On November 12, 2020, Harmony Biosciences Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2020. A copy of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

On November 12, 2020, the Company posted an investor presentation to its website at https://ir.harmonybiosciences.com (the "Investor Presentation"). A copy of the Investor Presentation is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The Company expects to use the Investor Presentation, in whole or in part, and possibly with modifications, in connection with presentations to investors, analysts and others.

The information contained in the Investor Presentation is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission ("SEC") filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Investor Presentation speaks only as of the date of this Current Report on Form 8-K. The Company undertakes no duty or obligation to publicly update or revise the information contained in the Investor Presentation, although it may do so from time to time. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure. In addition, the exhibit furnished herewith contains statements intended as "forward-looking statements" that are subject to the cautionary statements about forward-looking statements set forth in such exhibit. By furnishing the information contained in the Investor Presentation, the Company makes no admission as to the materiality of any information in the Investor Presentation that is required to be disclosed solely by reason of Regulation FD.

This Current Report on Form 8-K and its contents (including Exhibits 99.1 and 99.2) are furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Note Regarding Forward-Looking Statements

Certain statements in this Current Report on Form 8-K constitute "forward-looking statements" within the meaning of the federal securities laws. These statements are based on management's current opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results. These forward-looking statements are only predictions, not historical fact, and involve certain risks and uncertainties, as well as assumptions. Actual results, levels of activity, performance, achievements and events could differ materially from those stated, anticipated or implied by such forward-looking statements. While the Company believes that its assumptions are reasonable, it is very difficult to predict the impact of known factors, and, of course, it is impossible to anticipate all factors that could affect actual results. There are many risks and uncertainties that could cause actual results to differ materially from forward-looking statements made herein including the risks discussed under the heading "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 to be filed with the SEC, as well as other factors described from time to time in the Company's filings with the SEC. Such forward-looking statements are made only as of the date of this Current Report on Form 8-K. The Company undertakes no obligation to publicly update or revise any forward-looking statement because of new information, future events or otherwise, except as otherwise required by law. If it does update one or more forward-looking statements, no inference should be made that the Company will make additional updates with respect to those or other forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1*	Press release issued by the Company dated November 12, 2020.
99.2*	Investor Presentation dated November 12, 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: November 12, 2020

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

HARMONY BIOSCIENCES REPORTS THIRD QUARTER 2020 FINANCIAL RESULTS AND BUSINESS UPDATES

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, PA and CHICAGO, IL, November 12, 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 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

Harmony Biosciences Investor Contact:

