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): April 30, 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 April 30, 2024, Harmony Biosciences Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 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 April 30, 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 April 30, 2024.
99.2*	Investor Presentation dated April 30, 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: April 30, 2024

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

HARMONY BIOSCIENCES REPORTS STRONG FIRST QUARTER FINANCIAL RESULTS AND ACCELERATION OF ITS GROWTH STRATEGY; ADVANCES PITOLISANT FRANCHISE TO EXTEND REVENUE POTENTIAL BEYOND 2040; STRENGHTENS SLEEP/WAKE LEADERSHIP AND DIVERSIFIES INTO RARE EPILEPSY

WAKIX® (pitolisant) Net Revenue of $154.6 Million for First Quarter 2024; ~30% Growth Year-over-Year

Supplemental New Drug Application for Pitolisant in Idiopathic Hypersomnia Planned for Second Half 2024

On Track Toward Pediatric Exclusivity to Extend WAKIX Exclusivity to September 2030: Pediatric Narcolepsy sNDA PDUFA Date of June 21, 2024; PWS Phase 3 TEMPO Study Initiated in March 2024

Pitolisant Franchise Revenue Potential Extended Beyond 2040 With Next-Generation Formulations; Reports Positive Pharmacokinetic Data on Next-Generation Formulation 1 (NG1); PDUFA Expected in 2026

Strengthens Leadership Position in Sleep/Wake with Licensing of TPM-1116, a Highly Potent and Selective Oral Orexin-2 Receptor Agonist

Establishes Potential Billion Dollar Plus Rare Epilepsy Franchise Through Acquisition of Epygenix Therapeutics, Inc.

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

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

PLYMOUTH MEETING, Pa., April 30, 2024 — Harmony Biosciences Holdings, Inc. (Nasdaq: HRMY), today reported year-over-year net revenue growth of 30 percent for

the quarter ended March 31, 2024 and accelerated its growth strategy with the addition of a rare epilepsy franchise to its expanding pipeline of innovative, late-stage CNS assets.

"We believe Harmony is well-positioned to become the leading patient-focused CNS biotechnology company delivering innovative treatments to patients living with unmet medical needs. We have transformed our business by executing a best-in-class launch of WAKIX in narcolepsy, advancing our pipeline through life cycle management and new indications, and diversifying our portfolio through strategic business development, having closed three transactions over the past eight months," said Jeffrey M. Dayno, M.D., President and Chief Executive Officer of Harmony. "We now have three late-stage orphan/rare CNS franchises, each with potential peak sales opportunities of $1B to $2B, comprised of eight assets advancing across thirteen development programs. We expect our pipeline 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. In addition, the durable commercial success of WAKIX is currently paving the way to surpassing $1 billion in the adult narcolepsy market alone."

Key Franchise Highlights:

Sleep/Wake

- WAKIX Net Revenue of $154.6 million in the first quarter of 2024, representing 30% growth over the same period in 2023.
- The average number of patients on WAKIX increased by approximately 150 patients sequentially to approximately 6,300 for the quarter ended March 31, 2024.
- Following a March 2024 meeting with FDA, we are moving forward with the Idiopathic Hypersomnia (IH) program and plan to submit a supplemental new drug application (sNDA) for pitolisant in IH in the second half of 2024.
- Reported positive pharmacokinetic (PK) data on Next-Gen pitolisant-based formulation 1 (NG1). Pivotal bioequivalence and dosing optimization studies will be initiated in the fourth quarter of 2024. PDUFA date expected in 2026. Provisional patent filed with the potential for patent protection out to 2044.
- On track to receive PK data on Next-Gen pitolisant-based formulation 2 (NG2) in the first half of 2024.
- Pediatric narcolepsy sNDA on track for PDUFA date of June 21, 2024.
- Initiated the Phase 3 TEMPO study in patients with Prader-Willi syndrome (PWS) in March 2024.
- On track towards gaining pediatric exclusivity to extend WAKIX exclusivity to September 2030 based on progress in the pediatric narcolepsy submission and advancement of the PWS Phase 3 TEMPO study.

