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 1, 2022

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 1, 2022, Harmony Biosciences Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2022. 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 1, 2022, 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 Annual Report on Form 10-K for the year ended December 31, 2021 which was 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 1, 2022
99.2*	Investor Presentation dated November 1, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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

SIGNATURES

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

HARMONY BIOSCIENCES HOLDINGS, INC.

Date: November 1, 2022

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

Exhibit 99.1

HARMONY BIOSCIENCES REPORTS THIRD QUARTER 2022 FINANCIAL RESULTS AND BUSINESS UPDATES

WAKIX® (pitolisant) Net Revenue of $117.2 Million for Third Quarter 2022 Increase of ~45% vs. the Same Period in 2021

Average Number of Patients on WAKIX Increased to ~4,600

Prader-Willi Syndrome (PWS) Phase 2 Proof-Of-Concept Study Topline Data Showed Positive Signal in Treating Excessive Daytime Sleepiness

Good Momentum in Phase 3 Idiopathic Hypersomnia (IH) INTUNE Study

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

PLYMOUTH MEETING, PA, November 1, 2022 — 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, 2022.

"We delivered another strong quarter of performance, reflecting the underlying demand for WAKIX and the significant unmet need that persists in the narcolepsy market," stated John C. Jacobs, President and Chief Executive Officer of Harmony.

"In addition, we are encouraged by the positive signal seen on the primary outcome of excessive daytime sleepiness from our Phase 2 proof-of-concept study in Prader Willi syndrome and the progress we are making in our clinical programs, as we continue executing on our three-pillar growth strategy."

Third Quarter 2022 Financial Results

Net product revenues for the quarter ended September 30, 2022 were $117.2 million, compared to $80.7 million for the same period in 2021. The 45.2% growth versus the

same period in 2021 is primarily attributed to strong commercial sales of WAKIX driven by continued organic demand. The average number of patients on WAKIX increased to approximately 4,600 for the quarter ended September 30, 2022.

GAAP net income for the quarter ended September 30, 2022, was $87.9 million, or $1.44 per diluted share, compared to a GAAP net loss of $9.6 million, or ($0.17) per diluted share, for the same period in 2021. The increase in GAAP net income was primarily driven by the release of the valuation allowance on our deferred tax assets, which resulted in a $74.5 million income tax benefit for the quarter ended September 30, 2022, partially offset by a $30.0 million initial licensing fee as part of the 2022 Licensing and Commercialization Agreement with Bioprojet (the "2022 LCA"). Non-GAAP adjusted net income was $58.1 million, or $0.95 per diluted share, for the quarter ended September 30, 2022, compared to Non-GAAP adjusted net income of $23.4 million, or $0.41 per diluted share, for the same period in 2021.

Reconciliations of applicable GAAP financial measures to Non-GAAP financial measures are included at the end of this press release.

Harmony's operating expenses include the following:

- Research and Development expenses were $40.5 million in the third quarter of 2022, as compared to $11.7 million for the same quarter in 2021, representing a 245.4% increase, driven by a $30.0 million initial licensing fee as part of the 2022 LCA;
- Sales and Marketing expenses were $20.5 million in the third quarter of 2022, as compared to $16.5 million for the same quarter in 2021, representing a 24.2% increase;
- General and Administrative expenses were $21.3 million in the third quarter of 2022, as compared to $16.9 million for the same quarter in 2021, representing a 26.5% increase; and
- Total Operating Expenses were $82.3 million in the third quarter of 2022, as compared to $45.1 million for the same quarter in 2021, representing a 82.7% increase.

As of September 30, 2022, Harmony had cash, cash equivalents and investment securities of $316.0 million.

Recent Updates

- Closed the 2022 LCA, focused on developing innovative therapeutics based on pitolisant, and expanding Harmony's opportunity in narcolepsy, and potentially other indications mutually agreed upon by the parties.
- Announced topline data from the PWS Phase 2 proof-of-concept study which

showed a positive signal on improvement in the primary outcome related to excessive daytime sleepiness.
- Good momentum in patient enrollment in the Phase 3 registrational trial in adult patients with IH (INTUNE Study), with over 70% of the planned clinical trial sites activated.
- Enrollment continues in the Myotonic Dystrophy (DM1) study. Anticipate topline data from this Phase 2 proof-of-concept trial in 2023.
- Submitted a request for a Pediatric Written Request to the U.S. Food and Drug Administration (FDA) in pursuit of obtaining pediatric exclusivity for WAKIX.
- Initiated pre-clinical proof-of-concept study in PWS for HBS-102.

