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): August 6, 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 August 6, 2024, Harmony Biosciences Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2024. 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 August 6, 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, 2023, which was filed with the Securities and Exchange Commission ("SEC,") on February 22, 2024, 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 August 6, 2024.
99.2*	Investor Presentation dated August 6, 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: August 6, 2024

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

HARMONY BIOSCIENCES REPORTS STRONG SECOND QUARTER 2024 FINANCIAL RESULTS AND ADVANCES PITOLISANT HIGH-DOSE PROGRAM TOWARD EXPECTED PDUFA DATE IN 2028

WAKIX® (pitolisant) Net Revenue of $172.8 Million for Second Quarter 2024; ~29% Growth Year-over-Year

Next Generation Pitolisant High-Dose (HD) Program Advances Based on Pilot Pharmacokinetic (PK) Data with PDUFA Date Expected in 2028 to Extend Pitolisant Franchise Beyond 2040

WAKIX Patent Upheld Again - U.S. Patent and Trademark Office (USPTO) Issues Final Denial After Two Attempts to Challenge the WAKIX Patent

Received U.S. Food and Drug Administration (FDA) Approval and Launched WAKIX for the Treatment of EDS in Pediatric Patients with Narcolepsy Providing the First and Only Non-Scheduled Treatment Option

On Track to Submit Supplemental New Drug Application for Pitolisant in Idiopathic Hypersomnia (IH) in Fourth Quarter 2024

Reiterates 2024 Net Product Revenue Guidance of $700 - $720 Million

Company to Host Investor Day in New York City on October 1st

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

PLYMOUTH MEETING, PA., August 6, 2024 — Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY), today reported year-over-year net revenue growth of 29 percent for the quarter ended June 30, 2024. In addition, with the goal of addressing ongoing unmet medical needs in the narcolepsy market, the next generation pitolisant-HD development program is advancing and on track towards an expected PDUFA date in

2028.

“We made substantial progress and continue to advance our pitolisant high-dose development program, targeting a PDUFA date in 2028, giving us the opportunity to extend the pitolisant franchise beyond 2040,” said Jeffrey M. Dayno, M.D., President and Chief Executive Officer of Harmony. “In addition, we are executing on our late-stage pipeline across three orphan/rare CNS franchises, which we expect to deliver at least one new product or indication launch every year over the next five years, with multi-billion-dollar revenue potential extending beyond 2040. We also delivered another strong quarter of revenue growth for WAKIX, confirming our confidence in WAKIX being a billion dollar plus market opportunity in narcolepsy alone, while gaining the approval and launching WAKIX in pediatric narcolepsy.”

Key Franchise Highlights:

Sleep/Wake

- WAKIX Net Revenue of $172.8 million in the second quarter of 2024, representing 29% growth over the same period in 2023.
- The average number of patients on WAKIX increased by approximately 250 patients sequentially to approximately 6,550 for the quarter ended June 30, 2024.
- WAKIX patent upheld again. We announced that the USPTO has issued a final denial of the petition for reexamination, which was filed by a short seller. This denial is non-appealable and reinforces our confidence in the strength of our patents, the validity of the patent portfolio, and our ability to rigorously enforce the intellectual property rights protecting WAKIX.
- Received FDA approval for WAKIX for the treatment of EDS in pediatric patients 6 years and older with narcolepsy on June 21, 2024, and executed commercial launch July 1, 2024.
- On track to submit supplemental new drug application (sNDA) for pitolisant in IH in the fourth quarter of 2024.
- Pitolisant Gastro-Resistant (GR): On track to initiate Dosing Optimization study in the fourth quarter of 2024 and Pivotal Bioequivalence study in the first quarter of 2025. PDUFA date expected in 2026. Provisional patent filed with the potential for patent protection out to 2044.
- Pitolisant HD: Pilot PK data showed meaningful differentiation with at least a ~ 20% increase in relative bioavailability and a decrease in the variability of the PK profile compared to an equivalent WAKIX dose of 35.6 mg, the highest labeled dose. Formulation optimization work continues, and we plan to study up to two times the current highest labeled dose of WAKIX, where we expect to demonstrate a further increase in relative bioavailability and decrease in variability in the PK profile. An optimized PK profile, along with a higher dose, GR

coating and targeting unique symptoms (e.g., fatigue in narcolepsy, in addition to EDS and cataplexy) is expected to provide a differentiated product profile and label compared to WAKIX. PDUFA date expected in 2028. Provisional patent filed with the potential for patent protection out to 2044.
- Patient enrollment is ongoing in Phase 3 TEMPO study in patients with Prader-Willi syndrome (PWS).
- TPM-1116, a highly potent and selective oral orexin-2 receptor agonist that will be evaluated for the treatment of narcolepsy and other sleep-wake disorders. IND enabling studies are ongoing and we expect to file an IND in mid-2025 and initiate first-in-human studies in the second half of 2025.
- Completed pre-clinical POC study for HBS-102 in PWS with encouraging initial results; final study report and results to be shared later this year.

Neurobehavioral

- On track for topline data from the Phase 3 RECONNECT registrational trial of ZYN002 in Fragile X syndrome (FXS) in mid-2025.
- Phase 3 preparation ongoing for ZYN002 in 22q11.2 deletion syndrome (22q).

