**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): February 22, 2024**

# 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 February 22, 2024, Harmony Biosciences Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 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 February 22, 2024, the Company posted an investor presentation to its website at ttps://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 the 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, 2022, which was filed with the Securities and Exchange Commission ("SEC,") on February 21, 2023, 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 February 22, 2024. |
| 99.2* | Investor Presentation dated February 22, 2024 |
| 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: February 22, 2024

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

**HARMONY BIOSCIENCES REPORTS FOURTH QUARTER AND FULL YEAR 2023 FINANCIAL RESULTS AND BUSINESS UPDATES**

WAKIX® *(pitolisant) Net Revenue of $168.4 Million for Fourth Quarter and $582.0 Million for Full Year 2023; Representing Growth of ~31% and ~33%, Respectively*

*U.S. Food and Drug Administration (FDA) Granted Priority Review for WAKIX in Pediatric Narcolepsy; PDUFA Date of June 21, 2024*

*Meeting with FDA to Discuss Idiopathic Hypersomnia Development Program Scheduled for March 2024*

*FDA Granted Orphan Drug Designation to Pitolisant for the Treatment of Prader-Willi Syndrome; On Track to Initiate Phase 3 TEMPO Study in First Quarter 2024*

*2024 Net Product Revenue Projected Between $700 -$720 Million*

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

PLYMOUTH MEETING, Pa., February 22, 2024 — Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY), today reported net revenue growth of more than 30% for the fourth quarter and full year ended December 31, 2023.

“Harmony delivered another year of outstanding performance in 2023, with continued strong growth for WAKIX, demonstrating its durability going into year five on the market,” stated Jeffrey M. Dayno, M.D., President and Chief Executive Officer of Harmony. “In addition to our strong commercial execution, we advanced all our clinical development programs for pitolisant, moved the Next-Generation formulations of pitolisant into the clinic, expanded our pipeline and diversified our portfolio with the acquisition of Zynerba and the ongoing Phase 3 trial in Fragile X syndrome. Harmony continues to be a growth story and we look forward to continued strong execution in 2024.”

**Key Business Updates**

- FDA granted priority review of supplemental new drug application (sNDA) for WAKIX in pediatric narcolepsy; PDUFA date of June 21, 2024
- Meeting with the FDA to discuss Idiopathic Hypersomnia (IH) development program scheduled for March 2024
- FDA granted Orphan Drug designation to pitolisant for the treatment of Prader-Willi syndrome (PWS); on track to initiate the Phase 3 TEMPO study in patients with PWS in the first quarter of 2024
- Reported positive Phase 2 proof-of-concept (POC) data in EDS and fatigue in Myotonic Dystrophy Type 1 (DM1) in the fourth quarter of 2023
- On track to report pharmacokinetic (PK) data on next-gen pitolisant-based formulations in the first half of 2024
- Expect to complete patient enrollment in the Phase 3 pivotal RECONNECT trial for Fragile X syndrome (FXS) in the first quarter of 2025 with topline data expected in mid-2025
- On track to report pre-clinical POC data for HBS-102 in PWS in the first half of 2024
- Repurchased approximately 3.2 million shares of common stock for $100 million in full-year 2023 and expect to continue the opportunistic repurchase of shares under the remaining share repurchase program authorization of $150 million.

**Fourth Quarter 2023 Financial Results**

Net product revenue for the quarter ended December 31, 2023 was $168.4 million, compared to $128.3 million for the same period in 2022. The 31% growth versus the same period in 2022 is primarily attributed to strong commercial sales of WAKIX driven by continued organic demand tapping into a large market opportunity (approximately 80,000 patients diagnosed with narcolepsy in the US). The average number of patients on WAKIX increased by approximately 350 sequentially to approximately 6,150 for the quarter ended December 31, 2023.

GAAP net income for the quarter ended December 31, 2023, was $26.6 million, or $0.45 per diluted share, compared to GAAP net income of $48.5 million, or $0.79 per diluted share, for the same period in 2022. Non-GAAP adjusted net income was $42.8 million, or $0.73 per diluted share, for the quarter ended December 31, 2023, compared to Non-GAAP adjusted net income of $61.9 million, or $1.01 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 $30.3 million in the fourth quarter of 2023, as compared to $10.1 million for the same quarter in 2022, representing a 200% increase. Expenses in the fourth quarter of 2023 included one-time Zynerba transaction related costs of $6.0 million;
- Sales and Marketing expenses were $26.9 million in the fourth quarter of 2023, as compared to $21.1 million for the same quarter in 2022, representing a 28% increase;
- General and Administrative expenses were $27.9 million in the fourth quarter of 2023, as compared to $22.6 million for the same quarter in 2022, representing a 23% increase. Expenses in the fourth quarter of 2023 included one-time Zynerba transaction related costs of $3.8 million; and
- Total Operating Expenses were $85.1 million in the fourth quarter of 2023, as compared to $53.8 million for the same quarter in 2022, representing a 58% increase. Total Operating Expenses in the fourth quarter of 2023 included one-time Zynerba transaction related costs of $9.8 million.

**Full Year 2023 Financial Results**

Net product revenue for the year ended December 31, 2023 was $582.0 million, compared to $437.9 million for 2022. The 33% growth versus the same period in 2022 is primarily attributed to strong commercial sales of WAKIX driven by continued organic demand tapping into a large market opportunity.