- Strengthened our leadership position, and created opportunity for long-term revenue generation, in sleep medicine with an exclusive licensing agreement with Bioprojet to develop, manufacture and commercialize 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. Expect to file IND by mid-2025 and initiate first-in-human studies in the second half of 2025.

Neurobehavioral

- On track 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; IP protection for ZYN002 in FXS out to 2040.
- Phase 3 preparation ongoing for ZYN002 in 22q11.2 deletion syndrome (22q).

Rare Epilepsy

- Acquired Epygenix Therapeutics, Inc., and establishes rare epilepsy franchise.
- Lead product, clemizole hydrochloride (EPX-100), is a potent, oral, centrally acting serotonin (5HT2) agonist, currently in a pivotal registrational trial for Dravet syndrome (DS) with topline data expected in 2026.
- Phase 3 trial for Lennox-Gastaut syndrome (LGS) expected to initiate in the second half of 2024.
- Proven mechanism of action with potential for improved benefit/risk profile compared to current treatment options.
- EPX-100 has been granted Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) for both DS and LGS by FDA.
- IP protection for EPX-100 out to 2034.
- A second investigational product, EPX-200, is a potent, oral, centrally acting and selective 5HT2C agonist, and is currently in IND-enabling studies.
- EPX-200 also received ODD from FDA for DS and LGS as well as RPDD for LGS.

First Quarter 2024 Financial Results

Net product revenue for the quarter ended March 31, 2024, was $154.6 million, compared to $119.1 million for the same period in 2023. The 30% 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). The average number of patients on WAKIX increased by approximately 150 patients sequentially to approximately 6,300 for the quarter ended March 31, 2024.

GAAP net income for the quarter ended March 31, 2024, was $38.3 million, or $0.67 per diluted share, compared to GAAP net income of $29.5 million, or $0.48 per diluted

share, for the same period in 2023. Non-GAAP adjusted net income was $50.7 million, or $0.88 per diluted share, for the quarter ended March 31, 2024, compared to Non-GAAP adjusted net income of $40.1 million, or $0.66 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 $22.2 million in the first quarter of 2024, as compared to $13.3 million for the same quarter in 2023, representing a 67% increase;
- Sales and Marketing expenses were $27.2 million in the first quarter of 2024, as compared to $22.6 million for the same quarter in 2023, representing a 21% increase;
- General and Administrative expenses were $25.7 million in the first quarter of 2024, as compared to $22.1 million for the same quarter in 2023, representing a 16% increase; and
- Total Operating Expenses were $75.1 million in the first quarter of 2024, as compared to $57.9 million for the same quarter in 2023, representing a 30% increase.

As of March 31, 2024, Harmony had cash, cash equivalents and investments of $453.6 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 March 31, 2024, was $150 million.

Conference Call Today at 8:30 a.m. ET
We are hosting our first quarter 2024 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 HRMYQ124.

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 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.[1] Approximately 85% of Dravet Syndrome cases are caused by de novo loss-of-function (LOF) mutations in a voltage-gated sodium channel gene, SCN1A1.[2] DS has an estimated incidence rate of 1:15,700.[3]

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.[2,4] As a result, patients experience multiple seizure types, including atonic seizures, and developmental, cognitive, and behavioral issues.[3] LGS affects approximately 48,000 patients in the U.S. [5]

(1) EpyGenix Company Presentation: https://www.epygenix.com/news
(2)EpyGenixPoster:https://www.epygenix.com/_files/ugd/4ad619_2db63a277738444c85e70a47b816a67c.pdf
(3) Wu, E., et. al. (2015). Incidence of Dravet Syndrome in a US Population. *Pediatrics 136(5):* 1310-e1315. doi: 10.1542/peds.2015-1807. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4621800/
(4) https://www.epygenix.com/rare-genetic-epilepsy
(5) https://www.lgsfoundation.org/about-lgs-2/how-many-people-have-lgs/

