
**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 9, 2021

HARMONY BIOSCIENCES HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39450
(Commission
File Number)

82-2279923
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 9, 2021, Harmony Biosciences Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter and nine months ended September 30, 2021. 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 9, 2021, 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-K for the year ended December 31, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1*	Press release issued by the Company dated November 9, 2021.
99.2*	Investor Presentation dated November 9, 2021.
104	Cover Page Interactive Data File (embedded withing 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: November 9, 2021

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



HARMONY BIOSCIENCES REPORTS THIRD QUARTER 2021 FINANCIAL RESULTS AND BUSINESS UPDATES

WAKIX® (pitolisant) Net Revenue of \$80.7 Million for Third Quarter 2021 Increase of 77% vs. the Same Period in 2020

Average Number of Patients on WAKIX Increased to ~3,500

Announced Inclusion of WAKIX In American Academy of Sleep Medicine's (AASM) Updated Clinical Practice Guideline

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

PLYMOUTH MEETING, PA, November 9, 2021 — 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 reported financial results and business updates for the quarter ended September 30, 2021.

"The company continues to execute on optimizing the performance of WAKIX, demonstrated by another solid quarter of sequential revenue growth with an average number of patients on WAKIX of approximately 3,500," stated John C. Jacobs, President and Chief Executive Officer of Harmony. "Inclusion of WAKIX in the recently updated AASM clinical practice guideline is further evidence of its favorable benefit-risk profile. We believe this updated clinical practice guideline has resulted in increased awareness of WAKIX by healthcare professionals who are seeking meaningfully differentiated treatment options for people living with narcolepsy. Our vision remains focused on building Harmony into a leading neurological disease company serving patients suffering from rare diseases, for which there is high unmet medical need. In addition to optimizing WAKIX's performance, our three-pillar growth strategy also includes broadening the clinical utility of WAKIX in additional indications, as well as acquiring new assets."

Third Quarter 2021 Financial Results

Net product revenues for the quarter ended September 30, 2021 were \$80.7 million, compared to \$45.6 million for the same period in 2020. The 77.0% growth versus the same period in 2020 can be primarily attributed to strong commercial sales of WAKIX driven by organic demand.

For the quarter ended September 30, 2021, GAAP net loss available to shareholders was \$9.6 million, or a loss of \$0.17 per diluted share driven by a one time charge of \$26.1 million related to the extinguishment of our prior less advantageous debt facility. This compares to a net loss available to shareholders of \$4.1 million, or a loss of \$0.14 per diluted share, for the same period in 2020. Non-GAAP adjusted net income was \$30.4 million, or \$0.51 per diluted share, for the quarter ended September 30, 2021, compared to a non-GAAP adjusted net income of \$7.7 million, or \$0.25 per diluted share, for the same period in 2020.

Reconciliations of applicable GAAP measures to non-GAAP adjusted information are included at the end of the press release.

The components of Harmony's operating expenses include:

- Research and Development expenses were \$11.7 million in the third quarter of 2021 as compared with \$4.2 million for the same quarter in 2020;
- Sales and Marketing expenses were \$16.5 million in the third quarter of 2021 as compared to \$12.6 million for the same quarter in 2020, representing a 30.8% increase;
- General and Administrative expenses were \$16.9 million in the third quarter of 2021 as compared to \$10.5 million for the same quarter in 2020, representing a 60.4% increase; and
- Total Operating Expenses were \$45.1 million in the third quarter of 2021 as compared with \$27.3 million for the same quarter in 2020, representing a 64.9% increase.

As of September 30, 2021, Harmony had cash and cash equivalents of \$189.7 million.

In August 2021, Harmony entered into a strategic financing collaboration with Blackstone to provide up to \$330 million in financing which includes \$200 million to refinance the Company's existing debt at a lower interest rate, \$100 million for drawdown within the next twelve months, and a \$30 million equity investment in Harmony common stock.