GAAP net income for the year ended December 31, 2023, was $128.9 million, or $2.13 per diluted share, compared to GAAP net income of $181.5 million, or $2.97 per diluted share, for 2022. The decrease 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 year ended December 31, 2022. Non-GAAP adjusted net income was $188.4 million, or $3.12 per diluted share, for the year ended December 31, 2023, compared to Non-GAAP adjusted net income of $183.5 million, or $3.00 per diluted share, for 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 $76.1 million for the year ended December 31, 2023, as compared to $70.9 million for the prior year, representing a 7% increase. Expenses in 2023 included one-time Zynerba transaction related costs of $6.0 million;
- Sales and Marketing expenses were $97.4 million for the year ended December 31, 2023, as compared to $79.3 million for the prior year, representing a 23% increase;

- General and Administrative expenses were $95.3 million for the year ended December 31, 2023, as compared to $84.0 million for the prior year, representing a 13% increase. Expenses in 2023 included one-time Zynerba transaction related costs of $3.8 million; and
- Total Operating Expenses were $268.8 million for the year ended December 31, 2023, as compared to $234.2 million for the prior year, representing a 15% increase. Total Operating Expenses in 2023 included one-time Zynerba transaction related costs of $9.8 million.

As of December 31, 2023, Harmony had cash, cash equivalents and investment securities of $425.6 million, compared to $345.7 million on December 31, 2022.

**2024 Net Product Revenue Guidance**

Expect full year 2024 net product revenue of $700 million to $720 million.

**Conference Call Today at 8:30 a.m. ET**
We are hosting our fourth quarter and full year 2023 financial results conference call and webcast today at 8:30 a.m. Eastern Time. The live and replay 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) 579-2543 (domestic) or +1 (785) 424-1789 (international), and reference passcode HRMYQ423.

**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 ($H_3$) 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 170,000 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 Prader-Willi Syndrome**
PWS is an orphan/rare, genetic neurological disorder with many of the symptoms resulting from hypothalamic dysfunction. The hypothalamus is the part of the brain that controls both sleep-wake state stability and signals that mediate the balance between hunger and satiety, resulting in two of the main symptoms in patients with PWS; EDS and hyperphagia (an intense persistent sensation of hunger accompanied by food preoccupations, an extreme drive to consume food, food-related behavior problems, and a lack of normal satiety). Other features include low muscle tone, short stature, behavioral problems, and cognitive impairment. Approximately 15,000 to 20,000 people in the U.S. live with PWS, and over half of them experience EDS and the majority of them have behavioral disturbances.

**About Myotonic Dystrophy Type 1**
Myotonic dystrophy Type 1 (DM1) is the most common form of adult-onset muscular dystrophy. It is a genetic disorder inherited in an autosomal-dominant pattern. Latest estimates suggest a prevalence of about one per 2,100 people with the genetic defect

for DM1. This equates to about 150,000 people in the U.S. with the genetic defect for DM1. Estimates suggest there are 40,000 people currently diagnosed with DM1 in the U.S., with up to 90% of them reporting EDS and fatigue and over 60% of them experiencing cognitive dysfunction.

**About Fragile X Syndrome**
Fragile X syndrome (FXS) is a rare genetic disorder that is the leading known cause of both inherited intellectual disability and autism spectrum disorder. The disorder negatively affects synaptic function, plasticity and neuronal connections, and results in a spectrum of intellectual disabilities and behavioral symptoms, such as social avoidance and irritability. While the exact prevalence is unknown, upwards of 80,000 patients in the U.S. and 121,000 patients in the European Union and the UK are believed to have FXS, based on FXS prevalence estimates of approximately 1 in 4,000 to 7,000 in males and approximately 1 in 8,000 to 11,000 in females. There is a significant unmet medical need in patients living with FXS as there are currently no FDA approved treatments for this disorder.

FXS is caused by a mutation in FMR1, a gene which modulates a number of systems, including the endocannabinoid system, and most critically, codes for a protein called FMRP. The FMR1 mutation manifests as multiple repeats of a DNA segment, known as the CGG triplet repeat, resulting in deficiency or lack of FMRP. FMRP helps regulate the production of other proteins and plays a role in the development of synapses, which are critical for relaying nerve impulses, and in regulating synaptic plasticity. In people with full mutation of the FMR1 gene, the CGG segment is repeated more than 200 times, and in most cases causes the gene to not function. Methylation of the FMR1 gene also plays a role in determining functionality of the gene. In approximately 60% of patients with FXS, who have complete methylation of the FMR1 gene, no FMRP is produced, resulting in dysregulation of the systems modulated by FMRP.

**About ZYN002**
ZYN002 is the first-and-only pharmaceutically manufactured synthetic cannabidiol devoid of THC and formulated as a patent-protected permeation-enhanced gel for transdermal delivery through the skin and into the circulatory system. The product is manufactured through a synthetic process in a cGMP facility and is not extracted from the cannabis plant. ZYN002 does not contain THC, the compound that causes the euphoric effect of cannabis, and has the potential to be a nonscheduled product if approved. Cannabidiol, the active ingredient in ZYN002, has been granted orphan drug designation by the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of FXS and for the treatment of 22q. Additionally, ZYN002 has received FDA Fast Track designation for the treatment of behavioral symptoms in patients with FXS.