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 (LOSS)
(In thousands, except share and per share data)

	Three Months Ended	
	March 31, 2024	March 31, 2023
Net product revenue	$ 154,615	$ 119,126
Cost of product sold	27,484	20,780
Gross profit	127,131	98,346
Operating expenses:		
Research and development	22,189	13,289
Sales and marketing	27,233	22,572
General and administrative	25,676	22,062
Total operating expenses	75,098	57,923
Operating income	52,033	40,423
Other expense (income), net	(141)	2
Interest expense	(4,535)	(5,731)
Interest income	4,428	3,086
Income before income taxes	51,785	37,780
Income tax benefit (expense)	(13,451)	(8,295)
Net income	$ 38,334	$ 29,485
EARNINGS PER SHARE:		
Basic	$ 0.68	$ 0.49
Diluted	$ 0.67	$ 0.48
Weighted average number of shares of common stock - basic	56,771,251	59,732,157
Weighted average number of shares of common stock - diluted	57,597,627	61,221,511

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

	March 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 332,981	$ 311,660
Investments, short-term	39,369	41,800
Trade receivables, net	79,719	74,140
Inventory, net	5,857	5,363
Prepaid expenses	12,894	12,570
Other current assets	8,683	5,537
Total current assets	479,503	451,070
NONCURRENT ASSETS:		
Property and equipment, net	213	371
Restricted cash	270	270
Investments, long-term	81,244	72,169
Intangible assets, net	131,147	137,108
Deferred tax asset	147,639	144,162
Other noncurrent assets	6,969	6,298
Total noncurrent assets	367,482	360,378
TOTAL ASSETS	$ 846,985	$ 811,448
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 15,144	$ 17,730
Accrued compensation	7,317	23,747
Accrued expenses	91,699	99,494
Current portion of long-term debt	15,000	15,000
Other current liabilities	25,093	7,810
Total current liabilities	154,253	163,781
NONCURRENT LIABILITIES:		
Long-term debt, net	174,996	178,566
Other noncurrent liabilities	2,342	2,109
Total noncurrent liabilities	177,338	180,675
TOTAL LIABILITIES	331,591	344,456
COMMITMENTS AND CONTINGENCIES (Note 13)		
STOCKHOLDERS' EQUITY:		
Common stock—$0.00001 par value; 500,000,000 shares authorized at March 31, 2024 and December 31, 2023, respectively; 56,791,214 and 56,769,081 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	1	1
Additional paid in capital	620,507	610,266
Accumulated other comprehensive (loss) income	(171)	2
Accumulated deficit	(104,943)	(143,277)
TOTAL STOCKHOLDERS' EQUITY	515,394	466,992
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 846,985	$ 811,448

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

	Three Months Ended	
	March 31, 2024	March 31, 2023
GAAP net income	**$ 38,334**	**$ 29,485**
Non-GAAP Adjustments:		
Non-cash interest expense (1)	180	416
Depreciation	163	103
Amortization (2)	5,961	5,961
Stock-based compensation expense	10,434	6,561
Licensing fees and milestone payments (3)	-	750
Income tax effect related to non-GAAP adjustments (4)	(4,350)	(2,538)
Non-GAAP adjusted net income	$ 50,722	$ 40,738
GAAP reported net income per diluted share	**$ 0.67**	**$ 0.48**
Non-GAAP adjusted net income per diluted share	$ 0.88	$ 0.67
Weighted average number of shares of common stock used in non-GAAP diluted per share	57,597,627	61,221,511

(1) Includes amortization of deferred finance charges.
(2) Includes amortization of intangible asset related to WAKIX.
(3) Includes milestone payment related to HBS102 preclinical milestone in March 2023.
(4) Calculated using the reported effective tax rate for the periods presented less impact of valuation allowance release and discrete items.

