
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): February 28, 2022

HARMONY BIOSCIENCES HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39450
(Commission
File Number)

82-2279923
(IRS Employer
Identification No.)

630 W. Germantown Pike, Suite 215
Plymouth Meeting, PA 19462
(Address of principal executive offices) (Zip Code)

(484) 539-9800
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.00001 par value per share	HRMY	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On February 28, 2022, Harmony Biosciences Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2021. A copy of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

On February 28, 2022, the Company posted an investor presentation to its website at <https://ir.harmonybiosciences.com> (the "Investor Presentation"). A copy of the Investor Presentation is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. The Company expects to use the Investor Presentation, in whole or in part, and possibly with modifications, in connection with presentations to investors, analysts and others.

The information contained in the Investor Presentation is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission ("SEC") filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Investor Presentation speaks only as of the date of this Current Report on Form 8-K. The Company undertakes no duty or obligation to publicly update or revise the information contained in the Investor Presentation, although it may do so from time to time. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure. In addition, the exhibit furnished herewith contains statements intended as "forward-looking statements" that are subject to the cautionary statements about forward-looking statements set forth in such exhibit. By furnishing the information contained in the Investor Presentation, the Company makes no admission as to the materiality of any information in the Investor Presentation that is required to be disclosed solely by reason of Regulation FD.

This Current Report on Form 8-K and its contents (including Exhibits 99.1 and 99.2) are furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Note Regarding Forward-Looking Statements

Certain statements in this Current Report on Form 8-K constitute "forward-looking statements" within the meaning of the federal securities laws. These statements are based on management's current opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results. These forward looking statements are only predictions, not historical fact, and involve certain risks and uncertainties, as well as assumptions. Actual results, levels of activity, performance, achievements and events could differ materially from those stated, anticipated or implied by such forward-looking statements. While the Company believes that its assumptions are reasonable, it is very difficult to predict the impact of known factors, and, of course, it is impossible to anticipate all factors that could affect actual results. There are many risks and uncertainties that could cause actual results to differ materially from forward-looking statements made herein including the risks discussed under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 which was filed with the SEC, as well as other factors described from time to time in the Company's filings with the SEC. Such forward-looking statements are made only as of the date of this Current Report on Form 8-K. The Company undertakes no obligation to publicly update or revise any forward-looking statement because of new information, future events or otherwise, except as otherwise required by law. If it does update one or more forward-looking statements, no inference should be made that the Company will make additional updates with respect to those or other forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1*	Press release issued by the Company dated February 28, 2022
99.2*	Investor Presentation dated February 28, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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

SIGNATURES

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

HARMONY BIOSCIENCES HOLDINGS, INC.

Date: February 28, 2022

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



**HARMONY BIOSCIENCES REPORTS FOURTH QUARTER AND FULL YEAR 2021
FINANCIAL RESULTS AND BUSINESS UPDATES**

WAKIX® (pitolisant) Net Revenue Increased 62% Year-over-Year to \$91.2 Million for Fourth Quarter 2021 and 91% to \$305.4 Million for Full Year

Achieved First Full Year of Profitability and Net Income was \$22.7 Million for the Fourth Quarter 2021

Average Number of Patients on WAKIX Increased to ~3,800

On Track to Initiate the Phase 3 Clinical Trial in Patients with Idiopathic Hypersomnia First Half of This Year

Year-End 2021 Cash and Cash Equivalents of Approximately \$234 Million

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

PLYMOUTH MEETING, PA, February 28, 2022 — Harmony Biosciences Holdings, Inc. (“Harmony” or the “Company”) (Nasdaq: HRMY), a pharmaceutical company dedicated to developing and commercializing innovative therapies for patients with rare neurological diseases, today reported financial results and business updates for the fourth quarter and full year ended December 31, 2021.

“Our performance in 2021 demonstrated the team’s commitment and ability to execute on our three-pillar growth strategy designed to support long-term, sustainable value creation. The sequential quarter-over-quarter revenue growth we have achieved since launching WAKIX is supported by the positive feedback from both healthcare providers and patients who are gaining experience with WAKIX,” stated John C. Jacobs, President and Chief Executive Officer of Harmony. “In 2022, we expect ongoing growth of WAKIX due to continued strong underlying demand. We are also excited to initiate our Phase 3 registrational trial in Idiopathic Hypersomnia in the first half of this year. Finally, our dedicated business development team remains focused on acquiring new assets to

expand our portfolio beyond WAKIX.”