**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 and our future capabilities following the acquisition of Zynerba. 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 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 ability to recognize the intended benefits of our acquisition of Zynerba Pharmaceuticals; 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; statements related to our intended share repurchases and repurchase timeframe 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 22, 2024, 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 (LOSS)**
**(In thousands, except share and per share data)**

| | Three Months Ended | | Year Ended | |
|---|---|---|---|---|
| | December 31, 2023 | December 31, 2022 | December 31, 2023 | December 31, 2022 |
| Net product revenue | $ 168,412 | $ 128,308 | $ 582,022 | $ 437,855 |
| Cost of product sold | 43,152 | 26,885 | 121,236 | 83,481 |
| Gross profit | 125,260 | 101,423 | 460,786 | 354,374 |
| Operating expenses: | | | | |
| Research and development | 30,306 | 10,092 | 76,063 | 70,886 |
| Sales and marketing | 26,886 | 21,075 | 97,404 | 79,285 |
| General and administrative | 27,872 | 22,643 | 95,289 | 84,017 |
| Total operating expenses | 85,064 | 53,810 | 268,756 | 234,188 |
| Operating income | 40,196 | 47,613 | 192,030 | 120,186 |
| Loss on debt extinguishment | — | — | (9,766) | — |
| Other expense (income), net | 193 | 73 | 159 | 169 |
| Interest expense | (4,796) | (5,444) | (23,757) | (18,795) |
| Interest income | 4,096 | 1,861 | 14,730 | 3,126 |
| Income before income taxes | 39,689 | 44,103 | 173,396 | 104,686 |
| Income tax benefit (expense) | (13,082) | 4,406 | (44,543) | 76,782 |
| Net income | $ 26,607 | $ 48,509 | $ 128,853 | $ 181,468 |
| EARNINGS PER SHARE: | | | | |
| Basic | $ 0.46 | $ 0.82 | $ 2.17 | $ 3.07 |
| Diluted | $ 0.45 | $ 0.79 | $ 2.13 | $ 2.97 |
| Weighted average number of shares of common stock - basic | 58,320,400 | 59,478,933 | 59,469,648 | 59,173,121 |
| Weighted average number of shares of common stock - diluted | 58,853,292 | 61,620,712 | 60,372,397 | 61,097,045 |

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

| | December 31, 2023 | December 31, 2022 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | $ 311,660 | $ 243,784 |
| Investments, short-term | 41,800 | 79,331 |
| Trade receivables, net | 74,140 | 54,740 |
| Inventory, net | 5,363 | 4,297 |
| Prepaid expenses | 12,570 | 9,347 |
| Other current assets | 5,537 | 8,786 |
| Total current assets | 451,070 | 400,285 |
| NONCURRENT ASSETS: | | |
| Property and equipment, net | 371 | 573 |
| Restricted cash | 270 | 750 |
| Investments, long-term | 72,169 | 22,568 |
| Intangible assets, net | 137,108 | 160,953 |
| Deferred tax asset | 144,162 | 85,943 |
| Other noncurrent assets | 6,298 | 2,798 |
| Total noncurrent assets | 360,378 | 273,585 |
| TOTAL ASSETS | $ 811,448 | $ 673,870 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Trade payables | $ 17,730 | $ 3,786 |
| Accrued compensation | 23,747 | 11,532 |
| Accrued expenses | 99,494 | 59,942 |
| Current portion of long-term debt | 15,000 | 2,000 |
| Other current liabilities | 7,810 | 1,624 |
| Total current liabilities | 163,781 | 78,884 |
| NONCURRENT LIABILITIES: | | |
| Long-term debt, net | 178,566 | 189,647 |
| Other noncurrent liabilities | 2,109 | 2,501 |
| Total noncurrent liabilities | 180,675 | 192,148 |
| TOTAL LIABILITIES | 344,456 | 271,032 |
| COMMITMENTS AND CONTINGENCIES (Note 13) | | |
| STOCKHOLDERS' EQUITY: | | |
| Common stock—$0.00001 par value; 500,000,000 shares authorized at December 31, 2023 and December 31, 2022, respectively; - shares 56,769,081 and 59,615,731 issued and outstanding at December 31, 2023 and December 31, 2022, respectively | 1 | 1 |
| Additional paid in capital | 610,266 | 675,118 |
| Accumulated other comprehensive (loss) income | 2 | (151) |
| Accumulated deficit | (143,277) | (272,130) |
| TOTAL STOCKHOLDERS' EQUITY | 466,992 | 402,838 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | $ 811,448 | $ 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 | | Year Ended | |
|---|---|---|---|---|
| | December 31, 2023 | December 31, 2022 | December 31, 2023 | December 31, 2022 |
| **GAAP net income** | **$ 26,607** | **$ 48,509** | **$ 128,853** | **$ 181,468** |
| Non-GAAP Adjustments: | | | | |
| Non-cash interest expense (1) | 185 | 422 | 3,246 | 1,663 |
| Depreciation | 164 | 107 | 514 | 419 |
| Amortization (2) | 5,961 | 5,961 | 23,845 | 22,966 |
| Stock-based compensation expense | 8,894 | 7,671 | 31,205 | 26,905 |
| Transaction related costs (3) | 9,804 | - | 9,804 | - |
| Loss on debt extinguishment | - | - | 9,766 | - |
| Licensing fees and milestone payments (4) | - | - | 750 | 30,000 |
| Valuation allowance release | - | - | - | (74,474) |
| Income tax effect related to non-GAAP adjustments (5) | (8,789) | (731) | (19,624) | (5,409) |
| Non-GAAP adjusted net income | $ 42,826 | $ 61,939 | $ 188,359 | $ 183,538 |
| | | | | |
| **GAAP reported net income per diluted share** | **$ 0.45** | **$ 0.79** | **$ 2.13** | **$ 2.97** |
| Non-GAAP adjusted net income per diluted share | $ 0.73 | $ 1.01 | $ 3.12 | $ 3.00 |
| | | | | |
| Weighted average number of shares of common stock used in non-GAAP diluted per share | 58,853,292 | 61,620,712 | 60,372,397 | 61,097,045 |

(1) Includes amortization of deferred finance charges.
(2) Includes amortization of intangible asset related to WAKIX.
(3) Includes costs associated with the acquisition of Zynerba in October 2023. There were $2.3M of IPR&D charges and $3.7M of severance recorded in research and development expenses and $3.8M of severance recorded in general and administrative expenses.
(4) Includes a $0.8M milestone payment related to HBS-102 preclinical milestone in March 2023 and $30M licensing fee incurred upon closing the 2022 Licensing and Commercialization Agreement with Bioprojet in August 2022.
(5) Calculated using the reported effective tax rate for the periods presented less impact of valuation allowance release and discrete items.