Lisa Caperelli
610-608-0215
lcaperelli@harmonybiosciences.com

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

Exhibit 99.2

HARMONY BIOSCIENCES

Harmony Biosciences Q3 2020 Financial and Business Update

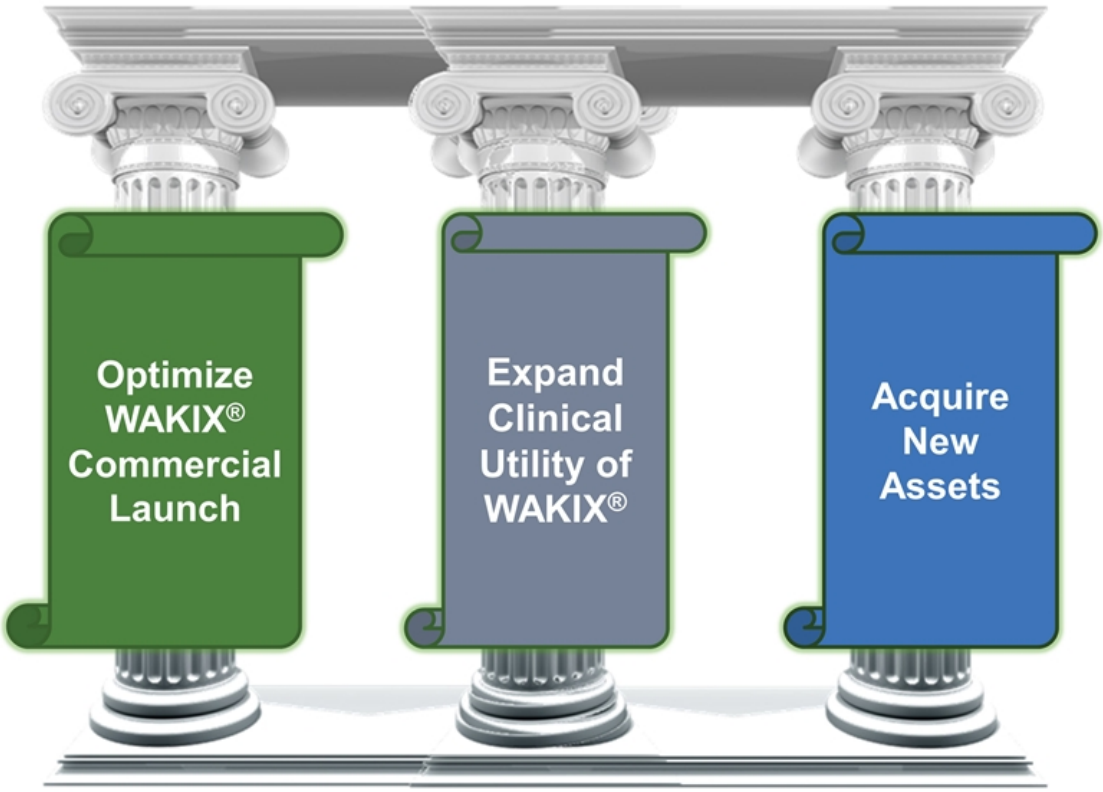
November 12, 2020

Legal Disclaimer

This presentation includes forward-looking statements within the meaning of the Private Securities Reform Act of 1995. All statements other than statements of historical facts contained in these materials or elsewhere, including statements regarding Harmony Biosciences Holdings, Inc.'s (the "Company") future financial position, business strategy and plans and objectives of management for future operations, should be considered forward-looking statements. Forward-looking statements use words like "believes," "plans," "expects," "intends," "will," "would," "anticipates," "estimates," and similar words or expressions in discussions of the Company's future operations, financial performance or the Company's strategies. These statements are based on current expectations or objectives that are inherently uncertain, especially in light of the Company's limited operating history. These and other important factors discussed under the caption "Risk Factors" in the Company's Quarter Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (the "SEC") on November 12, 2020 and its other filings with the SEC could cause actual results to differ materially and adversely from those indicated by the forward-looking statements made in this presentation. While the Company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change.

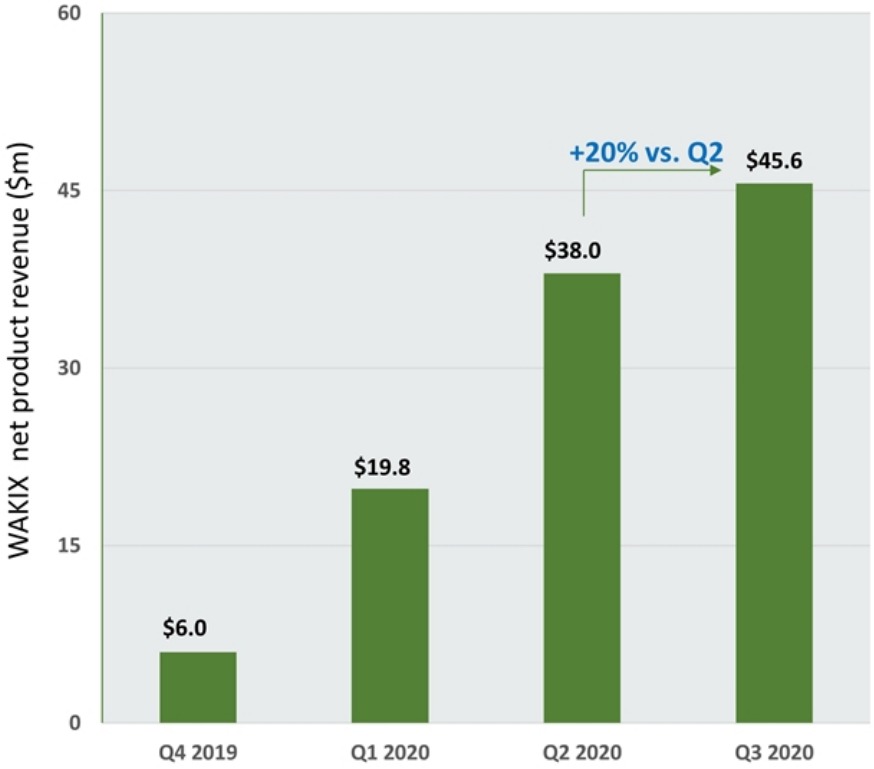
This presentation includes information related to market opportunity as well as cost and other estimates obtained from internal analyses and external sources. The internal analyses are based upon management's understanding of market and industry conditions and have not been verified by independent sources. Similarly, the externally sourced information has been obtained from sources the Company believes to be reliable, but the accuracy and completeness of such information cannot be assured. Neither the company, nor any of its respective officers, directors, managers, employees, agents, or representatives, (i) make any representations or warranties, express or implied, with respect to any of the information contained herein, including the accuracy or completeness of this presentation or any other written or oral information made available to any interested party or its advisor (and any liability therefore is expressly disclaimed), (ii) have any liability from the use of the information, including with respect to any forward-looking statements, or (iii) undertake to update any of the information contained herein or provide additional information as a result of new information or future events or developments.