Fourth Quarter 2021 Financial Results

Net product revenues for the quarter ended December 31, 2021 were \$91.2 million compared to \$56.3 million for the same period in 2020. The 62.0% growth versus the same period in 2020 can be primarily attributed to strong commercial sales of WAKIX driven by continued organic demand.

GAAP net income available to shareholders for the quarter ended December 31, 2021, was \$22.7 million, or \$0.38 per diluted share. This compares to a net loss available to shareholders of \$0.2 million, or a loss of \$0.00 per diluted share, for the same period in 2020. Non-GAAP adjusted net income was \$37.8 million, or \$0.63 per diluted share, for the quarter ended December 31, 2021, compared to a non-GAAP adjusted net income of \$15.1 million, or \$0.25 per diluted share, for the same period in 2020.

Reconciliations of applicable GAAP measures to non-GAAP adjusted information are included at the end of this press release.

The components of Harmony’s operating expenses include:

- Research and Development expenses were \$7.5 million in the fourth quarter of 2021 as compared to \$7.6 million for the same quarter in 2020, representing a 1.3% decrease;
- Sales and Marketing expenses were \$19.1 million in the fourth quarter of 2021 as compared to \$17.5 million for the same quarter in 2020, representing a 9.0% increase;
- General and Administrative expenses were \$18.2 million in the fourth quarter of 2021 as compared to \$13.5 million for the same quarter in 2020, representing a 35.2% increase; and
- Total Operating Expenses were \$44.8 million in the fourth quarter of 2021 as compared with \$38.6 million for the same quarter in 2020, representing a 15.9% increase.

Full Year 2021 Financial Results

Net product revenues for the year ended December 31, 2021 were \$305.4 million compared to \$159.7 million for 2020. The 91.2% growth versus 2020 can be primarily attributed to strong commercial sales of WAKIX driven by organic demand.

GAAP net income available to shareholders for the year ended December 31, 2021 was \$34.6 million, or \$0.38 per diluted share. This compares to a net loss available to shareholders of \$63.8 million, or a loss of \$2.48 per diluted share, for the prior year. Non-GAAP adjusted net income was \$122.5 million, or \$2.07 per diluted share, for the

year ended December 31, 2021, compared to a non-GAAP adjusted net income of \$5.5 million, or \$0.21 per diluted share, for the prior year.

Reconciliations of applicable GAAP measures to non-GAAP adjusted information are included at the end of this press release.

The components of Harmony's operating expenses include:

- Research and Development expenses were \$30.4 million for the year ended December 31, 2021 as compared with \$19.4 million for the prior year, representing a 56.1% increase;
- Sales and Marketing expenses were \$68.1 million for the year ended December 31, 2021 as compared to \$55.8 million for the prior year, representing a 22.0% increase;
- General and Administrative expenses were \$63.9 million for the year ended December 31, 2021 as compared to \$39.7 million for the prior year, representing a 60.8% increase; and
- Total Operating Expenses were \$162.4 million for the year ended December 31, 2021 as compared with \$115 million for the prior year, representing a 41.2% increase.

As of December 31, 2021, Harmony had cash and cash equivalents of \$234.3 million.

Clinical Development and Recent Updates

- The U.S. Food and Drug Administration ("FDA") accepted an Investigational New Drug application for pitolisant for the treatment of Idiopathic Hypersomnia ("IH"). Harmony is on track to initiate a Phase 3 clinical trial to evaluate the safety and efficacy of pitolisant in adult patients with IH in the first half of 2022.
 - In light of the ongoing COVID-19 pandemic, and recent emergence of the Omicron variant, the Company is updating the timing of its other life cycle management programs for pitolisant. We now anticipate topline data from the Phase 2 proof-of-concept trial in Prader-Willi Syndrome in the second half of 2022 and Myotonic Dystrophy topline data in 2023.
 - With regard to pediatric narcolepsy, our partner Bioprojet has completed its Phase 3 trial. We will look to the data as a key input to help inform our strategy related to pediatric exclusivity and a potential pediatric narcolepsy indication.
 - For HBS-102, our early-stage asset, we are exploring potential clinical targets within the realm of rare neurological diseases and plan to begin preclinical proof of concept studies on one or two of those potential targets in the second half of 2022.
 - Two post-hoc analyses highlighting clinically relevant data for pitolisant, which further elucidate the efficacy profile of WAKIX, were published during Q4 2021 in CNS Drugs. One is titled, "*Time to Onset of Response to Pitolisant for the*
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Treatment of Excessive Daytime Sleepiness and Cataplexy in Patients with Narcolepsy: An Analysis of Randomized Placebo-Controlled Trials,” and the other is “Clinical Impact of Pitolisant on Excessive Daytime Sleepiness and Cataplexy in Adults with Narcolepsy: An Analysis of Randomized Placebo-Controlled Trials.”