Conference Call Today at 8:30 a.m. ET
We are hosting our third quarter 2022 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 relations page of our website at https://ir.harmonybiosciences.com/. To participate in the live call by phone, dial (800) 225-9448 (domestic) or +1 (203) 518-9708 (international), and reference passcode HRMYQ322.

Non-GAAP Financial Measures
In addition to our GAAP results, we present certain Non-GAAP metrics including Non-GAAP adjusted net income and Non-GAAP adjusted net income per share, which we believe 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 Non-GAAP adjusted net income and Non-GAAP 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. The company uses these Non-GAAP measurements as an aid in monitoring our financial performance from quarter-to-quarter and year-to-year and for benchmarking against comparable companies.

Non-GAAP financial measures should not 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 our Non-GAAP financial measures; and we may in the future cease to exclude items that we have historically excluded for purposes of our 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 (H_3) receptor antagonist/inverse agonist. The mechanism of action of WAKIX is unclear; however, its efficacy could be mediated through its activity at H_3 receptors, thereby increasing the synthesis and release of histamine, a wake promoting neurotransmitter. WAKIX was designed and developed by Bioprojet (France). Harmony has an exclusive license from Bioprojet to develop, manufacture and commercialize pitolisant in the United States.

Indications and Usage

WAKIX is indicated for the treatment of excessive daytime sleepiness or cataplexy in adult patients with narcolepsy.

Important Safety Information

Contraindications

WAKIX is contraindicated in patients with known hypersensitivity to pitolisant or any component of the formulation. Anaphylaxis has been reported. WAKIX is also contraindicated in patients with severe hepatic impairment.

Warnings and Precautions

WAKIX prolongs the QT interval; avoid use of WAKIX in patients with known QT prolongation or in combination with other drugs known to prolong the QT interval. Avoid use in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and the presence of congenital prolongation of the QT interval.

The risk of QT prolongation may be greater in patients with hepatic or renal impairment due to higher concentrations of pitolisant; monitor these patients for increased QTc. Dosage modification is recommended in patients with moderate hepatic impairment and moderate or severe renal impairment (see full prescribing information). WAKIX is not recommended in patients with end-stage renal disease (ESRD).

Adverse Reactions

In the placebo-controlled clinical trials conducted in patients with narcolepsy with or without cataplexy, the most common adverse reactions (≥5% and 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 the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

About Narcolepsy
Narcolepsy is a rare, chronic, debilitating neurological disease of sleep-wake state instability that impacts approximately 165,000 Americans and is primarily characterized by excessive daytime sleepiness (EDS) and cataplexy – its two cardinal symptoms – along with other manifestations of REM sleep dysregulation (hallucinations and sleep paralysis), 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. In most patients, narcolepsy is caused by the loss of hypocretin/orexin, a neuropeptide in the brain that supports sleep-wake state stability. This disease 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 Idiopathic Hypersomnia
Idiopathic Hypersomnia (IH) is a rare and chronic neurological disease that is characterized by excessive daytime sleepiness (EDS) despite sufficient or even long sleep time. EDS in IH cannot be alleviated by naps, longer sleep or more efficient sleep. People living with IH experience significant EDS along with the symptoms of sleep inertia (prolonged difficulty waking up from sleep) and 'brain fog' (impaired cognition, attention, and alertness). The cause of IH is unknown, but it is likely due to alterations in areas of the brain that stabilize states of sleep and wakefulness. IH is one of the central disorders of hypersomnolence and, like narcolepsy, is a debilitating sleep disorder that can result in significant disruption in daily functioning.

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
At Harmony Biosciences, we specialize in developing and delivering treatments for rare neurological diseases that others often overlook. We believe that where empathy and innovation meet, a better life can begin for people living with neurological diseases. Established by Paragon Biosciences, LLC, in 2017 and headquartered in Plymouth Meeting, PA, our team of experts from a wide variety of disciplines and experiences is driven by our shared conviction that innovative science translates into therapeutic possibilities for our patients, who are at the heart of everything we do. For more information, please visit www.harmonybiosciences.com.