Clinical Development and Recent Updates

- The American Academy of Sleep Medicine published an updated clinical practice guideline which includes WAKIX as a recommended treatment option for adults
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living with narcolepsy. The new clinical practice guideline was published in the *Journal of Clinical Sleep Medicine* in a special article titled, "*Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline.*" The new guideline updates and replaces the previous AASM guideline published in 2007, and now includes WAKIX as a strong recommendation for the treatment of narcolepsy in adults based on data that showed clinically significant improvement in excessive daytime sleepiness (EDS) and cataplexy in patients treated with WAKIX.

- Enrollment continues in Harmony's Phase 2 proof of concept clinical trial evaluating the safety and efficacy of pitolisant for the treatment of EDS and other symptoms in patients with PWS with top line data anticipated in the first half of 2022.
- Our Phase 2 proof of concept clinical trial to evaluate the safety and efficacy of pitolisant for EDS and other non-muscular symptoms in adult patients with type 1 myotonic dystrophy (DM1) is advancing with additional clinical sites being activated during Q3. Top-line results are anticipated in the second half of 2022.
- In August 2021, Harmony acquired HBS-102 (formerly CSTI-100), a potential first-in-class molecule with a novel mechanism of action.

Conference Call Today at 8:30 a.m. ET

We are hosting our third quarter 2021 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 4387084. A replay will be accessible until November 16, 2021 by dialing (855) 859-2056 (domestic) or +1 (404) 537-3406 (international).

Non-GAAP Financial Measures

In addition to our GAAP results, we provide certain non-GAAP metrics including adjusted net income and adjusted net income per share. We believe that the presentation of these measures provides important supplemental information to management and investors regarding our performance. These measurements are not a substitute for GAAP measurements, and the manner in which we calculate adjusted net income and adjusted net income per share may not be identical to the manner in which other companies calculate adjusted net income and adjusted net income per share. Company management uses these non-GAAP measurements as an aid in monitoring our ongoing financial performance from quarter-to-quarter and year-to-year on a regular basis and for benchmarking against comparable companies.

These non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with our consolidated financial statements prepared in accordance with GAAP; have no standardized meaning prescribed by GAAP; and are not prepared under any

comprehensive set of accounting rules or principles. In addition, from time to time in the future there may be other items that we may exclude for purposes of its non-GAAP financial measures; and we may in the future cease to exclude items that it has historically excluded for purposes of its non-GAAP financial measures.

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 (H₃) receptor antagonist/inverse agonist. The mechanism of action of WAKIX is unclear; however, its efficacy could be mediated through its activity at H₃ 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 ($\geq 5\%$ and twice placebo) for WAKIX were insomnia (6%), nausea (6%), and anxiety (5%). Other adverse reactions that occurred at $\geq 2\%$ 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 HBS-102

HBS-102, an investigational compound, is a melanin-concentrating hormone (MCH) receptor 1 (MCHR1) antagonist that targets MCH neurons in the brain. It has the potential to be a first-in-class molecule with a novel mechanism of action that could offer a new approach to the treatment of a variety of rare neurological diseases.

About Harmony Biosciences

Harmony Biosciences is a commercial stage pharmaceutical company headquartered in Plymouth Meeting, PA. 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, 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 Harmony'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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 25, 2021, 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. AND SUBSIDIARY
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,	
	2021	2020	2021	2020
Net product revenues	\$ 80,732	\$ 45,609	\$ 214,227	\$ 103,454
Cost of product sold	14,604	7,890	37,701	17,820
Gross profit	66,128	37,719	176,526	85,634
Operating expenses:				
Research and development	11,739	4,230	22,916	11,829
Sales and marketing	16,480	12,601	49,009	38,297
General and administrative	16,856	10,508	45,704	26,280
Total operating expenses	45,075	27,339	117,629	76,406
Operating income	21,053	10,380	58,897	9,228
Loss on debt extinguishment	(26,146)	—	(26,146)	(22,639)
Other income (expense), net	—	(1,525)	(15)	(3,071)
Interest expense, net	(5,429)	(6,946)	(19,783)	(20,254)
(Loss) income before income taxes	(10,522)	1,909	12,953	(36,736)
Income tax benefit (expense)	902	—	(1,070)	—
Net (loss) income and comprehensive (loss) income	\$ (9,620)	\$ 1,909	\$ 11,883	\$ (36,736)
Accumulation of dividends on preferred stock	—	(6,013)	—	(26,904)
Net (loss) income available to common stockholders	\$ (9,620)	\$ (4,104)	\$ 11,883	\$ (63,640)
(LOSS) EARNINGS PER SHARE:				
Basic	\$ (0.17)	\$ (0.14)	\$ 0.21	\$ (4.15)
Diluted	\$ (0.17)	\$ (0.14)	\$ 0.20	\$ (4.15)
Weighted average number of shares of common stock - basic	57,722,163	30,212,959	57,188,101	15,324,362
Weighted average number of shares of common stock - diluted	57,722,163	30,212,959	58,776,158	15,324,362