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

We are hosting our fourth quarter and full-year 2021 financial results conference call and webcast today beginning at 8:30 a.m. Eastern Time. The live and replayed webcast of the call will be available on the investor relations page of our website at <https://ir.harmonybiosciences.com/>. To participate in the live call by phone, dial (833) 614-1471 (domestic) or +1 (914) 987-7209 (international), and reference passcode 4387084. A replay will be accessible until March 7, 2022 by dialing (855) 859-2056 (domestic) or +1 (404) 537-3406 (international).

Non-GAAP Financial Measures

In addition to our GAAP results, we present certain non-GAAP metrics including adjusted net income and 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 adjusted net income and 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. Company management uses these non-GAAP measurements as an aid in monitoring our ongoing financial performance from quarter-to-quarter and year-to-year on a regular basis and for benchmarking against comparable companies.

These non-GAAP financial measures should not be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with our consolidated financial statements prepared in accordance with GAAP; have no standardized meaning prescribed by GAAP; and are not prepared under any comprehensive set of accounting rules or principles. In addition, from time to time in the future there may be other items that we may exclude for purposes of our non-GAAP financial measures; and we may in the future cease to exclude items that we have historically excluded for purposes of our non-GAAP financial measures.

About WAKIX® (pitolisant) Tablets

WAKIX, a first-in-class medication, is approved by the U.S. Food and Drug Administration for the treatment of excessive daytime sleepiness or cataplexy in adult patients with narcolepsy and has been commercially available in the U.S. since Q4 2019. It was granted orphan drug designation for the treatment of narcolepsy in 2010, and breakthrough therapy designation for the treatment of cataplexy in 2018. WAKIX is a selective histamine 3 (H₃) receptor antagonist/inverse agonist. The mechanism of action of WAKIX is unclear; however, its efficacy could be mediated through its activity at H₃ receptors, thereby increasing the synthesis and release of histamine, a wake promoting

neurotransmitter. WAKIX was designed and developed by Bioprojet (France). Harmony has an exclusive license from Bioprojet to develop, manufacture and commercialize pitolisant in the United States.

Indications and Usage

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

Important Safety Information

Contraindications

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

Warnings and Precautions

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

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

Adverse Reactions

In the placebo-controlled clinical trials conducted in patients with narcolepsy with or without cataplexy, the most common adverse reactions ($\geq 5\%$ and twice placebo) for WAKIX were insomnia (6%), nausea (6%), and anxiety (5%). Other adverse reactions that occurred at $\geq 2\%$ and more frequently than in patients treated with placebo included headache, upper respiratory 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).

information).

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

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

Use in Specific Populations

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

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

WAKIX is extensively metabolized by the liver. WAKIX is contraindicated in patients with severe hepatic impairment. Dosage adjustment is required in patients with moderate hepatic impairment.

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

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

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

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

About Narcolepsy

Narcolepsy is a rare, chronic, debilitating neurological disease of sleep-wake state instability that impacts approximately 165,000 Americans and is primarily characterized by excessive daytime sleepiness (EDS) and cataplexy – its two cardinal symptoms – along with other manifestations of REM sleep dysregulation (hallucinations and sleep paralysis), which intrude into wakefulness. EDS is the inability to stay awake and alert

during the day and is the symptom that is present in all people living with narcolepsy. In most patients, narcolepsy is caused by the loss of hypocretin/orexin, a neuropeptide in the brain that supports sleep-wake state stability. This disease affects men and women equally, with typical symptom onset in adolescence or young adulthood; however, it can take up to a decade to be properly diagnosed.