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding our product WAKIX and our 2022 LCA with Bioprojet. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: our commercialization efforts and strategy for WAKIX; the rate and degree of market acceptance and clinical utility of WAKIX, pitolisant in additional indications, if approved, and any other product candidates we may develop or acquire, if approved; our research and development plans, including our development activities with Bioprojet and plans to explore the therapeutic potential of pitolisant in additional indications; our ongoing and planned clinical trials; the availability of favorable insurance coverage and reimbursement for WAKIX; the impact of the COVID-19 pandemic, including any current and future variants; the timing of and our ability to obtain regulatory approvals for pitolisant for other indications as well as any of our product candidates, including those we are developing with Bioprojet; our failure to achieve the potential benefits under our 2022 LCA with Bioprojet; our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; our ability to identify additional products or product candidates with significant commercial potential that are consistent with our commercial objectives; our commercialization, marketing and manufacturing capabilities and strategy; significant competition in our industry; our intellectual property position; loss or retirement of key members of management; failure to successfully execute our growth strategy, including any delays in our planned future growth; our failure to maintain effective internal controls; the impact of government laws and regulations; volatility and fluctuations in the price of our common stock; the significant costs and required management time as a result of operating as a public company; the fact that the price of Harmony's common stock may be volatile and fluctuate substantially; and the significant costs and required management time as a result of operating as a public company. These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 28, 2022, 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

CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME
(In thousands, except share and per share data)

	Three Months Ended		Nine Months Ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30 2021
Net product revenues	$ 117,206	$ 80,732	$ 309,547	$ 214,227
Cost of product sold	22,959	14,604	56,596	37,701
Gross profit	94,247	66,128	252,951	176,526
Operating expenses:				
Research and development	40,548	11,739	60,794	22,916
Sales and marketing	20,467	16,480	58,210	49,009
General and administrative	21,331	16,856	61,374	45,704
Total operating expenses	82,346	45,075	180,378	117,629
Operating income	11,901	21,053	72,573	58,897
Loss on debt extinguishment	—	(26,146)	—	(26,146)
Other expense (income), net	56	—	96	(15)
Interest expense, net	(3,990)	(5,429)	(12,086)	(19,783)
Income (loss) before income taxes	7,967	(10,522)	60,583	12,953
Income tax benefit (expense)	79,976	902	72,376	(1,070)
Net income	$ 87,943	$ (9,620)	$ 132,959	$ 11,883
Unrealized loss on investments	(149)	—	(178)	—
Comprehensive income	$ 87,794	$ (9,620)	$ 132,781	$ 11,883
EARNINGS PER SHARE:				
Basic	$ 1.48	$ (0.17)	$ 2.25	$ 0.21
Diluted	$ 1.44	$ (0.17)	$ 2.18	$ 0.20
Weighted average number of shares of common stock - basic	59,234,720	57,722,163	59,070,063	57,188,101
Weighted average number of shares of common stock - diluted	61,207,625	57,722,163	60,921,482	58,776,158

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

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 261,343	$ 234,309
Investments, short-term	46,420	—
Trade receivables, net	55,065	34,843
Inventory, net	3,900	4,432
Prepaid expenses	11,246	7,637
Other current assets	4,108	3,218
Total current assets	382,082	284,439
NONCURRENT ASSETS:		
Property and equipment, net	680	820
Restricted cash	750	750
Investments, long-term	8,280	—
Intangible assets, net	166,914	143,919
Deferred tax asset	81,679	—
Other noncurrent assets	3,079	3,515
Total noncurrent assets	261,382	149,004
TOTAL ASSETS	$ 643,464	$ 433,443
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 10,049	$ 1,001
Accrued compensation	8,331	9,165
Accrued expenses	85,606	40,249
Current portion of long-term debt	2,000	2,000
Other current liabilities	1,371	1,360
Total current liabilities	107,357	53,775
NONCURRENT LIABILITIES:		
Long-term debt, net	189,725	189,984
Other noncurrent liabilities	2,498	3,177
Total noncurrent liabilities	192,223	193,161
TOTAL LIABILITIES	299,580	246,936
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at September 30, 2022 and December 31, 2021, respectively; 59,304,408 shares and 58,825,769 issued and outstanding at September 30, 2022 and December 31, 2021, respectively	1	1
Additional paid in capital	664,700	640,104
Accumulated other comprehensive income (loss)	(178)	—
Accumulated deficit	(320,639)	(453,598)
TOTAL STOCKHOLDERS' EQUITY	343,884	186,507
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 643,464	$ 433,443