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

	September 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 189,704	\$ 228,631
Trade receivables, net	33,206	22,176
Inventory, net	4,805	3,823
Prepaid expenses	9,793	6,959
Other current assets	3,183	1,302
Total current assets	<u>240,691</u>	<u>262,891</u>
NONCURRENT ASSETS:		
Property and equipment, net	937	938
Restricted cash	750	750
Intangible assets, net	148,562	162,343
Other noncurrent assets	152	152
Total noncurrent assets	<u>150,401</u>	<u>164,183</u>
TOTAL ASSETS	\$ 391,092	\$ 427,074
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 4,179	\$ 2,556
Accrued compensation	6,785	8,942
Accrued expenses	34,223	122,727
Current portion of long term debt	2,000	—
Other current liabilities	436	314
Total current liabilities	<u>47,623</u>	<u>134,539</u>
NONCURRENT LIABILITIES:		
Long term debt, net	190,069	194,250
Other noncurrent liabilities	1,382	1,105
Total noncurrent liabilities	<u>191,451</u>	<u>195,355</u>
TOTAL LIABILITIES	239,074	329,894
COMMITMENTS AND CONTINGENCIES (Note 9)		
STOCKHOLDERS' EQUITY:		
Preferred stock - \$0.00001 par value; 10,000,000 shares and 00 shares authorized at September 30, 2021 and December 31, 2020, respectively; 00 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Common stock—\$0.00001 par value; 500,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 58,414,546 shares and 56,890,569 issued and outstanding at September 30, 2021 and December 31, 2020, respectively	1	1
Additional paid in capital	628,329	585,374
Accumulated deficit	(476,312)	(488,195)
TOTAL STOCKHOLDERS' EQUITY	152,018	97,180
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 391,092	\$ 427,074

HARMONY BIOSCIENCES HOLDINGS, INC.
RECONCILIATION OF GAAP TO NON-GAAP RESULTS
(In thousands except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net (loss) income	\$ (9,620)	\$ 1,909	\$ 11,883	\$ (36,736)
Non-GAAP Adjustments:				
Interest expense	5,429	6,946	19,783	20,254
Taxes	(902)	—	1,070	—
Depreciation	99	100	299	294
Amortization	4,573	1,867	13,781	5,560
EBITDA	(421)	10,822	46,816	(10,628)
Additional Non-GAAP Adjustments:				
Stock-based compensation expense	4,664	1,330	11,722	2,266
Loss on debt extinguishment	26,146	—	26,146	22,639
Warrant expense	—	1,525	—	3,109
Non-GAAP adjusted net income (loss)	\$ 30,389	\$ 13,677	\$ 84,684	\$ 17,386
Accumulation of yield on preferred stock	—	(6,013)	—	(26,904)
Non-GAAP adjusted net income (loss) available to common stockholders	30,389	7,664	84,684	(9,518)
GAAP reported net income (loss) per diluted share	\$ (0.17)	\$ (0.14)	0.20	\$ (4.15)
Non-GAAP adjusted net income (loss) per diluted share	\$ 0.51	\$ 0.25	1.44	\$ (0.62)
Weighted average number of shares of common stock used in non-GAAP diluted per share (1)	59,270,603	30,212,959	58,776,158	15,324,362