About Idiopathic Hypersomnia

Idiopathic Hypersomnia (IH) is a rare and chronic neurological disease that is characterized by excessive daytime sleepiness (EDS) despite sufficient or even long sleep time. EDS in IH cannot be alleviated by naps, longer sleep or more efficient sleep. People living with IH experience significant EDS along with the symptoms of sleep inertia (prolonged difficulty waking up from sleep) and 'brain fog' (impaired cognition, attention, and alertness). The cause of IH is unknown, but it is likely due to alterations in areas of the brain that stabilize states of sleep and wakefulness. IH is one of the central disorders of hypersomnolence and, like narcolepsy, is a debilitating sleep disorder that can result in significant disruption in daily functioning.

About HBS-102

HBS-102, an investigational compound, is a melanin-concentrating hormone (MCH) receptor 1 (MCHR1) antagonist that targets MCH neurons in the brain. It has the potential to be a first-in-class molecule with a novel mechanism of action that could offer a new approach to the treatment of a variety of rare neurological diseases.

About Harmony Biosciences

Harmony Biosciences is a commercial stage pharmaceutical company headquartered in Plymouth Meeting, PA. The Company was established by Paragon Biosciences, LLC, and is focused on providing novel treatment options for people living with rare neurological disorders who have unmet medical needs. For more information on Harmony, please visit the company's website: www.harmonybiosciences.com.

Forward Looking Statement

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

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Net product revenues	\$ 91,213	\$ 56,288	\$ 305,440	\$ 159,742
Cost of product sold	17,817	9,918	55,518	27,738
Gross profit	73,396	46,370	249,922	132,004
Operating expenses:				
Research and development	7,451	7,618	30,367	19,448
Sales and marketing	19,109	17,526	68,118	55,824
General and administrative	18,205	13,466	63,909	39,746
Total operating expenses	44,765	38,610	162,394	115,018
Operating income	28,631	7,760	87,528	16,986
Loss on debt extinguishment	—	—	(26,146)	(22,639)
Other income (expense), net	31	—	16	(3,071)
Interest expense, net	(4,187)	(7,966)	(23,970)	(28,220)
Income (loss) before income taxes	24,475	(206)	37,428	(36,944)
Income tax expense	(1,761)	—	(2,831)	—
Net income (loss) and comprehensive income (loss)	\$ 22,714	\$ (206)	\$ 34,597	\$ (36,944)
Accumulation of dividends on preferred stock	—	—	—	(26,904)
Net income (loss) available to common stockholders	\$ 22,714	\$ (206)	\$ 34,597	\$ (63,848)
EARNINGS (LOSS) PER SHARE:				
Basic	\$ 0.39	\$ (0.00)	\$ 0.60	\$ (2.48)
Diluted	\$ 0.38	\$ (0.00)	\$ 0.58	\$ (2.48)
Weighted average number of shares of common stock - basic	58,550,657	56,889,460	57,531,540	25,772,419
Weighted average number of shares of common stock - diluted	60,314,395	56,889,460	59,205,213	25,772,419