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

	Three Months Ended		Nine Months Ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
GAAP net income	**$ 87,943**	**$ (9,620)**	**$ 132,959**	**$ 11,883**
Non-GAAP Adjustments:				
Non-cash interest expense (1)	418	459	1,241	1,820
Depreciation	101	99	312	299
Amortization (2)	5,962	4,573	17,005	13,781
Stock-based compensation expense	6,967	4,664	19,234	11,722
Licensing fee (3)	30,000	-	30,000	-
Loss on debt extinguishment	-	26,146	-	26,146
Valuation allowance release	(74,474)	-	(74,474)	-
Income tax effect related to non-GAAP adjustments (4)	1,175	(2,943)	(2,341)	(4,442)
Non-GAAP adjusted net income	$ 58,092	$ 23,378	$ 123,936	$ 61,209
GAAP reported net income per diluted share	**$ 1.44**	**$ (0.17)**	**$ 2.18**	**$ 0.20**
Non-GAAP adjusted net income per diluted share	$ 0.95	$ 0.41	$ 2.03	$ 1.04
Weighted average number of shares of common stock used in non-GAAP diluted per share	61,207,625	57,722,163	60,921,482	58,776,158

(1) Includes amortization of deferred finance charges
(2) Includes amortization of intangible asset related to WAKIX.
(3) Amount represents initial licensing fee incurred upon closing the 2022 Licensing and Commercialization Agreement with Bioprojet.
(4) Calculated using the reported effective tax rate for the periods presented.

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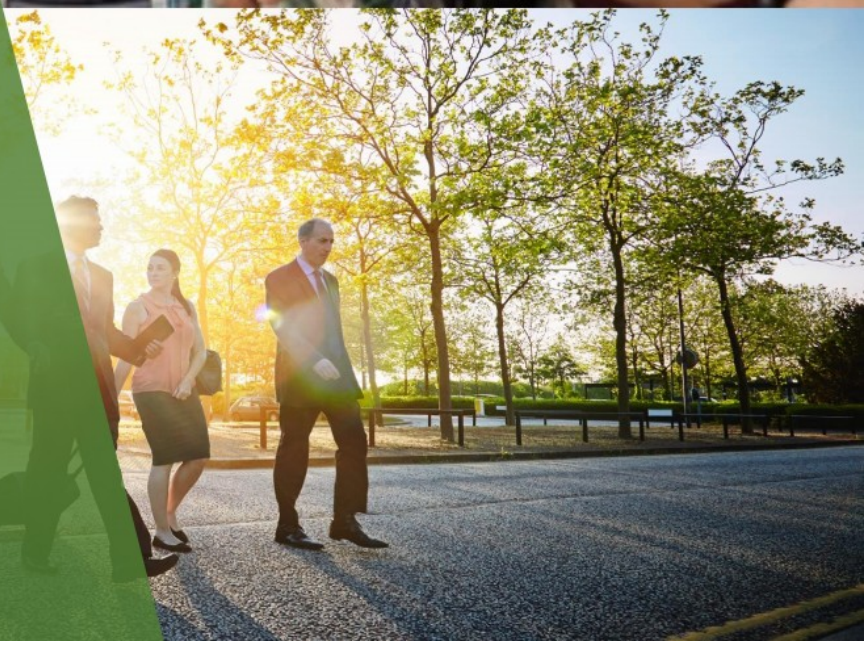
Harmony Biosciences Media Contact:
Nancy Leone
215-891-6046
nleone@harmonybiosciences.com