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Exhibi

HARMONY BIOSCIENCES

Q1 2024 Financial Results

April 30, 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.

Harmony Accelerates Growth Strategy
Three CNS Franchises - Each With Peak Sales Potential of $1B-$2B

Sleep/Wake

- **WAKIX potential $1B+ Net Revenue opportunity** in Narcolepsy alone with LOE out to 2030
- **On track towards pediatric exclusivity** to extend WAKIX exclusivity to September 2030
- **Near term catalysts** with potential new indications for pitolisant
  - **Pediatric Narcolepsy** – June 21, 2024 PDUFA
  - **IH** – sNDA planned for 2H 2024
- **Life cycle management for pitolisant with Next-Gen formulations** to extend the franchise revenue growth potential beyond 2040
  - **NG1 –** PDUFA date in 2026
  - **NG2 –** On track for PK data in 1H 2024
- **Strengthens leadership position with TPM-1116**, a highly potent and selective oral orexin-2 receptor agonist

Neurobehavioral

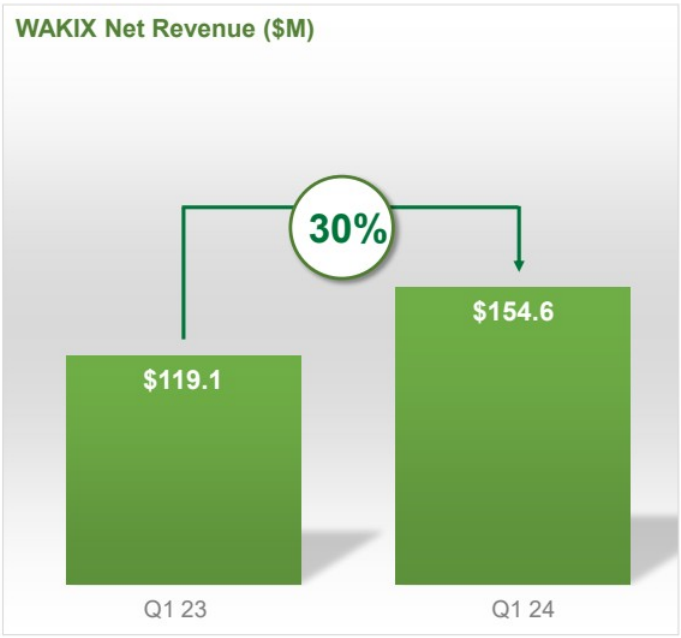
- **ZYN002 in Phase 3 RECONNECT study** for Fragile X syndrome (FXS); topline data expected Mid-2025
- **Phase 3 preparation ongoing** for 22q11.2(22q) deletion syndrome
- **A global opportunity** with **80,000 patients** each in FXS and 22q in the U.S. alone

Rare Ep

- Establishes franchise Epygenix Therapeutic
- Lead product, clemizo 100), **in pivotal regis Dravet syndrome (D** expected in 2026
- **Phase 3 trial for Len** syndrome (LGS) to in
- EPX-100 **has Orphar and Rare Pediatric D** from FDA for both DS
- EPX-200 in IND-enab