Harmony Biosciences Investor Contact:

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Harmony Biosciences Media Contact:

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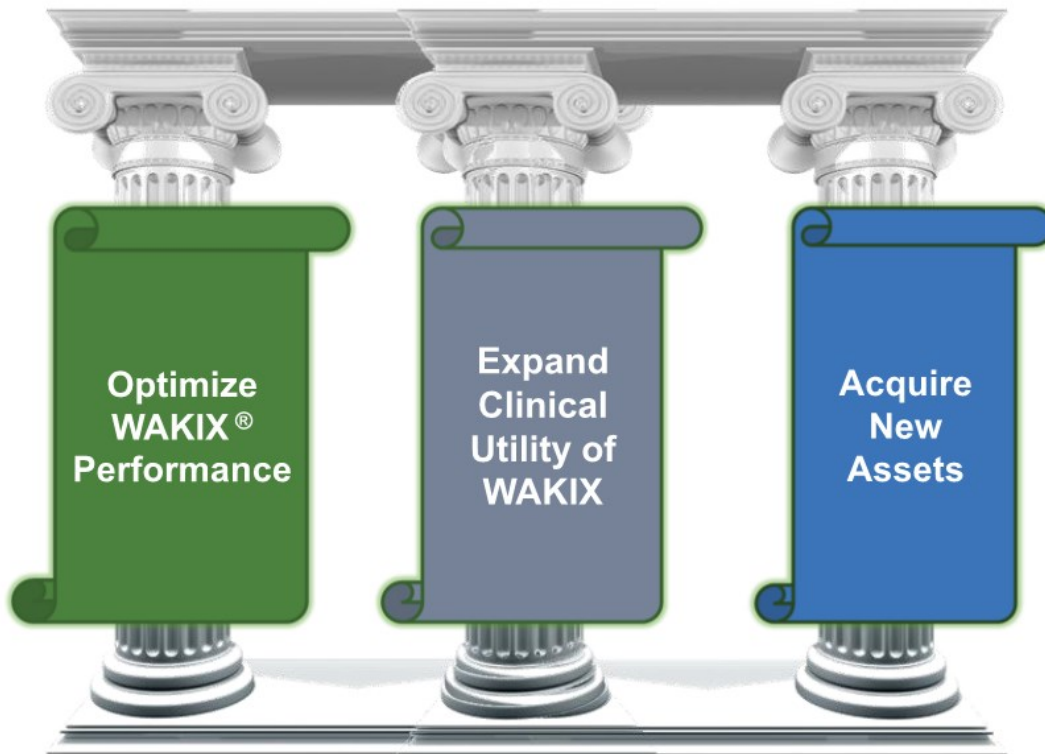
**Harmony Biosciences
Q3 2021 Financial and
Business Update**

November 9, 2021



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 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 25, 2021 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.



Q3 2021 WAKIX Revenue Performance



Continued Growth with Q3 Revenue of \$80.7M



WAKIX Net Revenue (\$m)

3Q20	2Q21	3Q21	3Q21 vs. 2Q21	3Q21 vs. 3Q20
\$45.6	\$73.8	\$80.7	9.4%	77%

Strong Revenue Growth in Q3 2021

- 9.4% growth Q3 2021 vs. Q2 2021
- 77% growth Q3 2021 vs. Q3 2020
- Continued sequential quarter over quarter growth from launch