Exhibit 99.2

HARMONY BIOSCIENCES

Harmony Biosciences Q3 2022 Financial and Business Update

November 1, 2022

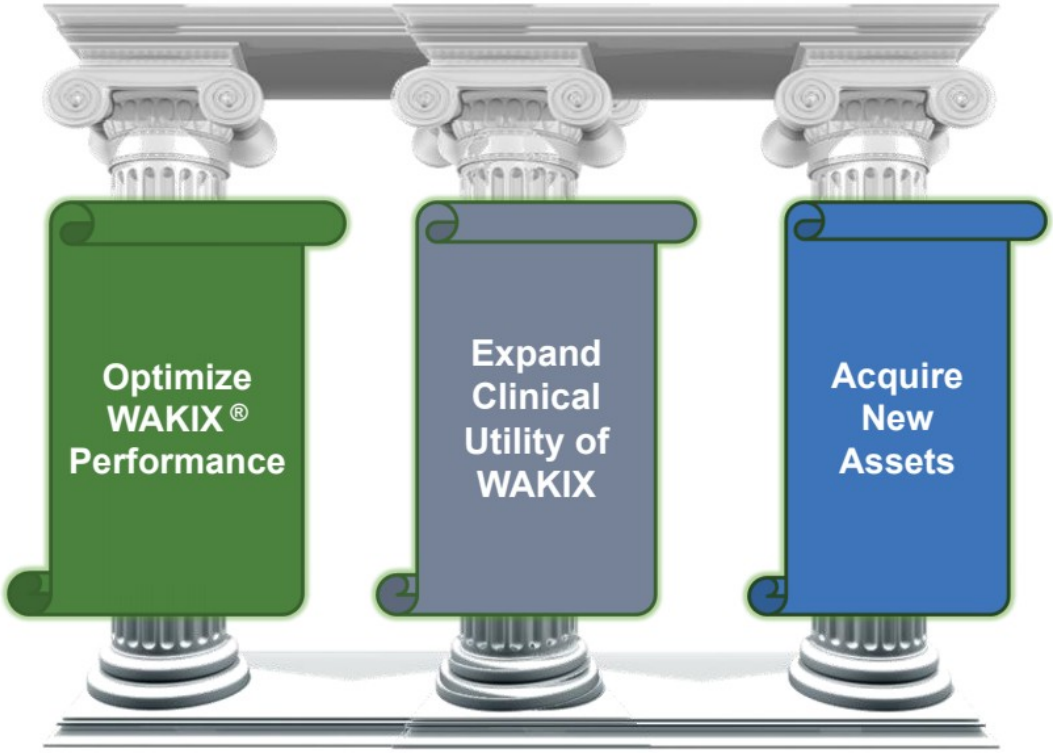


Legal Disclaimer

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 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on February 28, 2022, 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



Q3 2022 WAKIX® Net Revenue Performance

Q3 2022 Net Revenue of $117.2M

3Q21	2Q22	3Q22	Δ 3Q22 vs. 2Q22	Δ 3Q22 vs. 3Q21
$80.7	$107.0	$117.2	10%	45%

Strong Revenue Growth

- 45% growth Q3 2022 vs. Q3 2021
- 10% growth Q3 2022 vs. Q2 2022
- Strong momentum in top line prescription demand

Driving Growth Through Our Launch For WAKIX®
Q3 2022 Performance

Wakix pitolisant tablets

~85% In-Person Access to HCPs

Patient Outreach Programs & Support

~4,600 Average # of WAKIX Patients

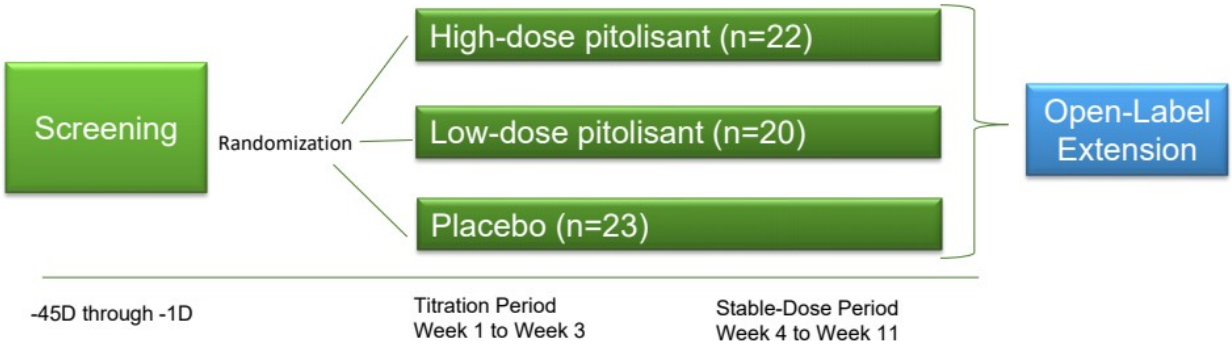
Healthcare Professional Educational Initiatives

Continued Growth in Depth & Breadth of Prescriber Base

Managed Care Education & Outreach

>80% U.S. Covered Lives With Formulary Access

Phase 2 Clinical Proof-of-Concept Trial of Pitolisant in PWS



Trial Design:

- Randomized, double-blind, placebo-controlled, parallel-group, POC, signal detection study
- 65 patients enrolled at 13 US sites; ages 6 – 65
  - Children ages 6 to < 12 (n=34)
  - Adolescents ages 12 to < 18 (n=19)
  - Adults 18 to 65 (n=12)

Objectives:

- Primary objective: to evaluate the safety and efficacy of pitolisant compared with placebo in treating EDS in patients with PWS
- Secondary objectives: caregiver assessment of severity based on EDS; clinician assessment of severity based on PWS symptoms; behavioral assessments; cognitive function; caregiver burden; long-term safety and effectiveness in patients with PWS from open-label extension