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

	December 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 234,309	\$ 228,631
Trade receivables, net	34,843	22,176
Inventory, net	4,432	3,823
Prepaid expenses	7,637	6,959
Other current assets	3,218	1,302
Total current assets	<u>284,439</u>	<u>262,891</u>
NONCURRENT ASSETS:		
Property and equipment, net	820	938
Restricted cash	750	750
Intangible assets, net	143,919	162,343
Other noncurrent assets	3,515	152
Total noncurrent assets	<u>149,004</u>	<u>164,183</u>
TOTAL ASSETS	<u>\$ 433,443</u>	<u>\$ 427,074</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	\$ 1,001	\$ 2,556
Accrued compensation	9,165	8,942
Accrued expenses	40,249	122,727
Current portion of long term debt	2,000	—
Other current liabilities	1,360	314
Total current liabilities	<u>53,775</u>	<u>134,539</u>
NONCURRENT LIABILITIES:		
Long term debt, net	189,984	194,250
Other noncurrent liabilities	3,177	1,105
Total noncurrent liabilities	<u>193,161</u>	<u>195,355</u>
TOTAL LIABILITIES	<u>246,936</u>	<u>329,894</u>
COMMITMENTS AND CONTINGENCIES (Note 9)		
STOCKHOLDERS' EQUITY:		
Preferred stock - \$0.00001 par value; 10,000,000 shares and 00 shares authorized at December 31, 2021 and December 31, 2020, respectively; 00 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	—	—
Common stock—\$0.00001 par value; 500,000,000 shares authorized at December 31, 2021 and December 31, 2020, respectively; 58,825,769 shares and 56,890,569 issued and outstanding at December 31, 2021 and December 31, 2020, respectively	1	1
Additional paid in capital	640,104	585,374
Accumulated deficit	(453,598)	(488,195)
TOTAL STOCKHOLDERS' EQUITY	<u>186,507</u>	<u>97,180</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 433,443</u>	<u>\$ 427,074</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Net (loss) income	\$ 22,714	\$ (206)	\$ 34,597	\$ (36,944)
Non-GAAP Adjustments:				
Interest expense	4,187	7,966	23,970	28,220
Taxes	1,761	—	2,831	—
Depreciation	117	100	416	394
Amortization	4,643	4,283	18,424	9,843
EBITDA	33,422	12,143	80,238	1,513
Additional Non-GAAP Adjustments:				
Stock-based compensation expense	4,383	2,924	16,105	5,190
Loss on debt extinguishment	—	—	26,146	22,639
Warrant expense	—	—	—	3,109
Non-GAAP adjusted net income	\$ 37,805	\$ 15,067	\$ 122,489	\$ 32,451
Accumulation of yield on preferred stock	—	—	—	(26,904)
Non-GAAP adjusted net income available to common stockholders	37,805	15,067	122,489	5,547
GAAP reported net income (loss) per diluted share	\$ 0.38	\$ (0.00)	0.58	\$ (2.48)
Non-GAAP adjusted net income per diluted share	\$ 0.63	\$ 0.25	2.07	\$ 0.21
Weighted average number of shares of common stock used in non-GAAP diluted per share	60,314,395	59,128,981	59,205,213	26,982,978

Harmony Biosciences Investor Contact:

Patti Bank
ICR Westwicke
415-513-1284
ir@harmonybiosciences.com

Harmony Biosciences Media Contact:

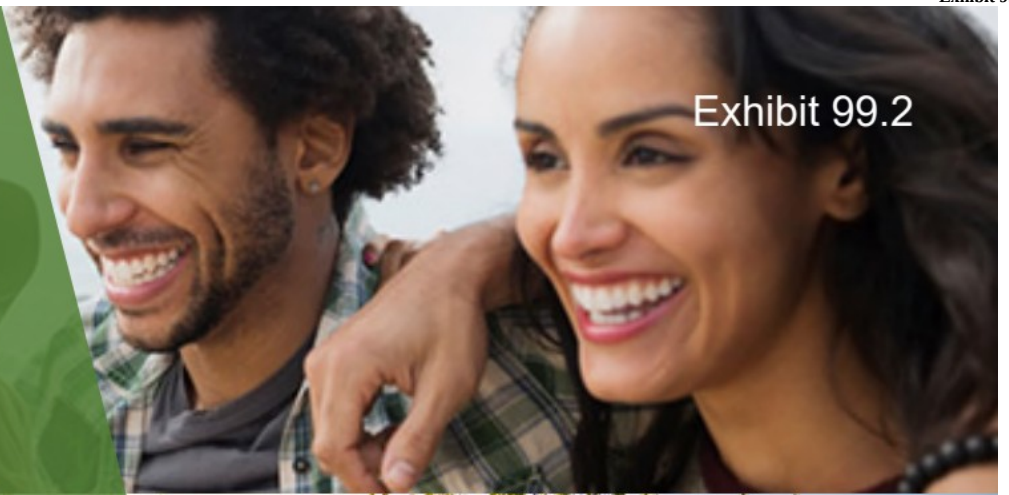
Nancy Leone
215-891-6046
nleone@harmonybiosciences.com