Rare Epilepsy

- EPX-100 is a potent, oral, centrally acting serotonin (5HT2) agonist, currently in a pivotal registrational trial (ARGUS) for Dravet syndrome (DS) with topline data expected in 2026.
- Phase 3 trial for Lennox-Gastaut syndrome (LGS), expected to initiate later this year.
- EPX-200 is a potent, oral, centrally acting and selective 5HT2C agonist, and is currently in IND-enabling stage.

Second Quarter 2024 Financial Results

Net product revenues for the quarter ended June 30, 2024, were $172.8 million, compared to $134.2 million for the same period in 2023. The 29% growth versus the same period in 2023 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) and the broad clinical utility of WAKIX across the approximately 9,000 HCPs that we call on (about 5,000 of whom do not participate in an oxybate REMS program). The average number of patients on WAKIX increased by approximately 250 sequentially to approximately 6,550 for the quarter ended June 30, 2024.

GAAP net income for the quarter ended June 30, 2024, was $11.6 million, or $0.20 earnings per diluted share, compared to GAAP net income of $34.3 million, or $0.56 earnings per diluted share, for the same period in 2023. The decrease in GAAP net

income was primarily driven by a $25.5 million upfront licensing fee paid as part of the 2024 Bioprojet Sublicensing Agreement for TPM-1116 and a $17.1 million IPR&D charge related to the acquisition of Epygenix. Non-GAAP adjusted net income was $60.6 million, or $1.05 earnings per diluted share, for the quarter ended June 30, 2024, compared to Non-GAAP adjusted net income of $45.9 million, or $0.76 per diluted share, for the same period in 2023.

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 $63.6 million in the second quarter of 2024, as compared to $15.0 million for the same quarter in 2023, representing a 325% increase, primarily driven by a $25.5 million upfront licensing fee as part of the 2024 Bioprojet Sublicense Agreement and a $17.1 million IPR&D charge related to the acquisition of Epygenix;
- Sales and Marketing expenses were $28.5 million in the second quarter of 2024, as compared to $24.5 million for the same quarter in 2023, representing a 16% increase;
- General and Administrative expenses were $27.2 million in the second quarter of 2024, as compared to $22.8 million for the same quarter in 2023, representing a 19% increase; and
- Total Operating Expenses were $119.3 million in the second quarter of 2024, as compared to $62.3 million for the same quarter in 2023, representing a 92% increase.

As of June 30, 2024, Harmony had cash, cash equivalents and investments of $434.1 million, compared to $425.6 million as of December 31, 2023.

Reiterates 2024 Net Product Revenue Guidance

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

Share Repurchase Program

The remaining amount of common stock authorized for repurchases as of June 30, 2024, was $150 million.

Investor Day on October 1st

The company will host an investor day in New York City on October 1st. Additional event details to follow.

Conference Call Today at 8:30 a.m. ET
We are hosting our second quarter 2024 financial results conference call and webcast today, beginning 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) 225-9448 (domestic) or +1 (203) 518-9708 (international), and reference passcode HRMYQ224.

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 (EDS) or cataplexy in adult patients with narcolepsy and for the treatment of excessive daytime sleepiness (EDS) in pediatric patients 6 years of age and older 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 at least 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 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 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 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 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 22q11.2 Deletion Syndrome
22q11.2 deletion syndrome (22q) is a disorder caused by a small missing piece of the 22nd chromosome. The deletion occurs near the middle of the chromosome at a location designated q11.2. It is considered a mid-line condition, with physical symptoms including characteristic palate abnormalities, heart defects, immune dysfunction, and esophageal/ GI issues, as well as debilitating neuropsychiatric and behavioral symptoms, including anxiety, social withdrawal, ADHD, cognitive impairment and autism spectrum disorder. It is estimated that 22q occurs in one in 4,000 live births, suggesting that there are approximately 80,000 people living with 22q in the U.S. and 129,000 in the European Union and the UK. Patients with 22q deletion syndrome are managed by multidisciplinary care providers, and there are currently no FDA approved treatments for this disorder.

About Clemizole hydrochloride (EPX-100)
EPX-100, clemizole hydrochloride, is under development for the treatment of Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS). EPX-100 acts by targeting central 5-hydroxytryptamine receptors to modulate serotonin signaling. The drug candidate is administered orally twice a day in a liquid formulation and has been developed based on a proprietary phenotype-based zebrafish drug screening platform.[1] DS is caused by a loss of function mutation in the SCN1A gene, and scn1 mutant zebrafish replicate the genetic etiology and phenotype observed in the majority of DS patients. The scn1Lab mutant zebrafish model that expresses voltage gated sodium channels has been used for high-throughput screening of compounds that modulate Nav1.1 in the central nervous system.

About Dravet Syndrome
Dravet syndrome (DS) is a severe and progressive epileptic encephalopathy that begins in infancy and causes significant impact on patient functioning. DS begins in the first

year of life and is characterized by high seizure frequency and severity, intellectual disability, and a risk of sudden unexpected death in epilepsy. Approximately 85% of Dravet Syndrome cases are caused by de novo loss-of-function (LOF) mutations in a voltage-gated sodium channel gene, SCN1A1. DS has an estimated incidence rate of 1:15,700.