Harmony's Strategy for Growth



WAKIX® Net Product Revenue

Q3 Net Product Revenue of $45.6M, 20% Increase over Q2 2020



Continued WAKIX growth in Q3 2020 vs. Q2 2020

- 20% increase in net revenue
- 22% growth in average number of patients
- Continued strength in demand, patient growth

Q3 2020 WAKIX® Launch Performance Metrics

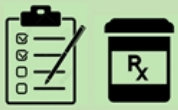
2,200

Average Number of Patients on WAKIX

>2,000

Unique HCP Prescribers Since Launch
(25% of Narcolepsy HCP Prescribers)

~80%



Targeted Account Lives Being Covered Positively
(~182M Lives)

Core Attributes of WAKIX® Product Profile Align with Existing Unmet Needs in Narcolepsy

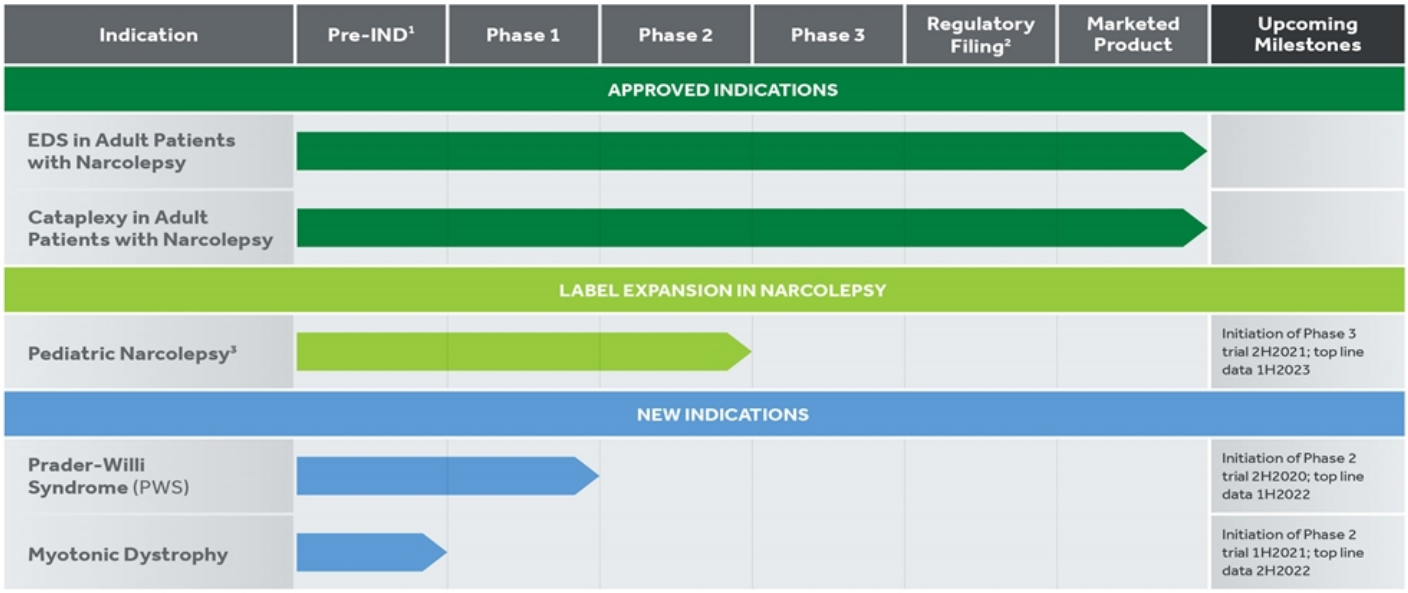
In descending order of importance as stated by combined HCP and patient audience