**Harmony Biosciences Investor Contact:**
Luis Sanay, CFA
445-235-8386
lsanay@harmonybiosciences.com

**Harmony Biosciences Media Contact:**
Cate McCanless
202-641-6086
cmccanless@harmonybiosciences.com

Exhibit

HARMONY BIOSCIENCES

# Q4 and Full Year 2023 Financial and Business Update

February 22, 2024

# Forward-Looking Statements

This presentation includes forward-looking statements within the meaning of the Private Securities Reform Act of 1995. All statements other t
historical facts contained in these materials or elsewhere, including statements regarding Harmony Biosciences Holdings, Inc.'s (the "Compa
position, business strategy and plans and objectives of management for future operations, should be considered forward-looking statements.
statements use words like "believes," "plans," "expects," "intends," "will," "would," "anticipates," "estimates," and similar words or expressions
Company's future operations, financial performance or the Company's strategies. These statements are based on current expectations or ob
inherently uncertain, especially in light of the Company's limited operating history. These and other important factors discussed under the cap
the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on February 22, 2024 and
SEC could cause actual results to differ materially and adversely from those indicated by the forward-looking statements made in this presen
Company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subse
views to change.

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

HARMONY BIOSCIENCES

# Strong Momentum in Execution of Our Growth Strategy

**Continued Strong Growth For WAKIX® in Adult Narcolepsy**

- FY 2023 WAKIX Net Revenue of $582.0M **+33% Year-over-Year Growth**
- **~6,150** average number of patients on WAKIX in Q4 2023
- **Continued strong growth** in average number of patients & WAKIX prescriber base
- **Demonstrated durability of the brand** entering year five on the market; **2024 Net Revenue guid**

**Strong Momentum in Advancing and Expanding the Pipeline**

- **FDA granted Priority Review for pediatric narcolepsy sNDA;** PDUFA date of June 21, 2024
- **Meeting with the FDA** to discuss Idiopathic Hypersomnia development program scheduled for Marc
- **FDA granted Orphan Drug designation** to Pitolisant for PWS; Phase 3 TEMPO study expected to initi
- **Reported positive topline results** from DM1 Phase 2 POC study in EDS and fatigue
- **Advanced Next-Gen pitolisant based** formulations into the clinic; on track to report pharmacokineti
- **Expanded the pipeline and diversified the portfolio** with acquisition of Zynerba; ZYN002 in Phase 3 X syndrome and Phase 3 ready for 22q deletion syndrome

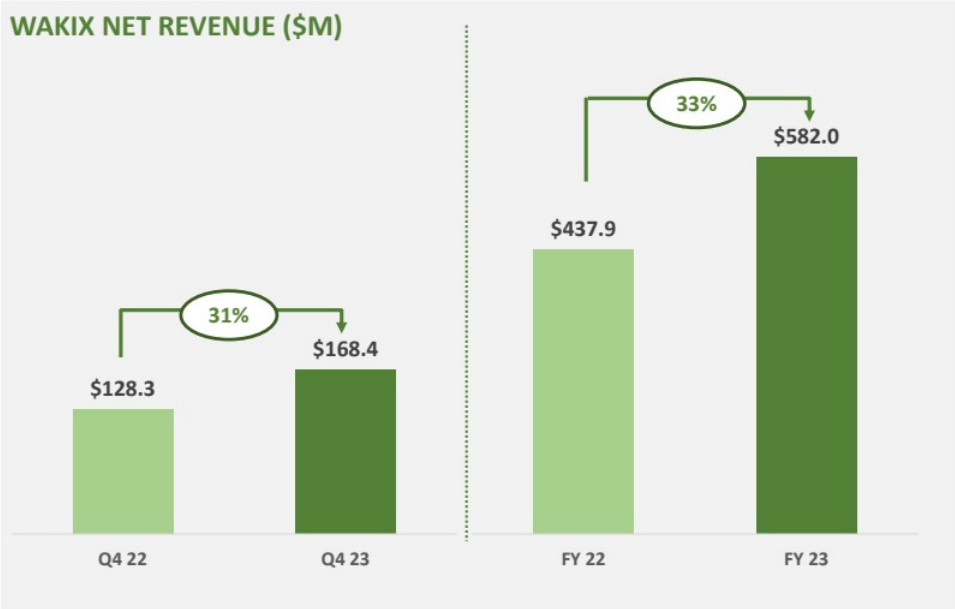
**Disciplined Capital Allocation to Maximize Shareholder Value**

- **Profitable, cash generating** with **$425.6M** on the balance sheet as of December 31, 2023
- **Share repurchase program**: Repurchased ~3.2M shares of common stock at an aggregate cost of remaining authorization of $150M
- **Well positioned** to execute on business development to build out robust pipeline

HARMONY BIOSCIENCES

# WAKIX® Net Revenue Performance

**CONFIDENT IN WAKIX BEING A POTENTIAL $1B+ OPPORTUNITY IN ADULT NARCOLEPSY ALONE WITH TH
CONTRIBUTE UP TO AN ADDITIONAL $1B, IF APPROVED IN OTHER CURRENT PITOLISANT LIFECYCLE MANAGEM**