About Lennox-Gastaut Syndrome
Lennox-Gastaut Syndrome (LGS) is a rare and drug-resistant epileptic encephalopathy characterized by onset in children between 3-5 years of age. The underlying cause of LGS is unknown and can be related to a wide range of factors including genetic differences and structural differences in the brain. As a result, patients experience multiple seizure types, including atonic seizures, and developmental, cognitive, and behavioral issues. LGS affects approximately 48,000 patients in the U.S.

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 full year 2024 net product revenue, expectations for the growth and value of WAKIX, plans to submit an sNDA for pitolisant in idiopathic hypersomnia; our future results of operations and financial position, business strategy, products, prospective products, product approvals, the plans and objectives of management for future operations and future results of anticipated products. 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 pitolisant in additional indications, if approved, and any other product candidates we may develop or acquire, if approved; our research and development plans, including our plans to explore the therapeutic potential of pitolisant in additional indications; our ongoing and planned clinical trials; our ability to expand the scope of our license agreements with Bioprojet Société Civile de Recherche ("Bioprojet"); 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 other product candidates; our estimates regarding expenses, future revenue, capital requirements and additional financing needs; our ability to identify, acquire and integrate 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 SUBSIDIARIES

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Net product revenue	$ 172,814	$ 134,216	$ 327,429	$ 253,342
Cost of product sold	32,144	25,008	59,628	45,788
Gross profit	140,670	109,208	267,801	207,554
Operating expenses:				
Research and development	63,583	14,969	85,772	28,258
Sales and marketing	28,507	24,528	55,740	47,100
General and administrative	27,224	22,809	52,900	44,871
Total operating expenses	119,314	62,306	194,412	120,229
Operating income	21,356	46,902	73,389	87,325
Other (expense) income, net	37	(31)	(104)	(29)
Interest expense	(4,404)	(6,218)	(8,939)	(11,949)
Interest income	4,705	3,442	9,133	6,528
Income before income taxes	21,694	44,095	73,479	81,875
Income tax expense	(10,103)	(9,795)	(23,554)	(18,090)
Net income	$ 11,591	$ 34,300	$ 49,925	$ 63,785
Unrealized (loss) income on investments	(63)	(491)	(236)	(371)
Comprehensive income	$ 11,528	$ 33,809	$ 49,689	$ 63,414
EARNINGS PER SHARE:				
Basic	$ 0.20	$ 0.57	$ 0.88	$ 1.07
Diluted	$ 0.20	$ 0.56	$ 0.87	$ 1.05
Weighted average number of shares of common stock - basic	56,802,357	59,974,123	56,786,873	59,853,808
Weighted average number of shares of common stock - diluted	57,541,696	60,743,953	57,571,570	60,997,410

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

	June 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 317,296	$ 311,660
Investments, short-term	29,614	41,800
Trade receivables, net	83,157	74,140
Inventory, net	5,643	5,363
Prepaid expenses	16,127	12,570
Other current assets	6,507	5,537
Total current assets	458,344	451,070
NONCURRENT ASSETS:		
Property and equipment, net	754	371
Restricted cash	270	270
Investments, long-term	87,178	72,169
Intangible assets, net	125,186	137,108
Deferred tax asset	180,186	144,162
Other noncurrent assets	6,465	6,298
Total noncurrent assets	400,039	360,378
TOTAL ASSETS	$ 858,383	$ 811,448
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 22,683	$ 17,730
Accrued compensation	9,641	23,747
Accrued expenses	91,644	99,494
Current portion of long-term debt	15,000	15,000
Other current liabilities	7,614	7,810
Total current liabilities	146,582	163,781
NONCURRENT LIABILITIES:		
Long-term debt, net	171,422	178,566
Other noncurrent liabilities	1,796	2,109
Total noncurrent liabilities	173,218	180,675
TOTAL LIABILITIES	319,800	344,456
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at June 30, 2024 and December 31, 2023, respectively; 56,833,771 and 56,769,081 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	1	1
Additional paid in capital	632,168	610,266
Accumulated other comprehensive (loss) income	(234)	2
Accumulated deficit	(93,352)	(143,277)
TOTAL STOCKHOLDERS' EQUITY	538,583	466,992
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 858,383	$ 811,448

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

	Three Months Ended		Six Months Ended	
	June 30, 2024	June 30, 2023	June 30, 2024	June 30, 2023
GAAP net income	**$ 11,591**	**$ 34,300**	**$ 49,925**	**$ 63,785**
Non-GAAP Adjustments:				
Non-cash interest expense (1)	176	424	356	840
Depreciation	91	103	254	206
Amortization (2)	5,961	5,961	11,922	11,922
Stock-based compensation expense	10,963	7,793	21,397	14,354
Licensing fee and milestone payments (3)	25,500	-	25,500	750
Transaction related costs (4)	17,095	-	17,095	-
Income tax effect related to non-GAAP adjustments (5)	(10,769)	(2,712)	(15,119)	(5,252)
Non-GAAP adjusted net income	$ 60,608	$ 45,869	$ 111,330	$ 86,605
GAAP reported net income per diluted share	**$ 0.20**	**$ 0.56**	**$ 0.87**	**$ 1.05**
Non-GAAP adjusted net income per diluted share	$ 1.05	$ 0.76	$ 1.93	$ 1.42
Weighted average number of shares of common stock used in non-GAAP diluted per share	57,541,696	60,743,953	57,571,570	60,997,410

(1) Includes amortization of deferred finance charges.
(2) Includes amortization of intangible asset related to WAKIX.
(3) Amount represents upfront licensing fee incurred upon closing the 2024 Bioprojet Sublicense Agreement and milestone payment related to HBS102 in March 2023.
(4) Includes IPR&D charge related to the acquisition of Epygenix.
(5) Calculated using the reported effective tax rate for the periods presented less impact of discrete items.