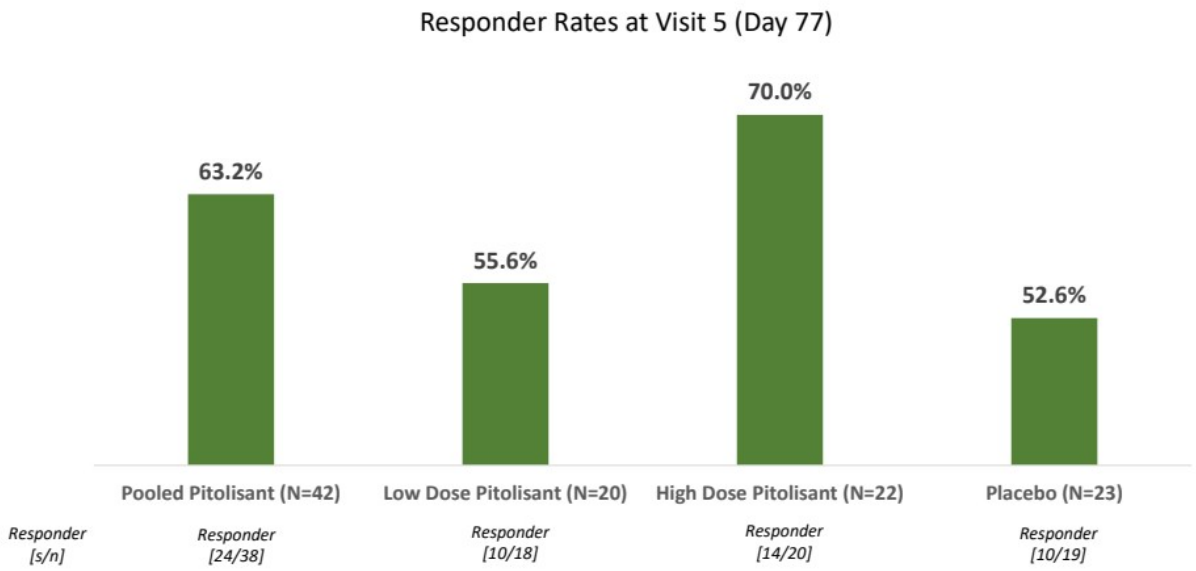
PWS Phase 2 POC Study Topline Data: Primary Endpoint

ESS-CHAD (Parent/Caregiver Version) Mean Change from Baseline to End of Treatment (Week 11)

Age	Low Dose Pitolisant (ESS-CHAD Δ from BL) (n; pitolisant dose)	High Dose Pitolisant (ESS-CHAD Δ from BL) (n; pitolisant dose)	Placebo (ESS-CHAD Δ from BL) (n)
Overall population	**-4.1**	**-4.9**	**-3.7**
(N=65)	(n=20)	(n=22)	(n=23)
Ages 6 to <12	**-3.7**	**-5.5**	**-2.1**
(N=34)	(n=12); 8.9mg	(n=11); 17.8mg	(n=11)
Ages 12 to <18	**-4.5**	**-4.2**	**-6.1**
(N=19)	(n=4); 13.35mg	(n=6); 26.7mg	(n=9)
Ages 18 to 65	**-5.0**	**-4.4**	**-2.3**
(N=12)	(n=4); 17.8mg	(n=5); 35.6mg	(n=3)

PWS Phase 2 POC Study Topline Data: Responder Analysis

Higher Responder Rate for Pitolisant vs. Placebo; Driven by High Dose Group



s = Number of responders
n = Number of subjects with baseline assessment and post-baseline assessment at the visit

A responder was defined as a subject with an improvement of ≥ 3 points from Baseline or a score ≤ 10 at EOT