## HIGHLIGHTS

- Q4 23 represented the highest Revenue in our history ($168.4I
- FY 23 Net Revenue of $582.0M
- Underlying demand drove cont digit revenue growth
  - Strong patient interest
  - Continue to add new presc WAKIX prescriber base

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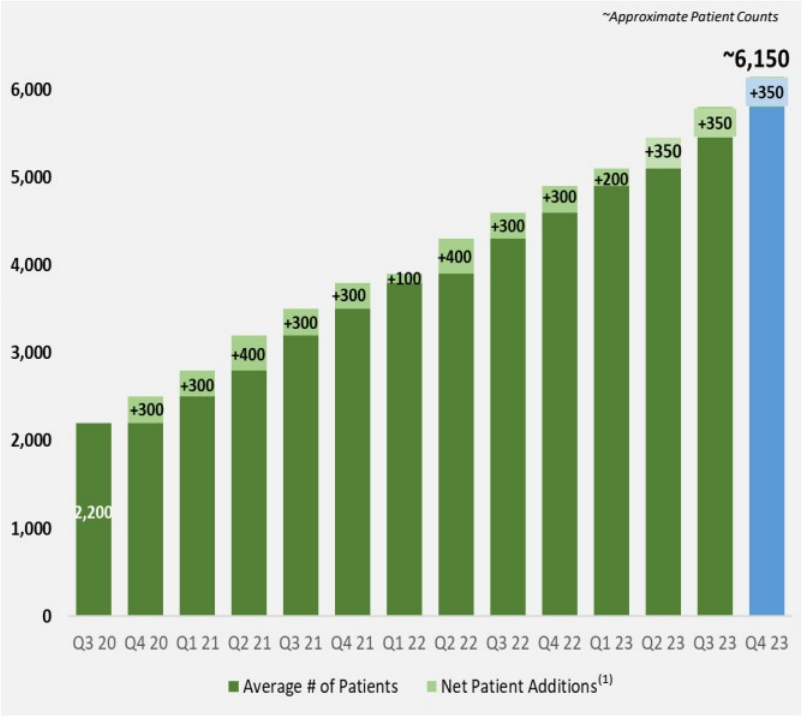
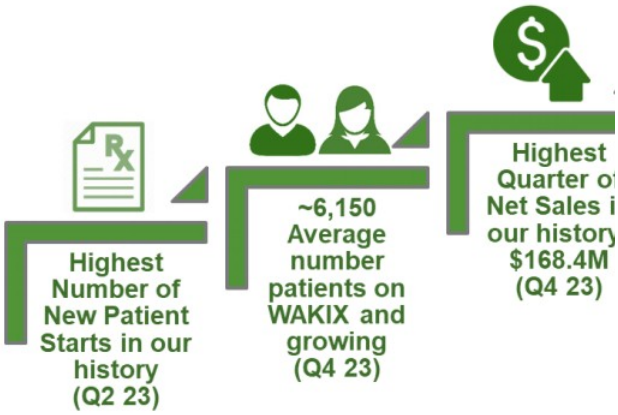
# Solid Business Fundamentals Driving Growth

## Continued Strong Performance in 2023 - Year 4 of Commercializa




## 2023 Highlights




**More unique prescribers of WAKIX than s**

**Strong market access coverage (~84%)** - *ev of generic and new oxybate opti*

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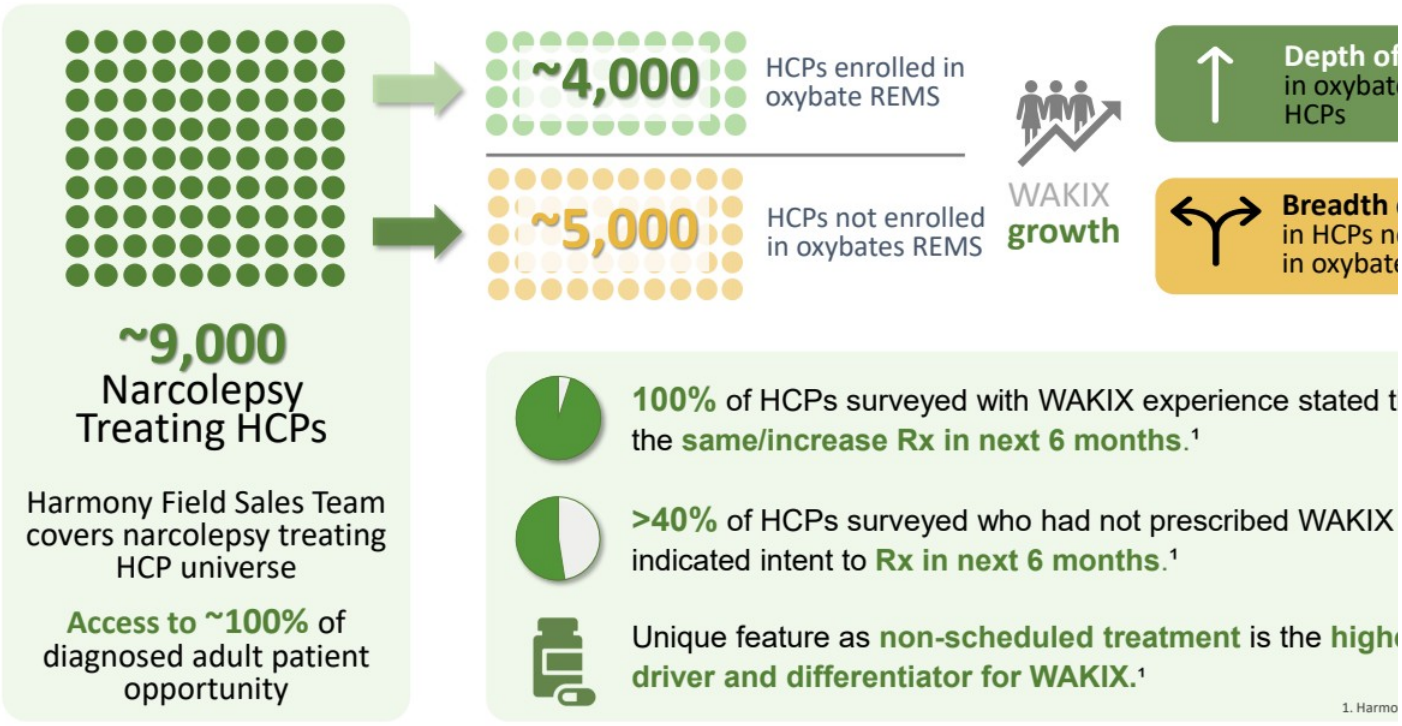
(1) Net Patient Additions based on previously disclosed quarterly average number of patients on WAKIX

