

**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): May 2, 2023

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:

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 May 2, 2023, Harmony Biosciences Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2023. 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 May 2, 2023, 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 May 2, 2023
99.2*	Investor Presentation dated May 2, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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

SIGNATURES

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

HARMONY BIOSCIENCES HOLDINGS, INC.

Date: May 2, 2023

By: /s/ Sandip Kapadia
Sandip Kapadia
Chief Financial Officer



HARMONY BIOSCIENCES REPORTS FIRST QUARTER 2023 FINANCIAL RESULTS AND BUSINESS UPDATES

WAKIX® (pitolisant) Net Revenue Increased ~40% Year-over-Year to \$119.1 Million for First Quarter 2023

Average Number of Patients on WAKIX Increased ~1,200 Year-over-Year to ~5,100 for First Quarter 2023

Exited First Quarter 2023 With ~5,200 Patients on WAKIX

WAKIX Surpassed \$1 Billion in Cumulative Net Revenue Since Launch

Anticipate Topline Data in Fourth Quarter 2023 in Phase 3 Idiopathic Hypersomnia (“IH”) INTUNE Study Given Continued Strong Momentum

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

PLYMOUTH MEETING, Pa., May 2, 2023 — Harmony Biosciences Holdings, Inc. (“Harmony” or the “Company”) (Nasdaq: HRMY), a pharmaceutical company dedicated to developing and commercializing innovative therapies for patients with rare neurological diseases, today reported financial results and business updates for the quarter ended March 31, 2023.

“We are pleased to report another quarter of strong performance and operational excellence across our business. We saw continued momentum in our commercial business for WAKIX, as well as in the advancement of our clinical development programs for pitolisant,” stated Jeffrey M. Dayno, M.D., President and Chief Executive Officer of Harmony.

“WAKIX commercial performance reflects its unique and meaningfully differentiated product profile, allowing us to reach an important milestone of surpassing \$1 billion in cumulative net revenue within the first three and half years since launch, one of the

most successful launches ever for a rare disease company. We have demonstrated strong and continued growth since the launch of WAKIX and remain a growth story, given the vast opportunity that remains in the narcolepsy market, the potential of our current life cycle management programs, new formulations of pitolisant that are being developed, and growth through business development.”

First Quarter 2023 Financial Results

Net product revenues for the quarter ended March 31, 2023 were \$119.1 million, compared to \$85.3 million for the same period in 2022. The 39.6% growth versus the same period in 2022 is primarily attributed to strong commercial sales of WAKIX driven by continued organic demand. The average number of patients on WAKIX increased by approximately 1,200 patients from the quarter ended March 31, 2022 to approximately 5,100 as of the quarter ended March 31, 2023. Exited the quarter ended March 31, 2023, with approximately 5,200 patients on WAKIX.

GAAP net income for the quarter ended March 31, 2023, was \$29.5 million, or \$0.48 earnings per diluted share, compared to GAAP net income of \$21.5 million, or \$0.35 earnings per diluted share, for the same period in 2022. Non-GAAP adjusted net income was \$40.1 million, or \$0.66 earnings per diluted share, for the quarter ended March 31, 2023, compared to Non-GAAP adjusted net income of \$31.1 million, or \$0.51 per diluted share, for the same period in 2022.

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 \$13.3 million in the first quarter of 2023, as compared to \$7.6 million for the same quarter in 2022, representing a 75.4% increase;
- Sales and Marketing expenses were \$22.6 million in the first quarter of 2023, as compared to \$17.6 million for the same quarter in 2022, representing a 28.4% increase;
- General and Administrative expenses were \$22.1 million in the first quarter of 2023, as compared to \$17.9 million for the same quarter in 2022, representing a 23.4% increase; and
- Total Operating Expenses were \$57.9 million in the first quarter of 2023, as compared to \$43.0 million for the same quarter in 2022, representing a 34.6% increase.

As of March 31, 2023, Harmony had cash, cash equivalents and investment securities of \$392.4 million, compared to \$345.7 million as of December 31, 2022.