WAKIX® Net Revenue Performance

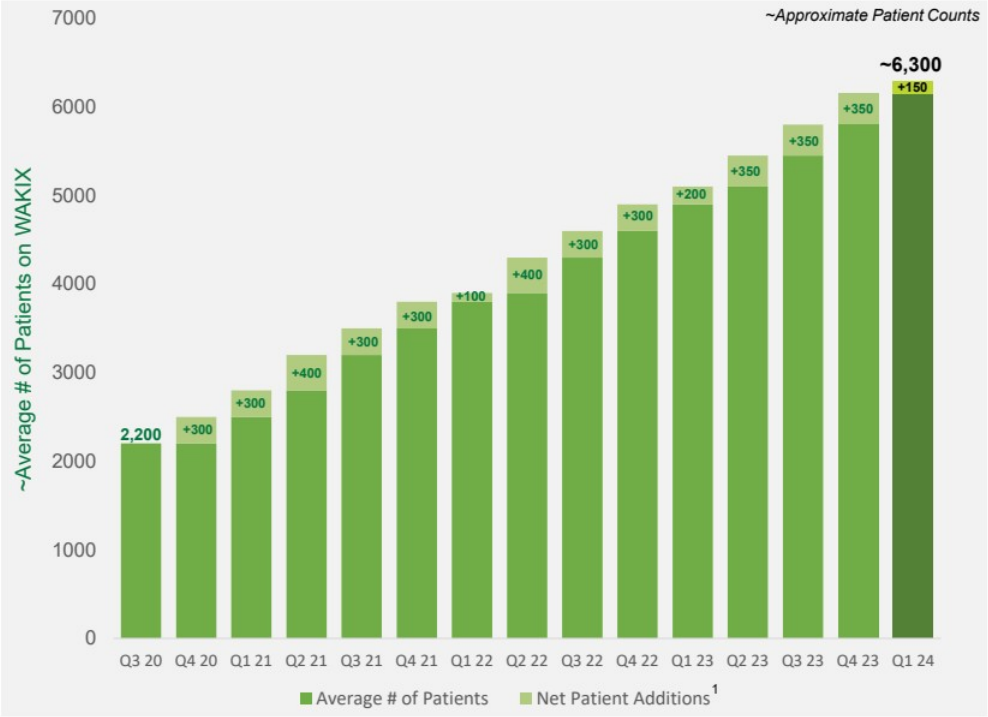
CONFIDENT IN WAKIX BEING A POTENTIAL $1B+ OPPORTUNITY IN ADULT NARCOLEPSY



HIGHLIGHTS

- Durable sales into year five on the r
  30% growth year-over-year
- Underlying demand drove continue
  growth
  - Strong patient interest
  - Continue to add new prescribers
    WAKIX prescriber base

Solid Business Fundamentals Driving Growth



Q1 24 Highlig

~6,300 Average number of patients on WAKIX and growing

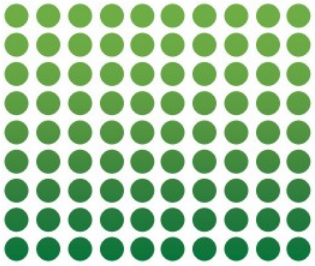
On c
to a
oppo
in ac
narc

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 Adult Narcolepsy



~9,000
Narcolepsy Treating HCPs

Harmony Field Sales Team covers narcolepsy treating HCP universe

Access to ~100% of diagnosed adult patient opportunity

~4,000 HCPs enrolled in oxybate REMS

~5,000 HCPs not enrolled in oxybates REMS

WAKIX **growth**

Depth of p in oxybate enrolled HC

Breadth of in HCPs not in oxybate

100% of HCPs surveyed with WAKIX experience stated they woul the **same/increase Rx in next 6 months**.[1]

~50% of HCPs surveyed who had not prescribed WAKIX to date i 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, January 2024

Building a Robust Late-Stage Pipeline

Extending the Pitolisant Franchise With Next-Gen Formulations (NG1)

Next-Gen Formulation 1

- **Description:** Enteric coated tablet formulation of pitolisant HCl
- **Clinical Development Objectives:**
  - Demonstrate bioequivalence (BE) to WAKIX; Abbreviated development program
  - Dosing optimization
- **Clinical Differentiation:**
  - Enteric coated tablet designed to potentially decrease GI side effects
  - Ability to start dosing at 17.8mg, at the beginning of the therapeutic range with potential to achieve clinical faster
- **Market Opportunity:**
  - Unique product offering for patients to co-exist with WAKIX; accretive opportunity
  - Target patients with previous WAKIX experience
- **PDUFA date expected in 2026**
- **Provisional patent filed with the potential for patent protection out to 2044**