Driving Growth Through Our Launch For WAKIX Q3 2021 Performance



Increased
Access to HCPs



~3,500

Average # of
WAKIX Patients

Patient Outreach
Programs & Support



~40%

Of 8,000 unique HCPs have
prescribed WAKIX since launch

Healthcare Professional
Educational Initiatives



~80%

U.S. Covered Lives With Formulary Access

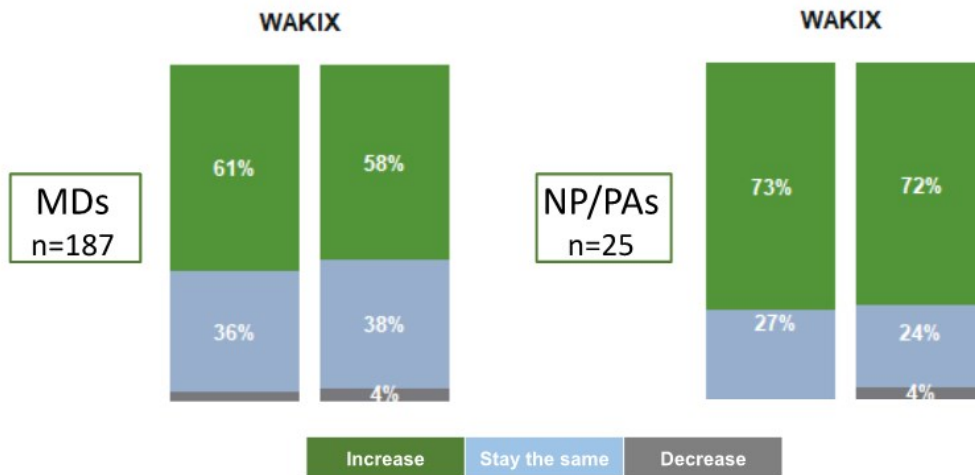
Managed Care
Education & Outreach



The Majority of HCPs (MDs & NP/PAs) Stated They Expect to Increase Future Use of WAKIX® in Both Type 1 & Type 2 Patients



Q: For WAKIX, do you expect your prescribing to increase, decrease or stay the same?



Top Reasons For Increasing Future Use of WAKIX	
To minimize use of stimulants	61%
Impact on EDS (Excessive Daytime Sleepiness) or improved alertness	58%
Non-scheduled treatment (not a controlled substance)	51%
Impact on cataplexy	48%
Novel mechanism of action	47%

Source: Harmony Market Research (total n=212); Q: MD-Type 1=172 respondents, Type 2=177 respondents; NP/PA=22 respondents, July 2021



AASM Treatment Guideline on Central Disorders of Hypersomnolence

Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline

Kiran Maski, MD, MPH; Lynn Marie Trotti MD, MSc; Suresh Kotagal, MD; Robert R Auger MD; James A Rowley MD; Sarah D Hashmi, MBBS, MSc, MPH; Nathaniel F Watson, MD, MSc

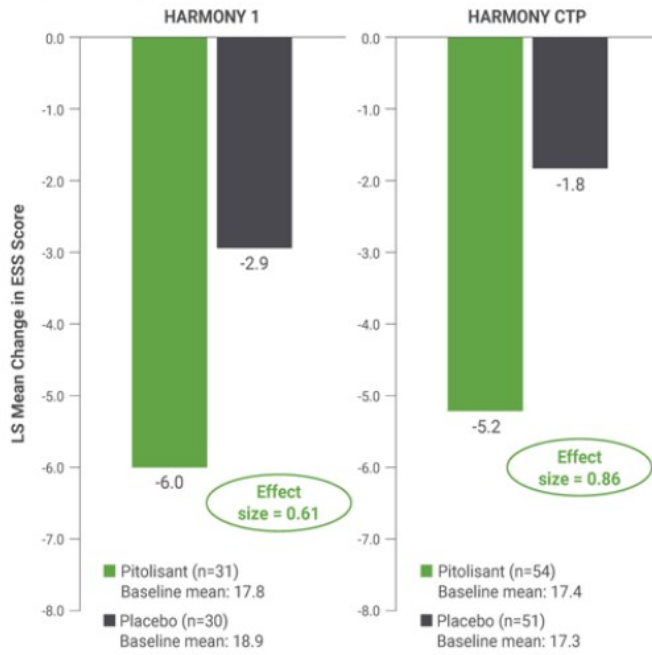
Table 2—Summary of recommended interventions in adult populations.