Exhibit 99.2



**Harmony Biosciences
Q4 2021 Financial and
Business Update**

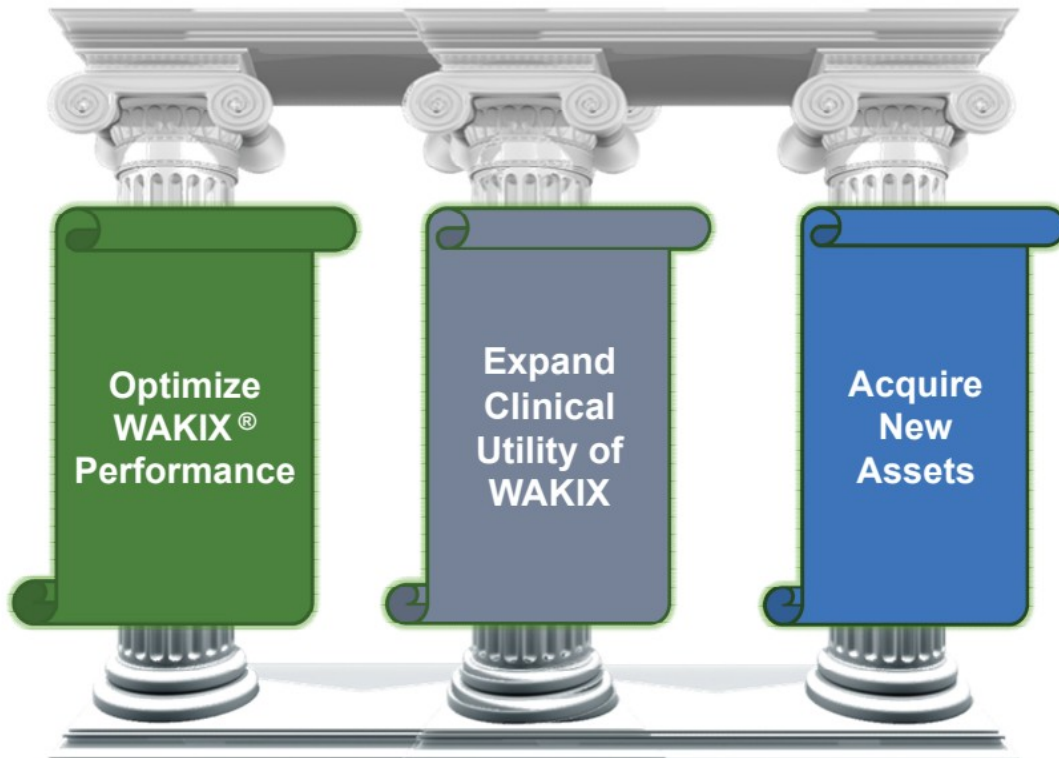
February 28, 2022



This presentation includes forward-looking statements within the meaning of the Private Securities Reform Act of 1995. All statements other than statements of historical facts contained in these materials or elsewhere, including statements regarding Harmony Biosciences Holdings, Inc.'s (the "Company") future financial position, business strategy and plans and objectives of management for future operations, should be considered forward-looking statements. Forward-looking statements use words like "believes," "plans," "expects," "intends," "will," "would," "anticipates," "estimates," and similar words or expressions in discussions of the Company's future operations, financial performance or the Company's strategies. These statements are based on current expectations or objectives that are inherently uncertain, especially in light of the Company's limited operating history. These and other important factors discussed under the caption "Risk Factors" in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on February 28, 2022 and its other filings with the SEC could cause actual results to differ materially and adversely from those indicated by the forward-looking statements made in this presentation. While the Company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change.