NG1 – Pilot Bioequivalence Study Data

Formulation	Cmax (ng/ml)	AUC_{0-t} (h*ng/ml)	AUC_{0-inf} (h*ng
Test formulation, NG1 (Enteric Coated Pitolisant Hcl)	15.29	242.27	256.
Reference formulation, Wakix (Pitolisant Hcl)	14.42	224.12	237.

- Cmax and AUC, the two important parameters to establish Bioequivalence (BE), are similar between the Test a Reference formulations indicating the rate and extent of absorption are similar in this pilot study
- Safety and tolerability: No AEs reported either with the test or the reference formulations
- **Next Steps:**
  - Pivotal BE study – Q4 24
  - Dosing Optimization study – Q4 24
  - PDUFA Date – 2026

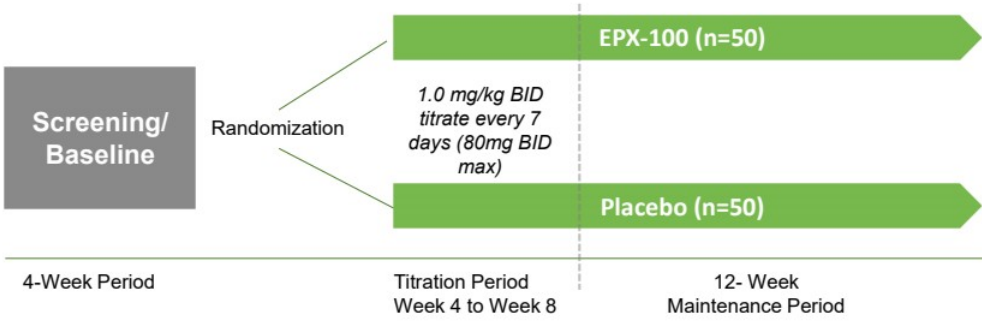
Extending the Pitolisant Franchise With Next-Gen Formulations (NG2)

ON TRACK FOR DATA IN FIRST HALF OF 2024

Next-Gen Formulation 2

- **Opportunity:** Extend franchise beyond 2040, with potential for new IP and opportunity to explore additional indications
- **Formulation:** Enhanced formulation designed to deliver an optimized PK profile and a higher dosage strength
- **Program:** Full development program
- **Status:** Pilot PK study initiated in Q4 23; data available in 1H 24

ARGUS Study in Dravet Syndrome



Trial Design:

- Randomized, double-blind, placebo-controlled, parallel-group study
- 1:1 clemizole hydrochloride: placebo
- ~100 patients; Age 2 years or older

Objectives / Endpoints:

- **Primary objective:** To evaluate the efficacy of EPX-100 compared with placebo as adjun and adult participants with Dravet Syndrome
- **Primary endpoint:** Mean percent change between EPX-100 vs placebo in countable cor frequency (CCSF)
- **Secondary Objective:** To evaluate the difference between EPX100 vs placebo in the nur convulsive seizure-free days relative to baseline
- **Secondary Endpoint:** The number of countable convulsive seizure-free days in the titrat phase relative to baseline

Financial Highlights

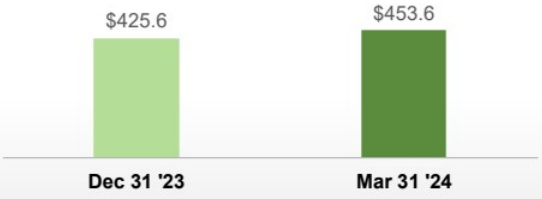
(In millions, USD)

Three Months Ended March 31, 2024

Net Product Revenue

Non-GAAP Adjusted Net Income(1)