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Exhibit 9

HARMONY BIOSCIENCES

Q2 2024 Financial Results

August 6, 2024

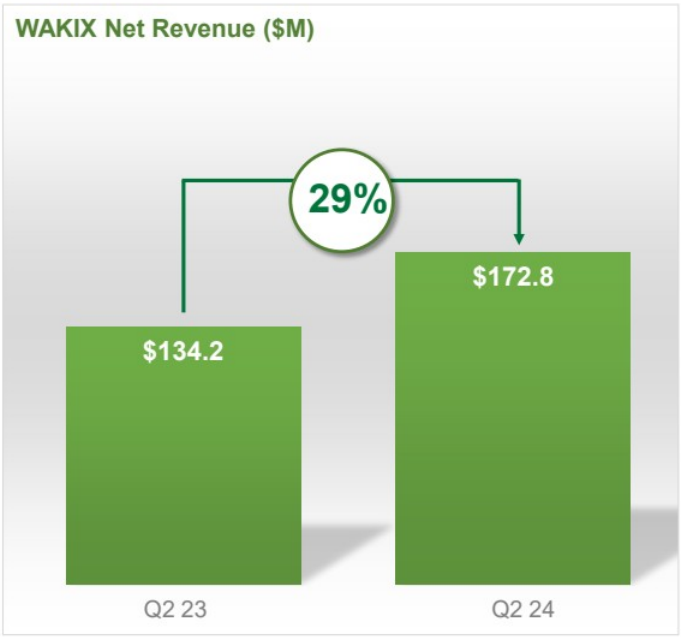
Forward-Looking Statements

This presentation includes forward-looking statements within the meaning of the Private Securities Reform Act of 1995. All statem other than statements of historical facts contained in these materials or elsewhere, including statements regarding Harmony Biosc Holdings, Inc.'s (the "Company") future financial position, business strategy and plans and objectives of management for future op should be considered forward-looking statements. Forward-looking statements use words like "believes," "plans," "expects," "inten "will," "would," "anticipates," "estimates," and similar words or expressions in discussions of the Company's future operations, finar performance or the Company's strategies. These statements are based on current expectations or objectives that are inherently u especially in light of the Company's limited operating history. These and other important factors discussed under the caption "Risk in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on February and its other filings with the SEC could cause actual results to differ materially and adversely from those indicated by the forward-l statements made in this presentation. While the Company may elect to update such forward-looking statements at some point in 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 ana and external sources. The internal analyses are based upon management's understanding of market and industry conditions and been verified by independent sources. Similarly, the externally sourced information has been obtained from sources the Company to be reliable, but the accuracy and completeness of such information cannot be assured. Neither the Company, nor any of its res officers, directors, managers, employees, agents, or representatives, (i) make any representations or warranties, express or implie respect to any of the information contained herein, including the accuracy or completeness of this presentation or any other writte information made available to any interested party or its advisor (and any liability therefore is expressly disclaimed), (ii) have any l from the use of the information, including with respect to any forward-looking statements, or (iii) undertake to update any of the inf contained herein or provide additional information as a result of new information or future events or developments.