# Prescriber Dynamics Support Continued WAKIX® Growth in Ad
# Narcolepsy

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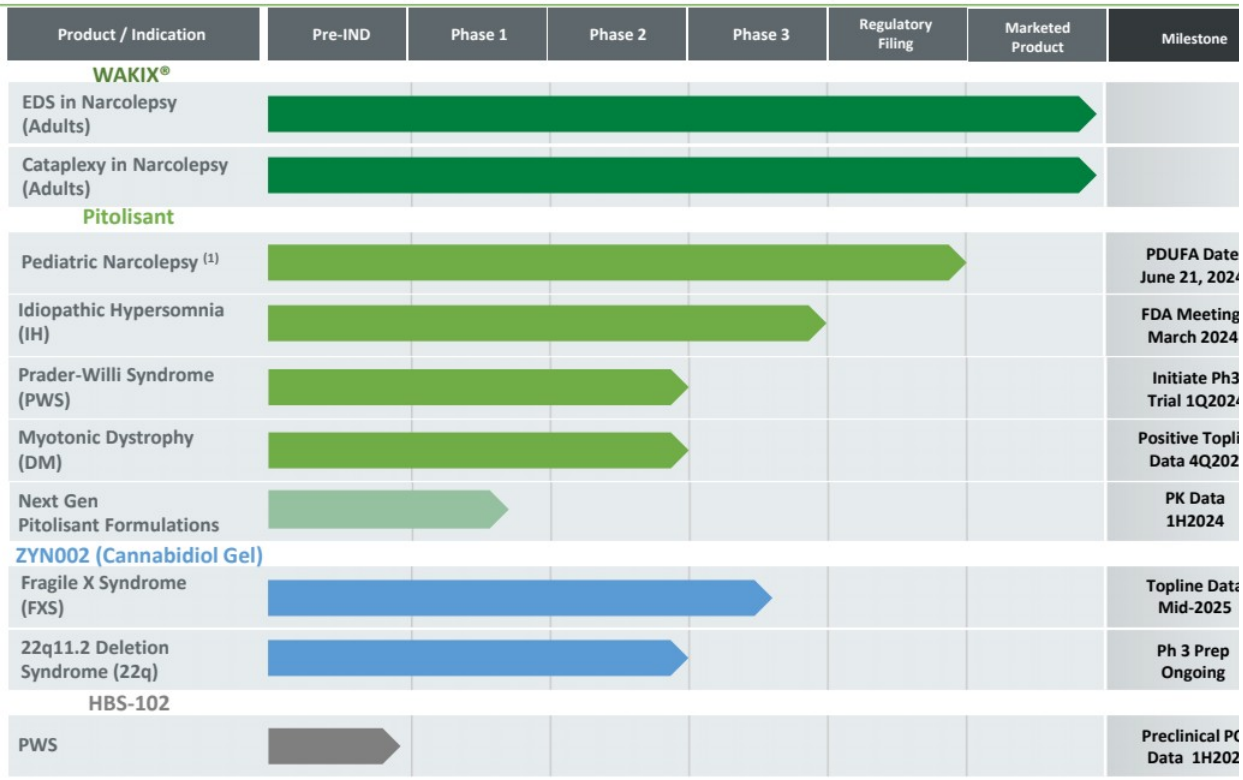
# Development Pipeline: Continues to Grow

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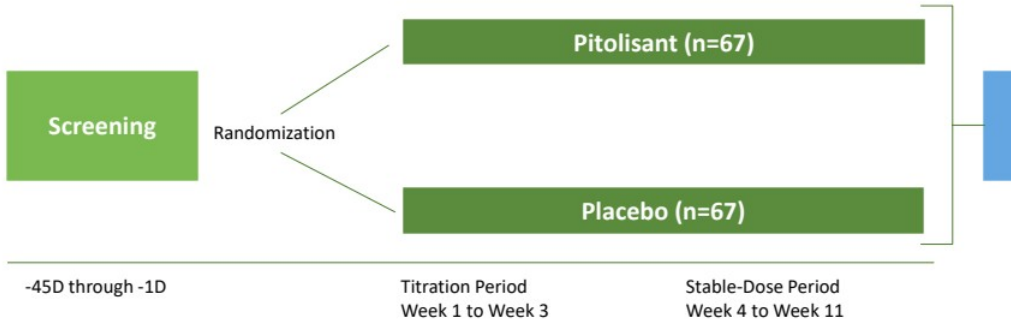
(1) Trial conducted by Bioprojet; received EMA approval on March 15, 2023.