Cash, Cash Equivalents & Investments



HIGHLIGHTS

- Durable sales into year f with 30% growth year-ov
- Improved profitability
- Continued cash generati strong balance sheet

(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 March 31,		% Change
	2024	2023	
Net Product Revenue	**$154.6**	**$119.1**	**30%**
Cost of Product Sold	27.5	20.8	32%
Total Operating Expenses	**$75.1**	**$57.9**	**30%**
R&D Expense	22.2	13.3	67%
S&M Expense	27.2	22.6	21%
G&A Expense	25.7	22.1	16%
Net Income	**$38.3**	**$29.5**	**30%**
Cash, cash equivalents & investments	**$453.6**		

GAAP vs NON-GAAP Reconciliation

(In millions, USD) Totals may not foot due to rounding	Three Months Ended March 31,	
	2024	2023
GAAP net income	**$38.3**	**$29.5**
Non-cash interest expense[1]	0.2	0.4
Depreciation	0.2	0.1
Amortization[2]	6.0	6.0
Stock-based compensation expense	10.4	6.6
Licensing fees and milestone payments[3]	-	0.8
Income tax effect related to Non-GAAP adjustments[4]	(4.4)	(2.5)
Non-GAAP adjusted net income	**$50.7**	**$40.7**
GAAP net income per diluted share	**$0.67**	**$0.48**
Non-GAAP adjusted net income per diluted share	**$0.88**	**$0.67**
Weighted average number of shares of common stock used in non-GAAP diluted per share	57,597,627	61,221,511

(1) Includes amortization of deferred finance charges.
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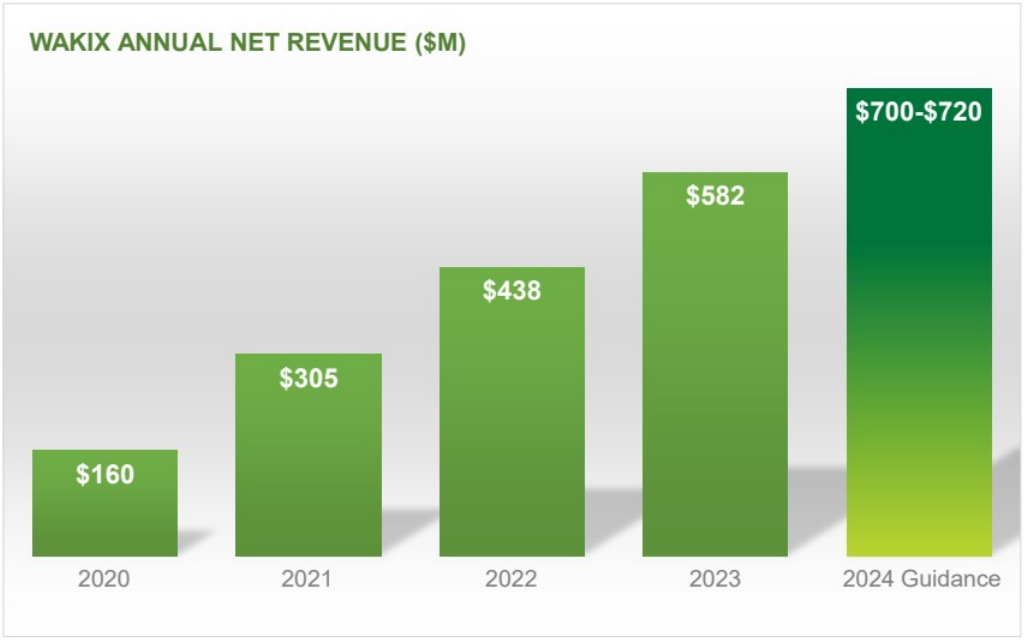
Reiterates 2024 Net Revenue Guidance

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



Reitera

2024 Gui

$700-$7


HARMONY
BIOSCIENCES
Thank You!