WAKIX® Net Revenue Performance

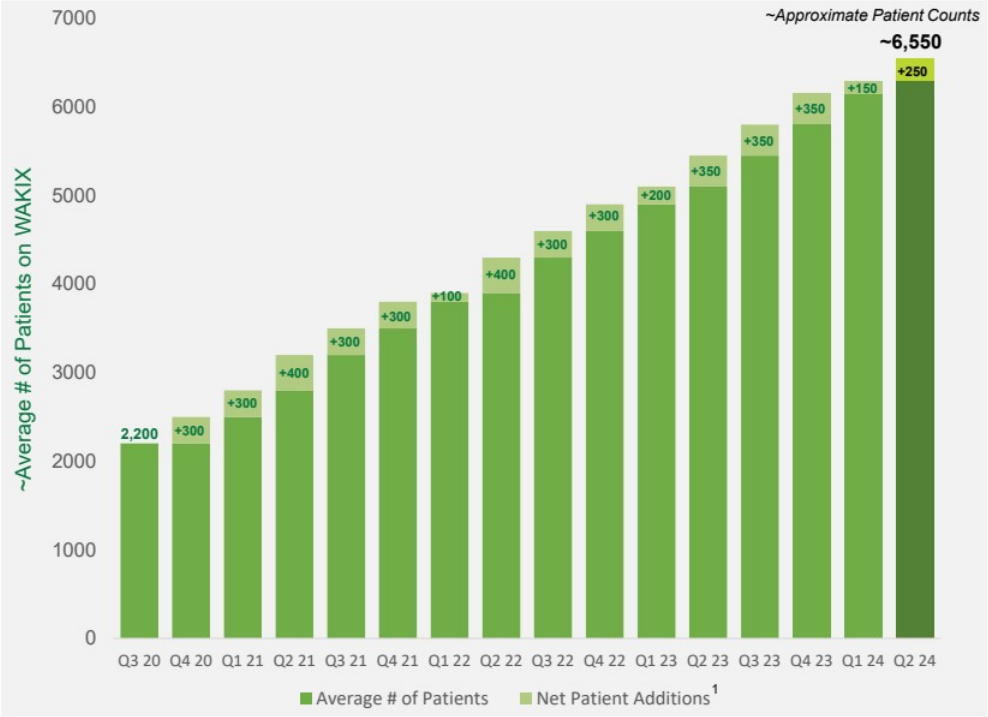
CONFIDENT IN WAKIX BEING A POTENTIAL $1B+ OPPORTUNITY IN NARCOLEPSY ALO



HIGHLIGHTS

- Durable sales growth into year five with 29% growth year-over-year
- Underlying demand drove continued growth
  - Strong patient interest
  - Broad clinical utility
  - Continue to add new prescribers WAKIX prescriber base

Solid Business Fundamentals Driving Growth



Q2 24 Highlig

~6,550 Average number of patients on WAKIX and growing

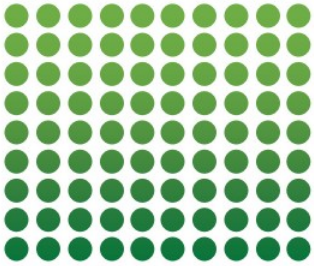
On o
$1B+
in na

More unique prescribers of sodium oxybat

Strong market access cove
even with the availability of g oxybate option

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

Prescriber Dynamics Support Continued WAKIX® Growth in Narcolepsy: Broad Clinical Utility



~9,000
Narcolepsy Treating HCPs

Harmony Field Sales Team covers narcolepsy treating HCP universe

Access to ~100% of diagnosed patient opportunity

HCPs enrolled in oxybate REMS

HCPs not enrolled in oxybates REMS

WAKIX **growth**

Depth of p in oxybate enrolled HC

Breadth of in HCPs not in oxybate

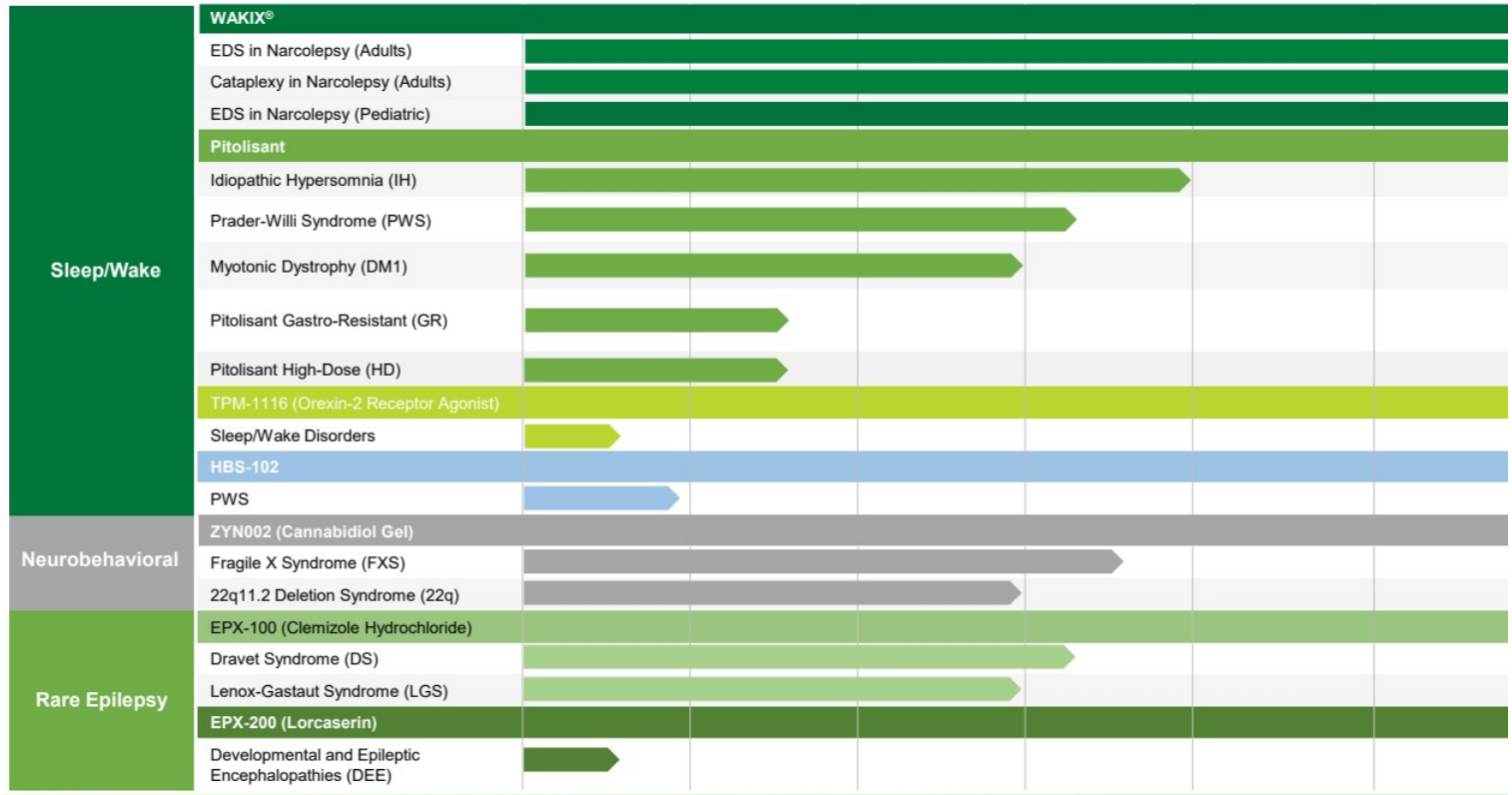
98% of HCPs surveyed with WAKIX experience stated they would the **same/increase Rx in next 6 months**.[1]