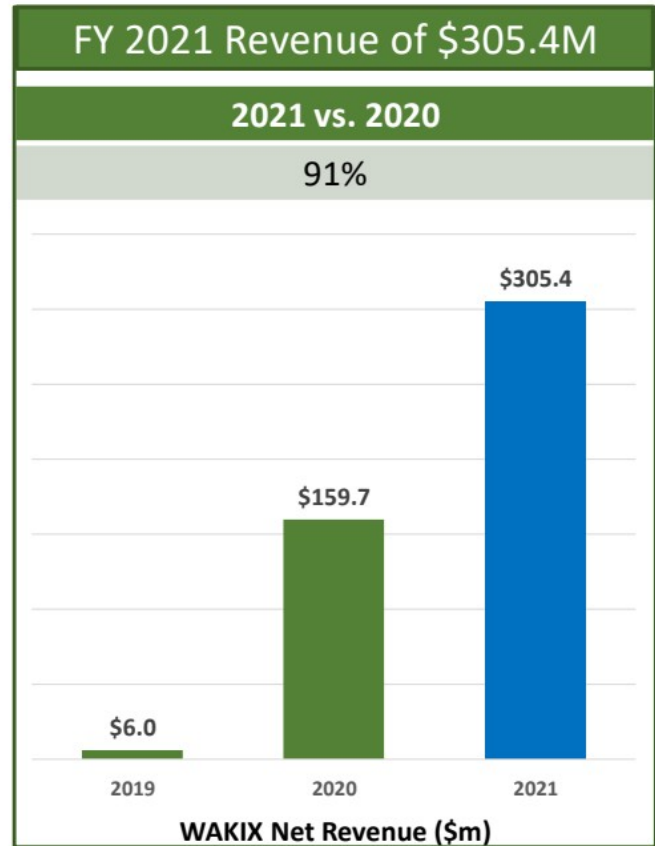
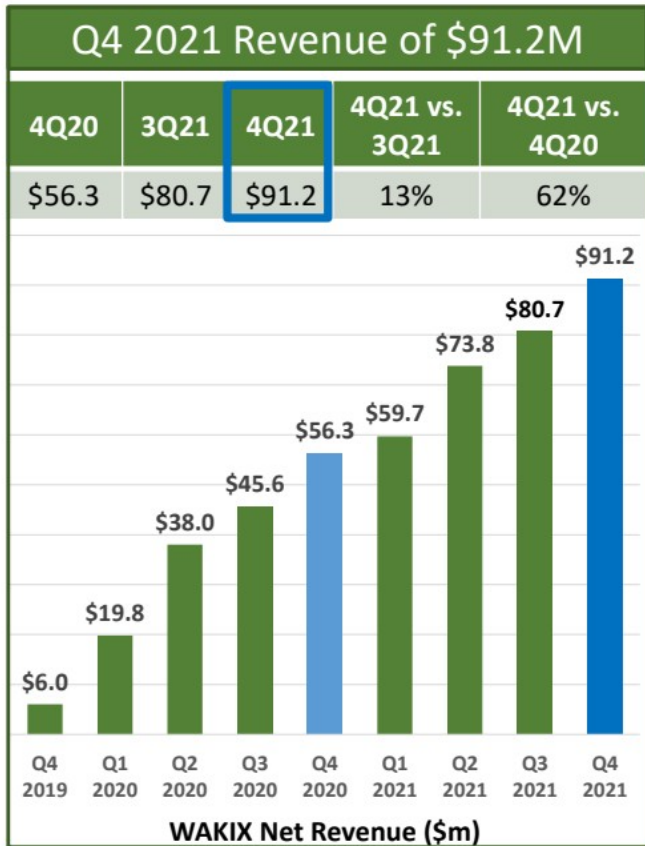
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Harmony's Strategy for Growth



Q4/FY 2021 WAKIX® Revenue Performance

Strong Sequential Growth QoQ, YoY



Driving Growth Through Our Launch For WAKIX Q4 2021 Performance



~2/3 In-Person
Access to HCPs



Patient Outreach
Programs & Support

~3,800 Average # of
WAKIX Patients



Healthcare Professional
Educational Initiatives

Continued Growth in
Depth & Breadth of Prescriber Base



Managed Care
Education & Outreach

~80%

U.S. Covered Lives With Formulary Access



CNS Drugs (2021) 35:1303–1315
<https://doi.org/10.1007/s40263-021-00866-1>

ORIGINAL RESEARCH ARTICLE



Time to Onset of Response to Pitolisant for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Patients With Narcolepsy: An Analysis of Randomized, Placebo-Controlled Trials

Nathaniel F. Watson¹ · Craig W. Davis² · Donna Zarycranski² · Ben Vaughn³ · Jeffrey M. Dayno² · Yves Dauvilliers^{4,5,6} · Jean-Charles Schwartz⁷