Company Updates

- Jeffrey M. Dayno, MD, was appointed President and Chief Executive Officer in April 2023. Dr. Dayno was also elected to join as a member of Harmony's Board of Directors.
- Kumar Budur, MD, MS, was appointed Chief Medical Officer in May 2023. Dr. Budur most recently served as Senior Vice President and Head of Clinical Development for Harmony.
- Continued strong momentum in the Phase 3 registrational trial (INTUNE Study) in adult patients with IH, with topline data anticipated in the fourth quarter of 2023.
- End-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") scheduled for late second quarter of 2023 to discuss the Prader-Willi Syndrome ("PWS") Phase 2 proof-of-concept study results and a proposed Phase 3 trial in patients with PWS.
- Enrollment continues in our Myotonic Dystrophy ("DM1") study. We anticipate topline data from this Phase 2 proof-of-concept trial in the fourth quarter of 2023.
- On March 15, 2023, our partner Bioprojet received approval of a pediatric narcolepsy indication from the European Medicines Agency. We are working with Bioprojet on the submission to FDA of a supplemental new drug application for pediatric narcolepsy.
- Regarding pediatric exclusivity, we are working with FDA to gain alignment in pursuit of pediatric exclusivity for WAKIX.

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

We are hosting our first quarter 2023 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) 343-4136 (domestic) or +1 (203) 518-9843 (international), and reference passcode HRMYQ123.

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. We use 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 (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 at least 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 tract infection, musculoskeletal pain, heart rate increased, hallucinations, irritability, abdominal pain, sleep disturbance, decreased appetite, cataplexy, dry mouth, and rash.

Drug Interactions

Concomitant administration of WAKIX with strong CYP2D6 inhibitors increases pitolisant exposure by 2.2-fold. Reduce the dose of WAKIX by half.

Concomitant use of WAKIX with strong CYP3A4 inducers decreases exposure of pitolisant by 50%. Dosage adjustments may be required (see full prescribing information).

H1 receptor antagonists that cross the blood-brain barrier may reduce the effectiveness of WAKIX. Patients should avoid centrally acting H1 receptor antagonists.

WAKIX is a borderline/weak inducer of CYP3A4. Therefore, reduced effectiveness of sensitive CYP3A4 substrates may occur when used concomitantly with WAKIX. The effectiveness of hormonal contraceptives may be reduced when used with WAKIX and effectiveness may be reduced for 21 days after discontinuation of therapy.

Use in Specific Populations

WAKIX may reduce the effectiveness of hormonal contraceptives. Patients using hormonal contraception should be advised to use an alternative non-hormonal contraceptive method during treatment with WAKIX and for at least 21 days after discontinuing treatment.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to WAKIX during pregnancy. Patients should be encouraged to enroll in the WAKIX pregnancy registry if they become pregnant. To enroll or obtain information from the registry, patients can call 1-800-833-7460. The safety and effectiveness of WAKIX have not been established in patients less than 18 years of age.

WAKIX is extensively metabolized by the liver. WAKIX is contraindicated in patients with

severe hepatic impairment. Dosage adjustment is required in patients with moderate hepatic impairment.

WAKIX is not recommended in patients with end-stage renal disease. Dosage adjustment of WAKIX is recommended in patients with moderate or severe renal impairment.

Dosage reduction is recommended in patients known to be poor CYP2D6 metabolizers; these patients have higher concentrations of WAKIX than normal CYP2D6 metabolizers.

Please see the **Full Prescribing Information** for WAKIX for more information.

To report suspected adverse reactions, contact Harmony Biosciences at 1-800-833-7460 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About 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 Statements

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

21, 2023, and our other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

HARMONY BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY
CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
Net product revenues	\$ 119,126	\$ 85,313
Cost of product sold	20,780	14,716
Gross profit	98,346	70,597
Operating expenses:		
Research and development	13,289	7,578
Sales and marketing	22,572	17,583
General and administrative	22,062	17,880
Total operating expenses	57,923	43,041
Operating income	40,423	27,556
Other income (expense), net	2	(2)
Interest expense, net	(2,645)	(4,169)
Income before income taxes	37,780	23,385
Income tax expense	(8,295)	(1,900)
Net income	\$ 29,485	\$ 21,485
Unrealized gain on investments	120	—
Comprehensive income	\$ 29,605	\$ 21,485
EARNINGS PER SHARE:		
Basic	\$ 0.49	\$ 0.36
Diluted	\$ 0.48	\$ 0.35
Weighted average number of shares of common stock - basic	59,732,157	58,908,526
Weighted average number of shares of common stock - diluted	61,221,511	60,586,875