Top Unmet Needs in Narcolepsy (*cited by patients and HCPs*)	WAKIX (pitolisant)*
Need for non-scheduled treatment options (low/no abuse potential)	First and only FDA approved non-scheduled treatment option for narcolepsy ✓
Need for more tolerable treatment regimens	Established Safety Profile No Boxed Warning, no REMS Program ✓
Need for more effective treatment options	Statistically significant reduction in EDS and cataplexy demonstrated in two Phase III trials ✓
Novel MOAs beyond currently available therapies needed	First-in-class molecule with a novel MOA H_3R antagonist/inverse agonist; works through histamine ✓
Need for less frequently dosed products; need for once-daily options	Convenient, once daily dosing in the morning upon wakening ✓

* Based on FDA approved product labeling

Source: Harmony ATU, July 2018 (n=286); Versta Research, Know Narcolepsy Survey ("Know Narcolepsy"), October 2018

Development Pipeline for Pitolisant



1. For each potential new indication, we do not anticipate being required to conduct additional preclinical studies or studies enabling an IND beyond those studies that are already included in the New Drug Application for WAKIX. Additional preclinical studies were not required to open the IND for PWS.
2. Includes New Drug Applications and supplemental New Drug Applications.
3. Current trial being conducted by Bioprojet. We plan to initiate a Phase 3 clinical trial in 2H2021 in pursuit of pediatric indications for both EDS and cataplexy as well as pediatric exclusivity.

Current LCM Programs for Pitolisant: Scientific Rationale

Prader-Willi Syndrome

- Rare, genetic multi-system disease characterized by hypothalamic dysfunction; decreased hypocretin levels in some patients[1,2]
- ~15-20,000 patients in US and more than 50% have EDS due to sleep-wake state instability of central origin and other factors[1]
- Primary endpoint is EDS; secondary outcomes: behavioral symptoms and cognitive function; exploratory endpoint in hyperphagia
- No approved treatments for EDS in PWS and significant unmet medical need

Myotonic Dystrophy

- Rare, genetic multi-system disease; myotonia and progressive muscle weakness hallmark symptoms; EDS most common non-muscular symptom (~80% - 90% of patients)[3,4]
- Two forms: DM1 (~140,000 patients in US) more common than DM2 (~3 - 29,000 US patients); earlier onset and more severe symptoms in DM1 compared to DM2 [3,4]
- EDS and fatigue second only to muscle weakness in symptom prevalence and impact; decreased hypocretin levels [3,4]
- No approved treatments and significant unmet medical need

1. Camfferman, Sleep Medicine Reviews, 2008; 2. Omokawa et al, American Journal of Medical Genetics, 2015; 3. Dauvilliers et al, Sleep Medicine Reviews, 2012; 4. Hagerman et al, Muscle Nerve, 2019

Q3 2020 Selected Financial Results

In millions, USD

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	2019
Net Product Revenues	**$45.6**		**$103.5**	
Cost of Products Sales	7.9		17.8	
Gross profit	37.7		85.6	
Total Operating Expenses	**$27.3**	**$29.8**	**$76.4**	**$112.2**
R&D Expense	4.2	4.3	11.8	62.3[1]
S&M Expense	12.6	12.9	38.3	27.5
G&A Expense	10.5	12.6	26.3	22.4
Net Income (Loss)	**$1.9**	**$(31.9)**	**$(36.7)**	**$(115.5)**
Cash & cash equivalents	$221.7			

NOTE:
[1] Includes $50M milestone which was due on FDA acceptance of NDA file


HARMONY
BIOSCIENCES
Thank You
November 12, 2020