# TEMPO:
# Global Phase 3 Trial of Pitolisant in PWS




## Trial Design:

- Randomized, double-blind, placebo-controlled, parallel-group study
- 1:1 pitolisant : placebo
- 134 patients; ages 6 and older

## Objectives / Endpoints:

- **Primary objective:** to evaluate the efficacy of pitolisant on EDS in patients with PWS
- **Primary endpoint:** change in severity of EDS as measured by PROMIS-SRI T-score from of the Double-Blind Treatment Period (Day 77)
- **Secondary objectives:** to evaluate the efficacy of pitolisant on irritability, hyperphagia problems in PWS
- **Secondary endpoints:** ABC-C Irritability domain, HQ-CT, ABC-C Other domains

# DM1 Phase 2 POC Study Topline Data

## Change in Daytime Sleepiness Scale (DSS) from Baseline to End of Treatment Period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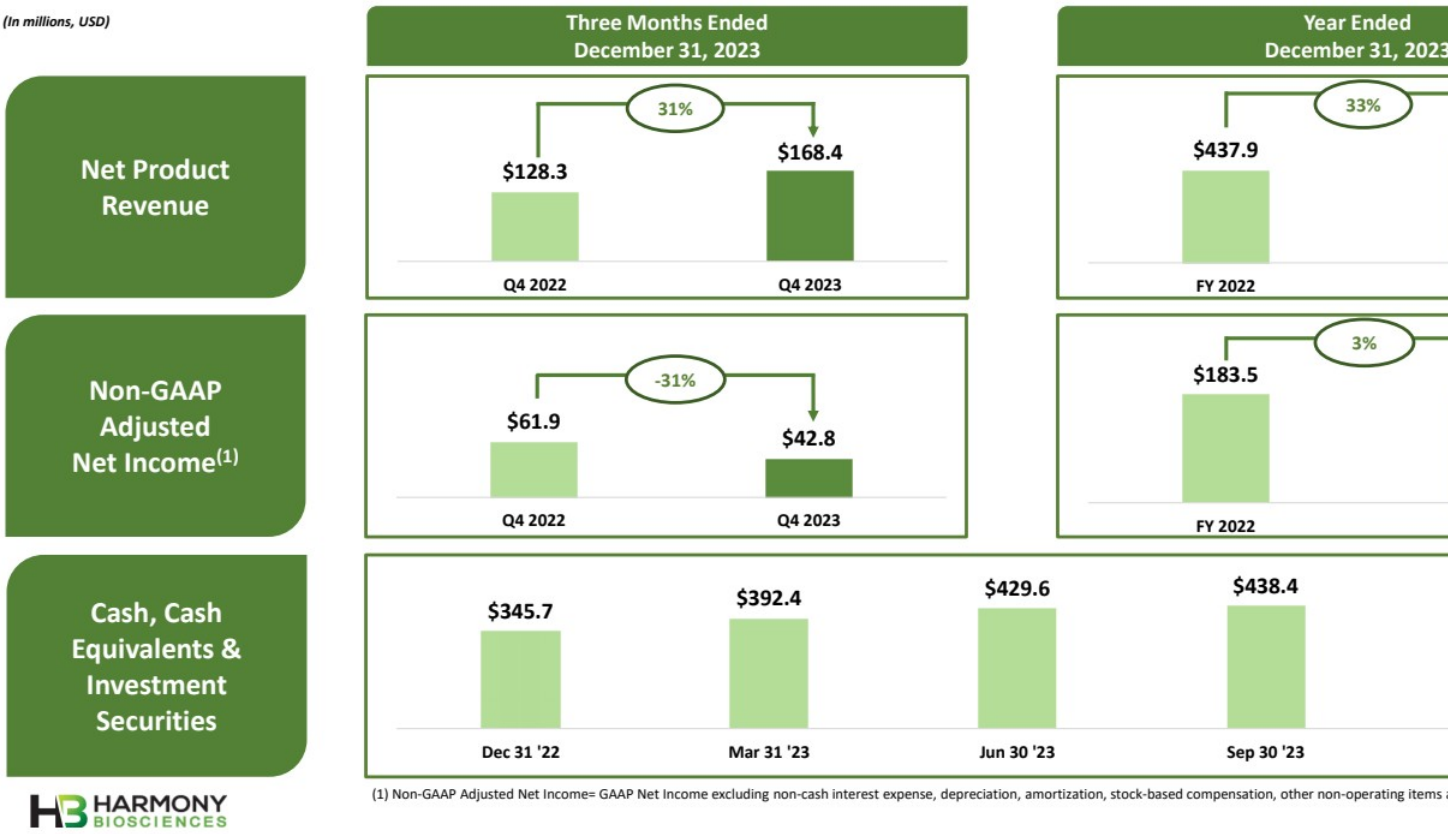
## Topline Data High

- **Clinically meaningful signal** in E CGI-S)
- **Clinically meaningful signal** in F
  - Mean change from baselin for high-dose and low-dose respectively, compared to
- **A clear and consistent dose-res** demonstrated across the efficac
- **Well tolerated** with an overall s profile consistent with the know
- **Next Steps:** Evaluate full data se opportunity. Potentially pivot to formulations of pitolisant to ad