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

	March 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 287,962	\$ 243,784
Investments, short-term	55,916	79,331
Trade receivables, net	52,575	54,740
Inventory, net	4,090	4,297
Prepaid expenses	11,399	9,347
Other current assets	6,145	8,786
Total current assets	418,087	400,285
NONCURRENT ASSETS:		
Property and equipment, net	470	573
Restricted cash	750	750
Investments, long-term	48,538	22,668
Intangible assets, net	154,992	160,953
Deferred tax asset	89,385	85,943
Other noncurrent assets	2,870	2,798
Total noncurrent assets	297,005	273,585
TOTAL ASSETS	\$ 715,092	\$ 673,870
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 6,414	\$ 3,786
Accrued compensation	5,691	11,532
Accrued expenses	56,810	59,942
Current portion of long-term debt	6,500	2,000
Other current liabilities	9,948	1,624
Total current liabilities	85,363	78,884
NONCURRENT LIABILITIES:		
Long-term debt, net	185,063	189,647
Other noncurrent liabilities	1,625	2,501
Total noncurrent liabilities	186,688	192,148
TOTAL LIABILITIES	272,051	271,032
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Common stock—\$0.00001 par value; 500,000,000 shares authorized at March 31, 2023 and December 31, 2022, respectively; 59,954,618 shares and 59,615,731 issued and outstanding at March 31, 2023 and December 31, 2022, respectively	1	1
Additional paid in capital	685,716	675,118
Accumulated other comprehensive income (loss)	(31)	(151)
Accumulated deficit	(242,645)	(272,130)
TOTAL STOCKHOLDERS' EQUITY	443,041	402,838
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 715,092	\$ 673,870

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

	Three Months Ended	
	March 31,	March 31,
	2023	2022
GAAP net income	\$ 29,485	\$ 21,485
Non-GAAP Adjustments:		
Non-cash interest expense (1)	416	412
Depreciation	103	117
Amortization (2)	5,961	5,082
Stock-based compensation expense	6,561	4,896
Income tax effect related to non-GAAP adjustments (3)	(2,400)	(854)
Non-GAAP adjusted net income	<u>\$ 40,126</u>	<u>\$ 31,138</u>
GAAP reported net income per diluted share	\$ 0.48	\$ 0.35
Non-GAAP adjusted net income per diluted share	\$ 0.66	\$ 0.51
Weighted average number of shares of common stock used in non-GAAP diluted per share	61,221,511	60,586,875

(1) Includes amortization of deferred finance charges

(2) Includes amortization of intangible asset related to WAKIX

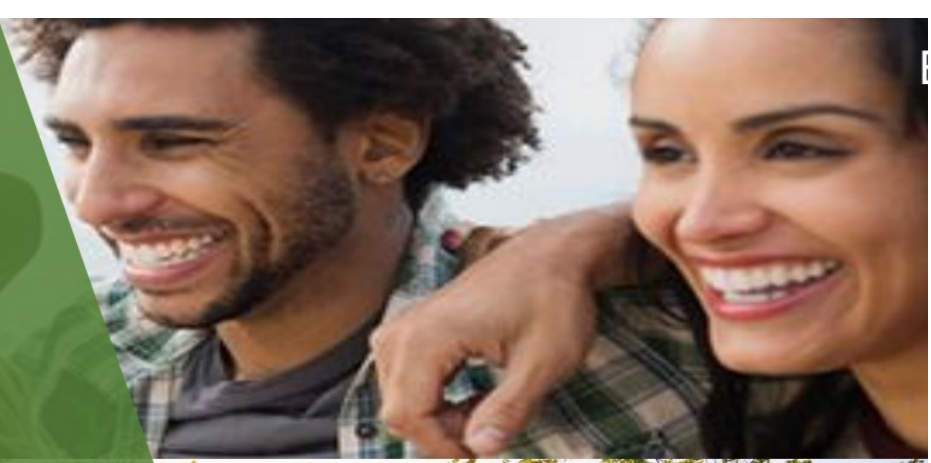
(3) Calculated using the reported effective tax rate for the periods presented less impact of discrete items

Harmony Biosciences Investor Contact:

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Harmony Biosciences Media Contact:

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Q1 2023 Financial and Business Update

May 2, 2023



Forward Looking Statements

This presentation includes forward-looking statements within the meaning of the Private Securities Reform Act of 1995. All statements other than historical facts contained in these materials or elsewhere, including statements regarding Harmony Biosciences Holdings, Inc.'s (the "Company") 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 that describe the Company's future operations, financial performance or the Company's strategies. These statements are based on current expectations and 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 21, 2023 and other SEC filings could cause actual results to differ materially and adversely from those indicated by the forward-looking statements made in this presentation. If 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 views change.