50% of HCPs surveyed who had not prescribed WAKIX to date inc intent to **Rx in next 6 months**.[1]

Unique feature as **non-scheduled treatment** is the **highest perfo driver and differentiator for WAKIX.**[1]

1. Harmony Market Research, May 2024

Robust Late-Stage Pipeline



Strengthening Our Leadership Position in Sleep/Wake: Pitolisant LCM Addressing Unmet Medical Needs With Meaningfully Differentiated Product Profiles

Pitolisant-HD PDUFA 2028	EDS & Cataplexy	Well tolerated; safety profile	Non-scheduled	Gastro-Resistant coating	No titration	Higher Do Enhance Efficac
Pitolisant-GR PDUFA 2026	EDS & Cataplexy	Well tolerated; safety profile	Non-scheduled	Gastro-Resistant coating	No titration	
WAKIX FDA Approval 2019	EDS & Cataplexy	Well tolerated; safety profile	Non-scheduled			

PATIENT AND HCP UNMET NEEDS

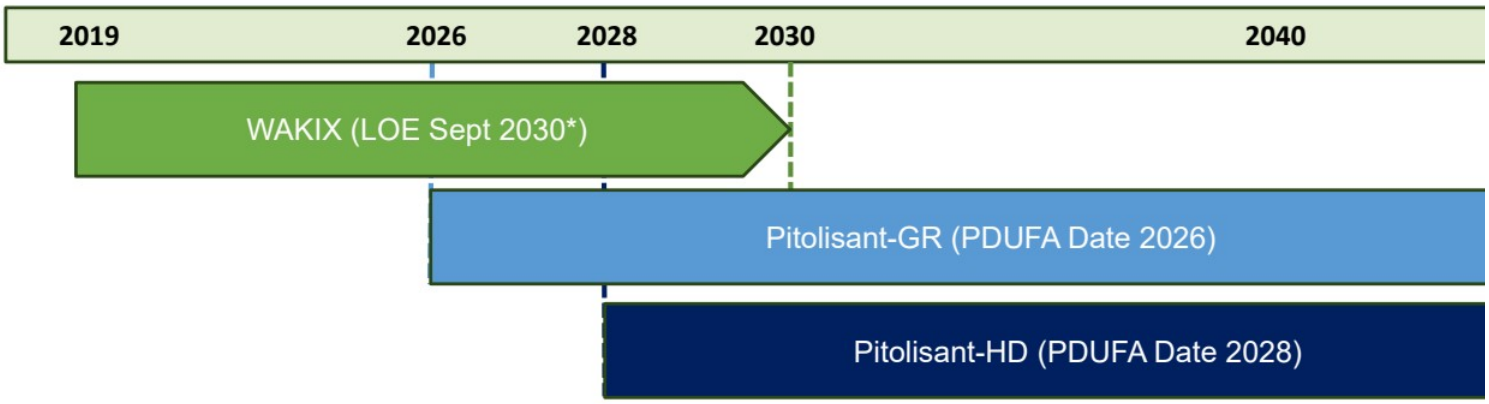
- 56% — Patients frustrated with side effects[1]
- 1 — One other treatment indicated for EDS & cataplexy
- 100% — Treatments scheduled as controlled substances (CII – CIV)

- 100% — Treatments Require titration
- 33% — Patients Don't achieve clinical benefit
- 88% — Patient report GI disturbances[2,3]
- 1 in 5 — Cite nausea as a side effect[4]

- 75% — Patients repor symptoms on
- 60% — Patients repor symptom and QoL.[6]

Source: 1. Versta Research, Know Narcolepsy Survey ("Know Narcolepsy"), October 2018 2. Barateau et al., Dauvilliers, 2019 3. Wang et al., 2023 4. Postmaketing study 5. McCullough et al. Novel treatments options Memorial Center - SLEEP 2019 Abstract 6. Droogleever et al. (2012). Severe fatigue in narcolepsy with cataplexy. Sleep, 21(2), 163-169