Intervention	Strength of Recommendation	Critical Outcomes Showing Clinically Significant Improvement*			
		Excessive Daytime Sleepiness	Cataplexy	Disease Severity	Quality of Life
Narcolepsy					
Modafinil	Strong	✓		✓	✓
Pitolisant	Strong	✓	✓	✓	
Sodium Oxybate	Strong	✓	✓	✓	
Solriamfetol	Strong	✓		✓	✓
Armodafinil	Conditional	✓		✓	
Dextroamphetamine	Conditional	✓	✓		
Methylphenidate	Conditional			✓	

*Accident risk and work/school performance/attendance were critical outcomes; however, no data were available. ✓ Critical outcomes showing clinically significant improvement.

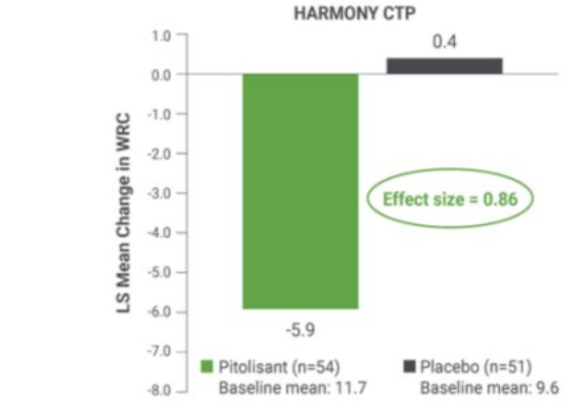
Adapted from: Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2021;17(9):1881–1893. <https://doi.org/10.5664/jcsm.9328>. Copyright American Academy of Sleep Medicine. Reproduced with permission.

Figure 1. Effect Size for Pitolisant in the Treatment of Excessive Daytime Sleepiness (HARMONY 1, HARMONY CTP)



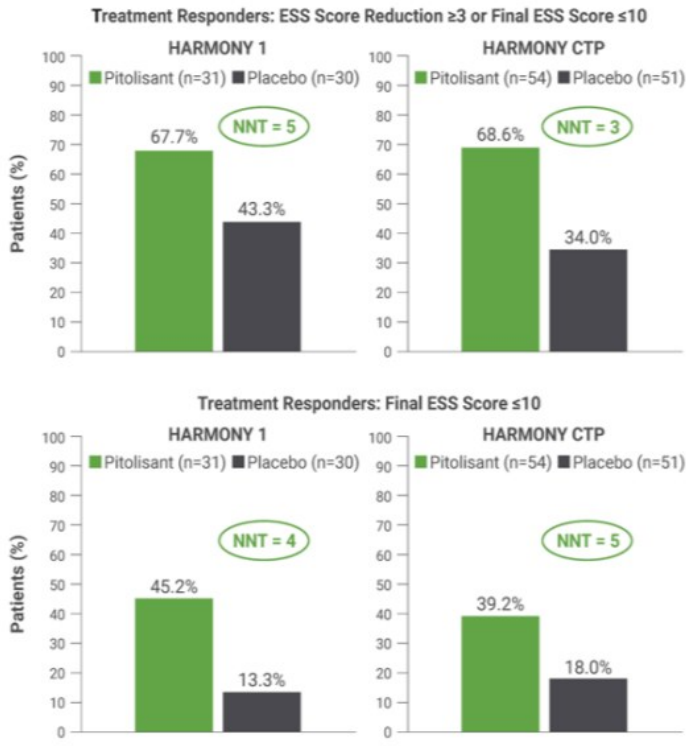
End of treatment defined as the mean of the last 2 assessments (LOCF).
 ESS = Epworth Sleepiness Scale; LOCF = last observation carried forward; LS = least-squares.