# 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

# Financial Summary

| *(In millions, USD)* Totals may not foot due to rounding | Three Months Ended December 31, | | % Change | Year Ended December 31, | | % C |
|---|---|---|---|---|---|---|
| | 2023 | 2022 | | 2023 | 2022 | |
| **Net Product Revenue** | **$168.4** | **$128.3** | **31%** | **$582.0** | **$437.9** | 3 |
| Cost of Product Sold | 43.2 | 26.9 | 61% | 121.2 | 83.5 | 4 |
| **Total Operating Expenses** | **$85.1** | **$53.8** | **58%** | **$268.8** | **$234.2** | 1 |
| R&D Expense (1) | 30.3 | 10.1 | NM | 76.1 | 70.9 | |
| S&M Expense | 26.9 | 21.1 | 28% | 97.4 | 79.3 | 2 |
| G&A Expense (2) | 27.9 | 22.6 | 23% | 95.3 | 84.0 | 1 |
| **Net Income** | **$26.6** | **$48.5** | **(45%)** | **$128.9** | **$181.5** | (2 |
| **Cash, cash equivalents & investment securities** | | | | **$425.6** | **$345.7** | 2 |

NM denotes not meaningful % change

(1) Includes one-time Zynerba transaction related costs of $6.0M for the three months and year ended December 31, 2023
(2) Includes one-time Zynerba transaction related costs of $3.8M for the three months and year ended December 31, 2023

HARMONY BIOSCIENCES

# GAAP vs NON-GAAP Reconciliation

| *(In millions, USD)* | Three Months Ended December 31, | | Year Ended December 3 |
|---|---|---|---|
| Totals may not foot due to rounding | 2023 | 2022 | 2023 |
| **GAAP net income** | **$26.6** | **$48.5** | **$128.8** |
| Non-cash interest expense[1] | 0.2 | 0.4 | 3.2 |
| Depreciation | 0.2 | 0.1 | 0.5 |
| Amortization[2] | 6.0 | 6.0 | 23.8 |
| Stock-based compensation expense | 8.9 | 7.7 | 31.2 |
| Transaction related costs[3] | 9.8 | - | 9.8 |
| Loss on debt extinguishment | - | - | 9.8 |
| Licensing fees and milestone payments[4] | - | - | 0.8 |
| Valuation allowance release | - | - | - |
| Income tax effect related to Non-GAAP adjustments[5] | (8.8) | (0.7) | (19.6) |
| **Non-GAAP adjusted net income** | **$42.8** | **$61.9** | **$188.4** |
| | | | |
| **GAAP net income per diluted share** | **$0.45** | **$0.79** | **$2.13** |
| **Non-GAAP adjusted net income per diluted share** | **$0.73** | **$1.01** | **$3.12** |
| Weighted average number of shares of common stock used in non-GAAP diluted per share | 58,853,292 | 61,620,712 | 60,372,397 |

HARMONY BIOSCIENCES

(1) Includes amortization of deferred finance charges.
(2) Includes amortization of intangible asset related to WAKIX.
(3) Includes costs associated with the acquisition of Zynerba in October 2023. There were $2.3M of IPR&D charges and $3.7M of severance recorded in research and development expenses and $3.8M of severance recorded in gene
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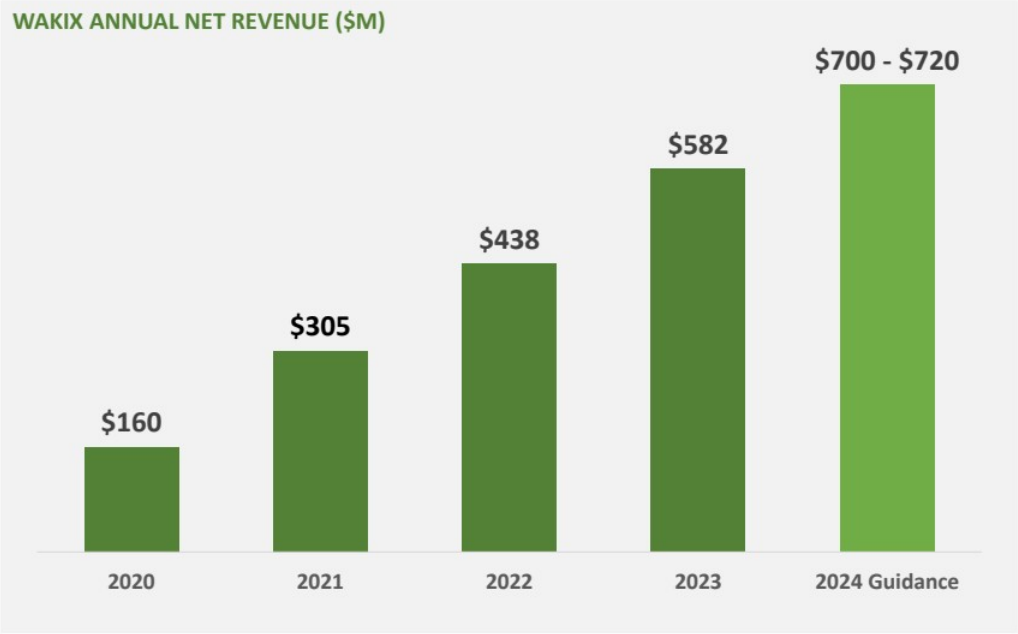
(4) Includes a $0.8M milestone payment related to HBS-102 preclinical milestone in March 2023 and $30M licensing fee incurred upon closing the 2022 Licensing and Commercialization Agreement with Bioprojet in August 2022.
(5) Calculated using the reported effective tax rate for the periods presented less impact of valuation allowance release and discrete items.

# 2024 Net Revenue Guidance

**CONFIDENT IN WAKIX BEING A POTENTIAL $1B+ OPPORTUNITY IN ADULT NARCOLEPSY ALONE WITH THE POTENTIAL TO ADDITIONAL $1B, IF APPROVED IN OTHER CURRENT PITOLISANT LIFECYCLE MANAGEMENT PROGRA**




**$582M**
Net

**33% Growt**

**$700-$720M**

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Thank You