Strengthening Our Leadership Position in Sleep/Wake: Extending The Pitolisant Franchise To the Mid 2040s



- Two meaningfully differentiated product profiles building off WAKIX with PDUFAs prior to LOE
  - **Pitolisant GR –** PDUFA date in 2026; supports expanding pitolisant patient base
  - **Pitolisant HD** - PDUFA date in 2028; designed to deliver meaningful differentiation, clinically s product profile
    - Provides an opportunity to introduce a differentiated product 18-24 months prior to WAKI
    - Harmony Commercial Model uniquely suited to maximize this opportunity
- Provisional patents filed out to 2044 to extend durable patient and net revenue growth for the pitoli to the mid 2040's

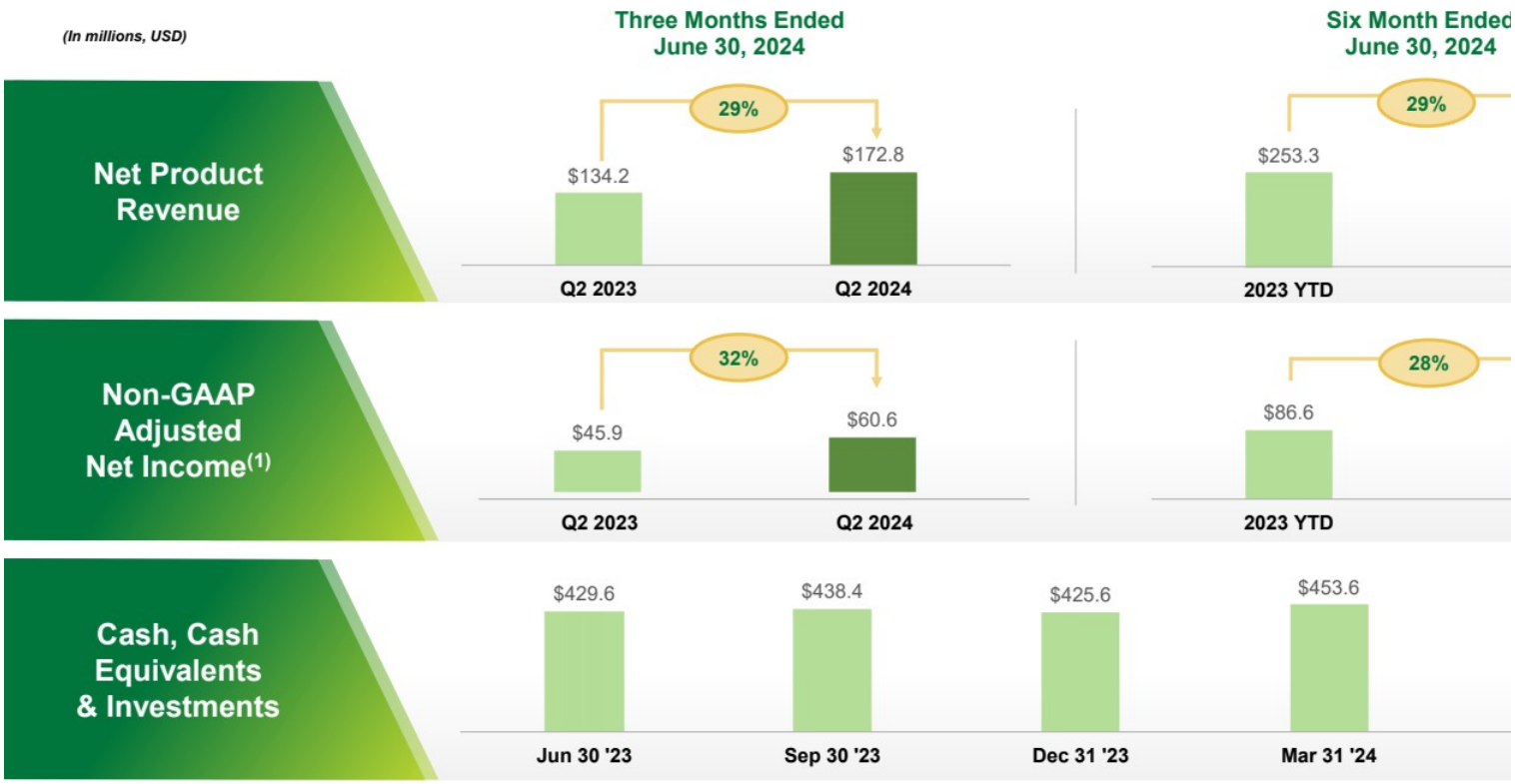
*Based on pediatric exclusivity

Pitolisant High-Dose (HD) Formulation: Differentiated Product Profile

Attributes	Development Plan	Potential differentiated features
Higher dose	Up to 2x compared to current highest WAKIX labeled dose	Better efficacy in EDS/cataplexy; Higher POS for fatigue in narcolepsy
Optimized PK profile	Pilot PK study	Higher relative bioavailability for the same dose compared to WAKIX; decreased variability
Gastro-resistant coating	Confirmed with dissolution assays	Designed to address GI issues in patients with narcolepsy; start at the therapeutic dose range
Differentiated Indications	Fatigue in Narcolepsy Sleep inertia in IH EDS and Fatigue in Myotonic Dystrophy	First product indication for these symptoms; Differentiated label compared to WAKIX
IP	Provisional patent filed	Potential IP until 2044