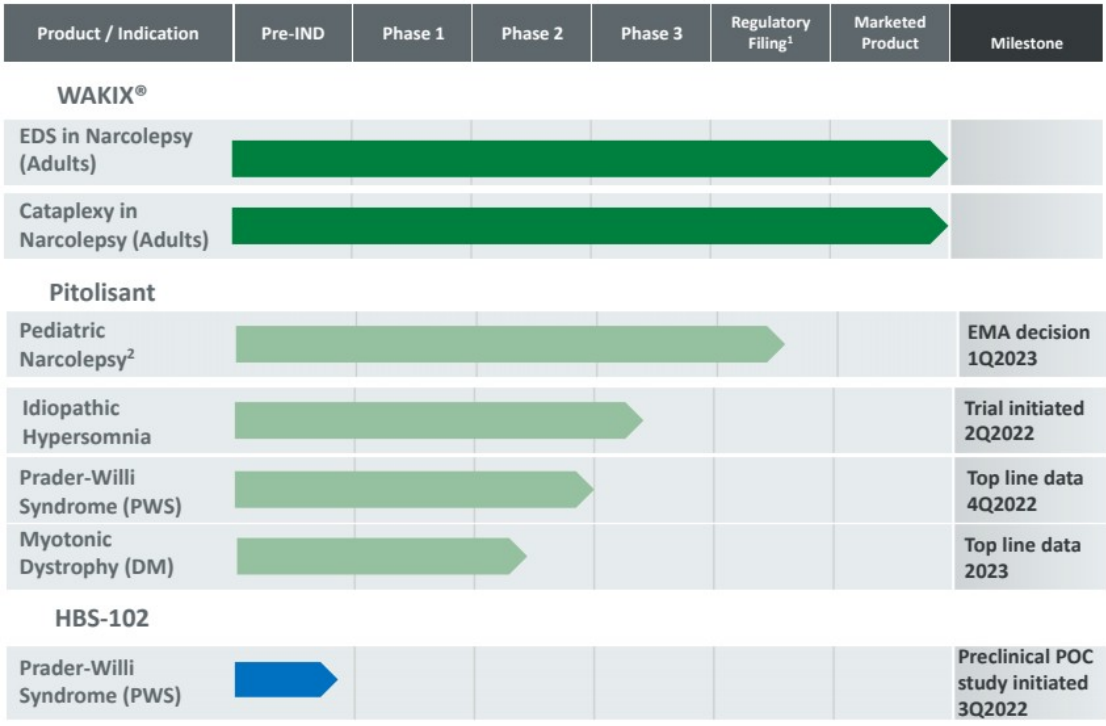
PWS Phase 2 POC Study Topline Data: Summary of Safety

Category	Pooled Pitolisant (N=42) [n; %]	Low Dose Pitolisant (N=20) [n; %]	High Dose Pitolisant (N=22) [n; %]	Placebo (N=23) [n; %]
Any TEAE	24 57.1%	13 65.0%	11 50.0%	15 65.2%
Any Treatment-Related TEAE	11 26.2%	7 35.0%	4 18.2%	7 30.4%
Any Severe TEAE	0	0	0	0
Any Severe Treatment-Related TEAE	0	0	0	0
Any Serious TEAE	0	0	0	1 4.3%
Any Serious Treatment-Related TEAE	0	0	0	0

TEAE: treatment-emergent adverse event

- The safety and tolerability profile of pitolisant in patients with Prader-Willi syndrome in this trial was consistent with the known safety/tolerability profile of pitolisant
- Most common adverse events:
  - Anxiety (11.9% pitolisant; 4.3% placebo)
  - Irritability (9.5% pitolisant; 4.3% placebo)
  - Headache (7.1% pitolisant; 4.3% placebo)