Figure 2. Effect Size for Pitolisant in the Treatment of Cataplexy (HARMONY CTP)



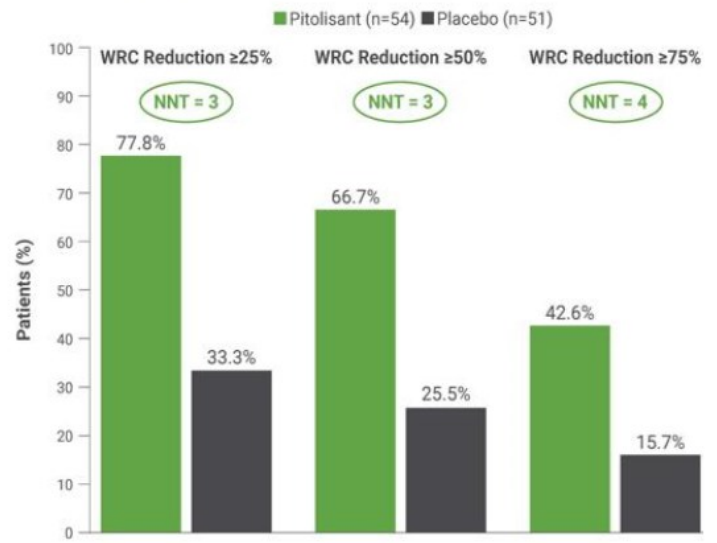
End of treatment defined as the stable-dose period (LOCF).
 LOCF = last observation carried forward; LS = least-squares; WRC = weekly rate of cataplexy.

Figure 3. NNT for Pitolisant in the Treatment of Excessive Daytime Sleepiness (HARMONY 1, HARMONY CTP)



Baseline mean ESS scores in HARMONY 1: pitolisant, 17.8; placebo, 18.9 and HARMONY CTP: pitolisant, 17.4; placebo, 17.3. ESS = Epworth Sleepiness Scale.

Figure 4. NNT for Pitolisant in the Treatment of Cataplexy (HARMONY CTP)



Baseline mean WRC: pitolisant, 11.7; placebo, 9.6. NNT = number needed to treat; WRC = weekly rate of cataplexy.

Harmony Pipeline



Product / Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Regulatory Filing ¹	Marketed Product	Upcoming Milestones
WAKIX®							
EDS in Narcolepsy (Adults)							
Cataplexy in Narcolepsy (Adults)							
Pitolisant							
Narcolepsy (Pediatrics) ²							
Prader-Willi Syndrome (PWS)							Top line data 1H2022
Myotonic Dystrophy (DM)							Top line data 2H2022
HBS-102							
Other Neurological Diseases							

1. Includes New Drug Applications and supplemental New Drug Applications.
 2. Current trial being conducted by Bioprojet.



Historical Financials



HB HARMONY
BIOSCIENCES

Q3 2021 Financial Summary *(in millions, USD)*

	Three Months Ended September 30,	
	2021	2020
Net Product Revenues	\$ 80.7	\$ 45.6
Cost of Product Sold	14.6	7.9
Total Operating Expenses	\$ 45.1	\$ 27.3
R&D Expense	11.7	4.2
S&M Expense	16.5	12.6
G&A Expense	16.9	10.5
Net (Loss) Income	\$ (9.6)	\$ 1.9
Cash & cash equivalents	\$ 189.7	

GAAP vs Non-GAAP Reconciliation *(in millions, USD)*

	Three Months Ended September,	
	2021	2020
GAAP reported net (loss) income	\$ (9.6)	\$ 1.9
Interest expense / income	5.4	6.9
Taxes	(0.9)	
Depreciation	0.1	0.1
Amortization	4.6	1.9
EBITDA	(0.4)	10.8
Stock-based compensation expense	4.7	1.3
Loss on debt extinguishment	26.1	
Warrant expense		1.5
Non-GAAP adjusted net income	30.4	13.7
Accumulation of yield on preferred stock		(6.0)
Non-GAAP adjusted net income (loss) available to common stockholders	\$ 30.4	\$ 7.7
GAAP reported net loss per diluted share	\$ (0.17)	\$ (0.14)
Non-GAAP adjusted net income per diluted share	\$ 0.51	\$ 0.25
Weighted average number of shares of common stock used in non-GAAP diluted per share	59,270,603	30,212,959

Totals may not foot due to rounding