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

Financial Summary

(In millions, USD) Totals may not foot due to rounding	Three Months Ended June 30,		% Change	Six Months Ended June 30,	
	2024	2023		2024	2023
Net Product Revenue	**$172.8**	**$134.2**	**29%**	**$327.4**	**$253.3**
Cost of Product Sold	32.1	25.0	28%	59.6	45.8
Total Operating Expenses	**$119.3**	**$62.3**	**92%**	**$194.4**	**$120.2**
R&D Expense (1)	63.6	15.0	NM	85.8	28.3
S&M Expense	28.5	24.5	16%	55.7	47.1
G&A Expense	27.2	22.8	19%	52.9	44.9
Net Income	**$11.6**	**$34.3**	**(66%)**	**$49.9**	**$63.8**
Cash, cash equivalents & investments	**$434.1**				

NM denotes not meaningful % change
(1) Includes upfront licensing fee of $25.5M related to the 2024 Bioprojet Sublicense Agreement and IPR&D charge of $17.1M related to the acquisition of Epygenix for the three months and six month ended June 30, 2024

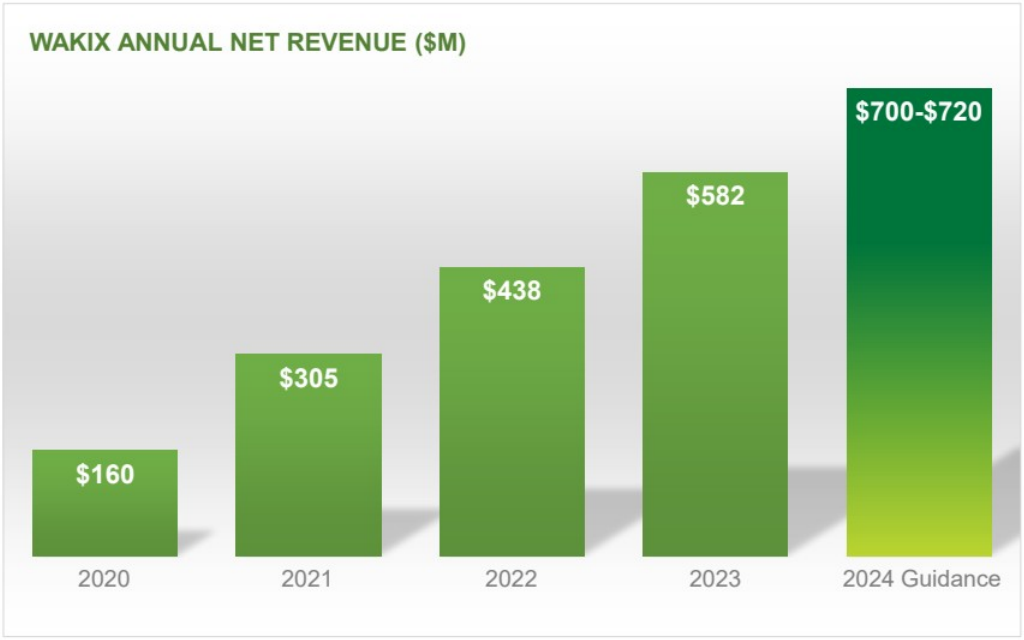
GAAP vs NON-GAAP Reconciliation

(In millions, USD)	Three Months Ended June 30,		Six Months June 3
Totals may not foot due to rounding	2024	2023	2024
GAAP net income	**$11.6**	**$34.3**	**$49.9**
Non-cash interest expense[1]	0.2	0.4	0.4
Depreciation	0.1	0.1	0.3
Amortization[2]	6.0	6.0	11.9
Stock-based compensation expense	11.0	7.8	21.4
Licensing fee and milestone payments[3]	25.5	-	25.5
Transaction related costs[4]	17.1	-	17.1
Income tax effect related to Non-GAAP adjustments[5]	(10.8)	(2.7)	(15.1)
Non-GAAP adjusted net income	**$60.6**	**$45.9**	**$111.3**
GAAP net income per diluted share	**$0.20**	**$0.56**	**$0.87**
Non-GAAP adjusted net income per diluted share	**$1.05**	**$0.76**	**$1.93**
Weighted average number of shares of common stock used in non-GAAP diluted per share	57,541,696	60,743,953	57,571,570

(1) Includes amortization of deferred finance charges.
(2) Includes amortization of intangible asset related to WAKIX.
(3) Amount represents upfront licensing fee incurred upon closing the 2024 Bioprojet Sublicense Agreement and milestone payment related to HBS102 in March 2023.
(4) Includes IPR&D charge related to the acquisition of Epygenix.
(5) Calculated using the reported effective tax rate for the periods presented less impact of discrete items.

Reiterates 2024 Net Revenue Guidance

CONFIDENT IN WAKIX BEING A POTENTIAL $1B+ OPPORTUNITY IN NARCOLEPSY ALO



Reitera

2024 Gui

$700-$7

HARMONY BIOSCIENCES

Thank You!