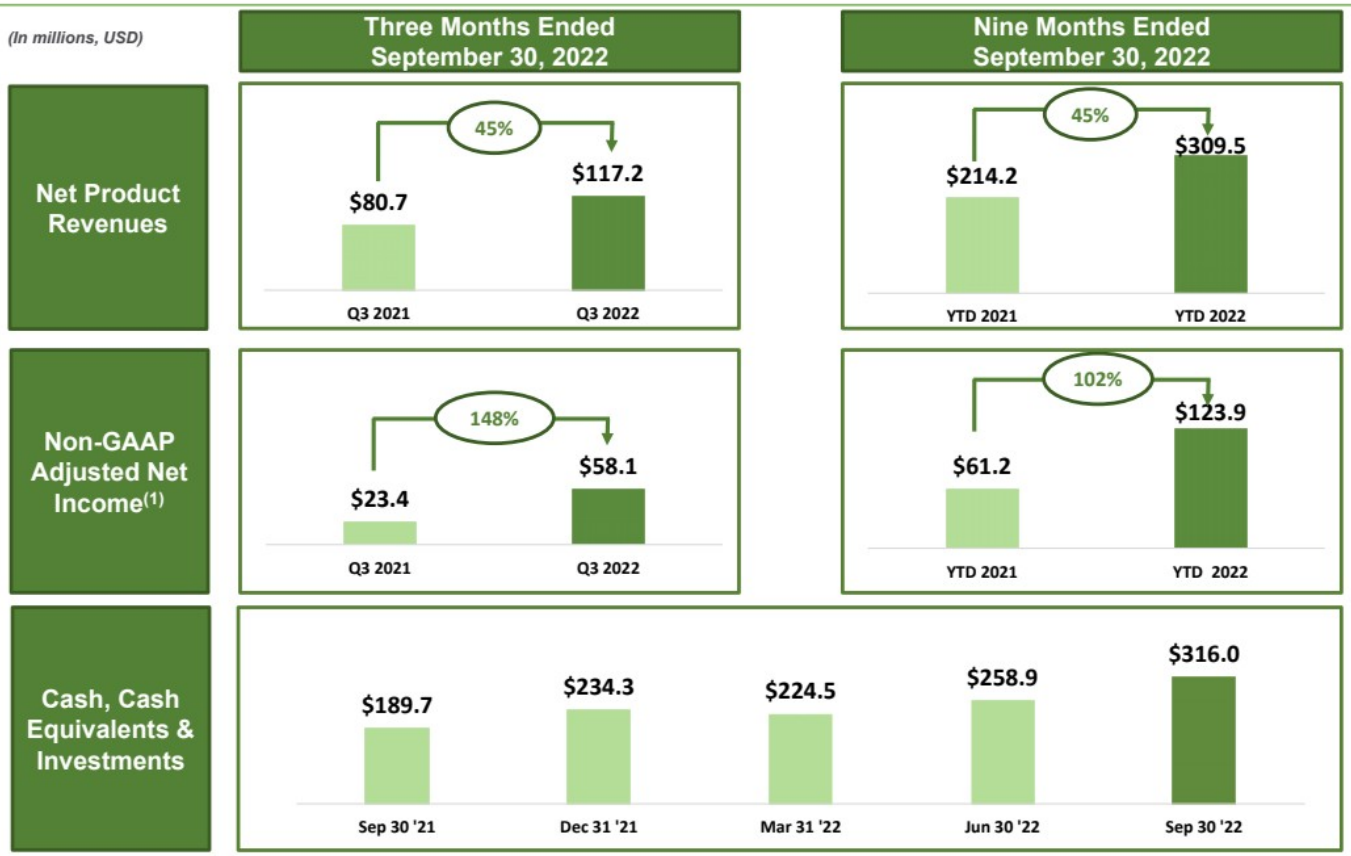
Harmony Development Pipeline



1. Includes New Drug Applications and supplemental New Drug Applications.
2. Trial conducted by Bioprojet and Bioprojet submitted regulatory package to EMA.

Financial Highlights

(In millions, USD)



(1) Non-GAAP Adjusted Net Income= GAAP Net Income excluding non-cash interest expense, depreciation, amortization, stock-based compensation, other non-operating items and tax effect of these items

Q3 2022 Financial Summary

(In millions, USD) Totals may not foot due to rounding	Three Months Ended September 30,		% Change
	2022	2021	
Net Product Revenues	**$117.2**	**$80.7**	**45%**
Cost of Product Sold	23.0	14.6	57%
Total Operating Expenses	**$82.3**	**$45.1**	**83%**
R&D Expense	40.5	11.7	NM
S&M Expense	20.5	16.5	24%
G&A Expense	21.3	16.9	27%
Net Income	**$87.9**	**($9.6)**	**NM**
Cash, cash equivalents & investment securities	**$316.0**		

NM denotes not meaningful % change

Q3 2022 GAAP vs Non-GAAP Reconciliation

(In millions, USD)	Three Months Ended September 30,	
Totals may not foot due to rounding	2022	2021
GAAP net income	**$87.9**	**($9.6)**
Non-cash interest expense(1)	0.4	0.5
Depreciation	0.1	0.1
Amortization(2)	6.0	4.6
Stock-based compensation expense	7.0	4.7
Licensing fee(3)	30.0	-
Loss on debt extinguishment	-	26.1
Valuation allowance release	(74.5)	-
Income tax effect related to Non-GAAP adjustments(4)	1.2	(2.9)
Non-GAAP adjusted net income	**$58.1**	**$23.4**
GAAP net income per diluted share	**$1.44**	**($0.17)**
Non-GAAP adjusted net income per diluted share	**$0.95**	**$0.41**
Weighted average number of shares of common stock used in non-GAAP diluted per share	61,207,625	57,722,163

(1) Includes amortization of deferred finance charges
(2) Includes amortization of intangible assets related to WAKIX
(3) Amount represents initial licensing fee incurred upon closing the 2022 Licensing and Commercialization Agreement with Bioprojet
(4) Calculated using the reported effective tax rate for the periods presented


HARMONY
BIOSCIENCES
Thank You