This presentation includes information related to market opportunity as well as cost and other estimates obtained from internal analyses and external analyses. Internal analyses are based upon management's understanding of market and industry conditions and have not been verified by independent third parties. 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 warranties, express or implied, with respect to any of the information contained herein, including the accuracy or completeness of this presentation; (ii) have any liability for any written or oral information made available to any interested party or its advisor (and any liability therefore is expressly disclaimed); (iii) undertake to update any of the information contained herein as a result of new information or future events or developments.



Our Corporate Growth Strategy



Optimize WAKIX®
Performance



Expand Clinical Utility of
Pitolisant



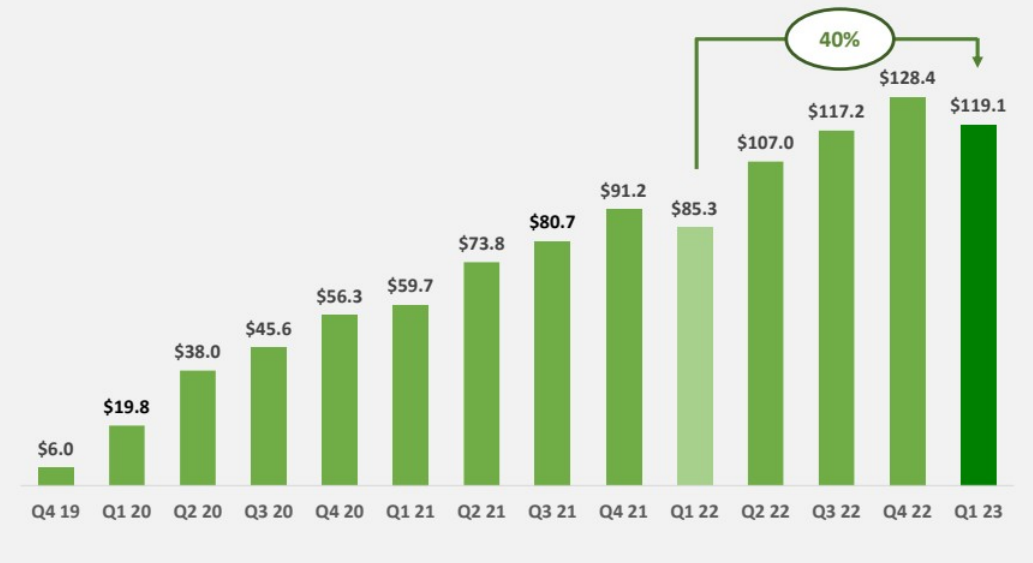
Acquire
New Assets

DESIGNED TO SUPPORT LONG TERM SUSTAINABLE GROWTH

WAKIX® Net Revenue Performance

CONFIDENT IN WAKIX BECOMING A POTENTIAL \$1B+ NARCOLEPSY OPPORTUNITY, WITH THE POTENTIAL TO CO AN ADDITIONAL \$1B, IF APPROVED IN IDIOPATHIC HYPERSOMNIA AND OTHER CURRENT LIFECYCLE MANAGEM

WAKIX QUARTERLY NET REVENUE (\$M)



HIGHLIGHTS

- Strong revenue growth of
- WAKIX Surpassed \$1 Billion Net Revenue Since Launch
- March 2023, the highest m prescription demand for W years and the strongest m patient starts in a year



Driving Growth Through Strong Commercialization of WAKIX®

Q1 2023 Performance



Development Pipeline

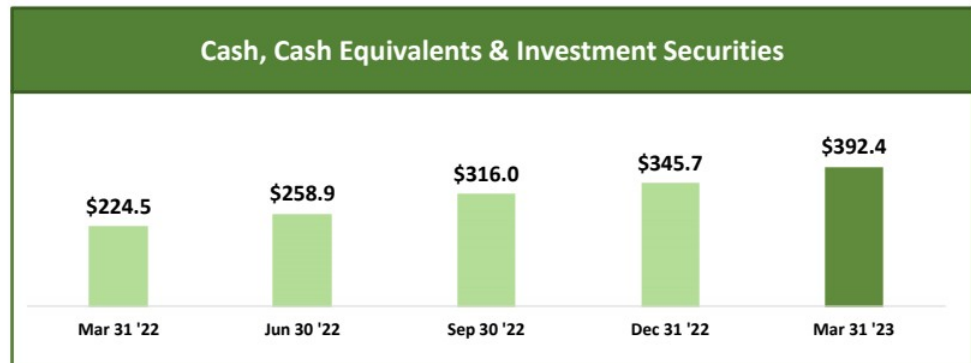
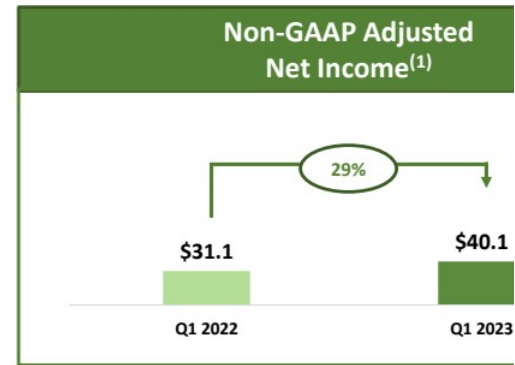
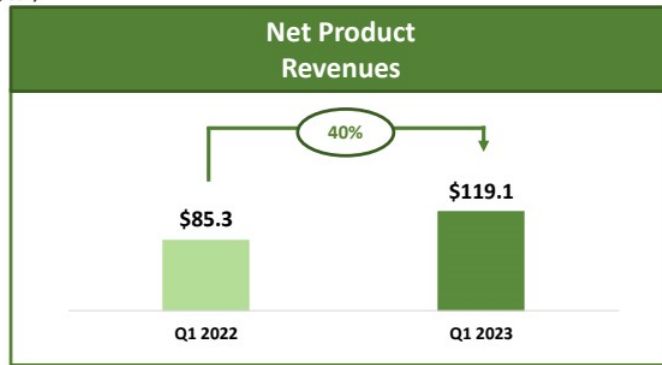
Product / Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Regulatory Filing ¹	Marketed Product	Milestone	
WAKIX®								
EDS in Narcolepsy (Adults)								
Cataplexy in Narcolepsy (Adults)								
Pitolisant								
Pediatric Narcolepsy ²								EMA Approval 1Q2023
Idiopathic Hypersomnia (IH)								Topline data 4Q2023
Prader-Willi Syndrome (PWS)								FDA EoP2 Meeting Late 2Q2023
Myotonic Dystrophy (DM)								Topline data 4Q2023
New Pitolisant Assets								New Bioproject Agreement Closed 3Q2023
HBS-102								
PWS								Preclinical PK study initiated 3Q2022



1. Includes New Drug Applications and supplemental New Drug Applications.
2. Trial conducted by Bioprojet and Bioprojet submitted regulatory package to EMA. Bioprojet received EMA approval on March 15, 2023.

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 the

Financial Summary

<i>(In millions, USD)</i>	Three Months Ended March 31,		% Change
	2023	2022	
Net Product Revenues	\$119.1	\$85.3	40%
Cost of Product Sold	20.8	14.7	41%
Total Operating Expenses	\$57.9	\$43.0	35%
R&D Expense	13.3	7.6	75%
S&M Expense	22.6	17.6	28%
G&A Expense	22.1	17.9	23%
Net Income	\$29.5	\$21.5	37%
Cash, cash equivalents & investment securities	\$392.4		

GAAP vs NON-GAAP Reconciliation

<i>(In millions, USD)</i>	Three Months Ended March 31,	
	2023	2022
Totals may not foot due to rounding		
GAAP net income	\$29.5	\$21.5
Non-cash interest expense ⁽¹⁾	0.4	0.4
Depreciation	0.1	0.1
Amortization ⁽²⁾	6.0	5.1
Stock-based compensation expense	6.6	4.9
Income tax effect related to Non-GAAP adjustments ⁽³⁾	(2.4)	(0.9)
Non-GAAP adjusted net income	\$40.1	\$31.1
GAAP net income per diluted share	\$0.48	\$0.35
Non-GAAP adjusted net income per diluted share	\$0.66	\$0.51
Weighted average number of shares of common stock used in non-GAAP diluted per share	61,221,511	60,586,875

(1) Includes amortization of deferred finance charges

(2) Includes amortization of intangible asset related to WAKIX

(3) Calculated using the reported effective tax rate for the periods presented less impact of valuation allowance release and discrete items



Harmony Continues To Be A Growth Story





Thank You