CNS Drugs (2022) 36:61–69
<https://doi.org/10.1007/s40263-021-00886-x>

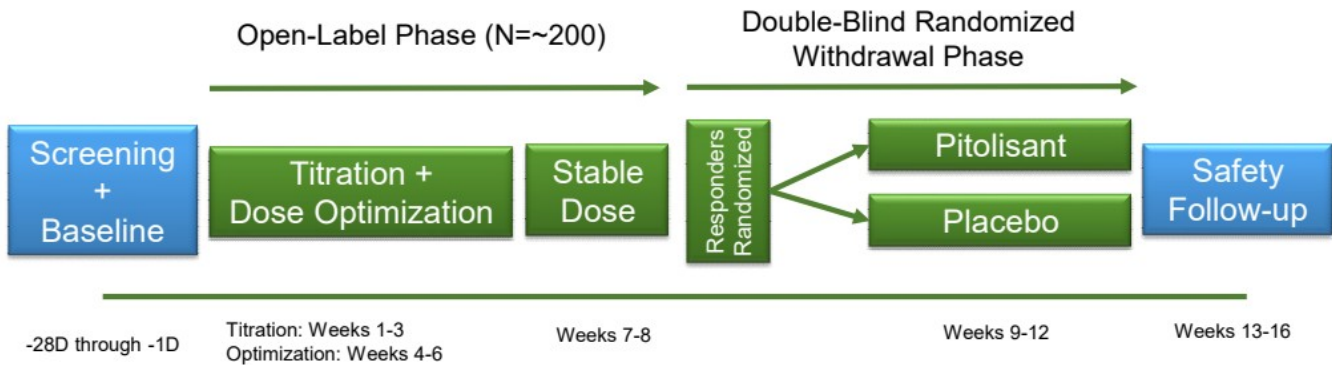
ORIGINAL RESEARCH ARTICLE



Clinical Impact of Pitolisant on Excessive Daytime Sleepiness and Cataplexy in Adults With Narcolepsy: An Analysis of Randomized Placebo-Controlled Trials

Gerard J. Meskill¹ · Craig W. Davis² · Donna Zarycranski² · Markiyam Doliba² · Jean-Charles Schwartz³ · Jeffrey M. Dayno²

Phase 3 Clinical Trial of Pitolisant in Idiopathic Hypersomnia: On Track to Initiate 1H2022



Trial Design:

- Double-blind, placebo-controlled, randomized withdrawal study in patients with IH ≥18 years old
- ~200 patients to be enrolled into open-label dose optimization phase; responders will subsequently be entered into the randomized withdrawal phase
- ~80 clinical trial sites in the US

Objectives:

- **Primary objective:** to evaluate the safety and efficacy of pitolisant compared with placebo in treating EDS in patients with IH ≥18 years old
- **Secondary objectives:** to assess the impact of pitolisant on overall symptoms of IH, patient impression of overall change in their IH, investigator assessment of overall IH severity, functional status and activities of daily living, sleep-related impairment, sleep inertia, and cognitive function

- Mechanism put in place for electronic signatures for 'e-consent' on Informed Consent Forms (ICFs); allows for remote screening
- Protocol amendments to allow for remote visits during the trial in both the PWS and DM1 Phase 2 trials; include telemedicine visits for clinical assessments and home nursing visits to perform ECGs and draw labs (for safety assessments)
- Connecting trial sites with additional sleep labs to perform objective sleep testing when their institution's sleep lab is not available due to resources or personnel being diverted to care for COVID patients
- Adding additional trial sites in regions of the country that are not as affected by COVID and/or directing patients from sites that are not able to enroll patients to those sites that are actively enrolling patients
- Other strategies to reduce overall burden of the trials for both patients/families and the clinical trial sites



Harmony Development Pipeline



Product / Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Regulatory Filing ¹	Marketed Product	Upcoming Milestones
WAKIX®							
EDS in Narcolepsy (Adults)							
Cataplexy in Narcolepsy (Adults)							
Pitolisant							
Pediatric Narcolepsy ²							Trial completed
Idiopathic Hypersomnia							Trial initiation 1H2022
Prader-Willi Syndrome (PWS)							Top line data 2H2022
Myotonic Dystrophy (DM)							Top line data 2023
HBS-102							
Other Neurological Diseases							Pre-clinical POC

1. Includes New Drug Applications and supplemental New Drug Applications.

2. Bioprojet conducted pediatric narcolepsy trial



Historical Financials



HB HARMONY
BIOSCIENCES

Q4 2021 Financial Highlights

(In millions, USD)

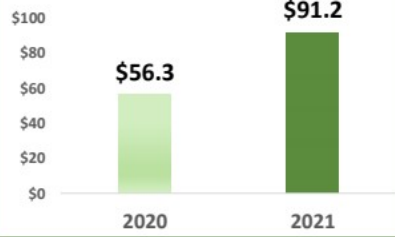
Q4 '21 Net Product Revenues

\$91.2M



62.0% vs prior year

Three Months Ended December 31, 2021



Year Ended December 31, 2021

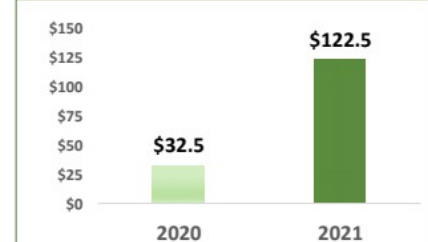
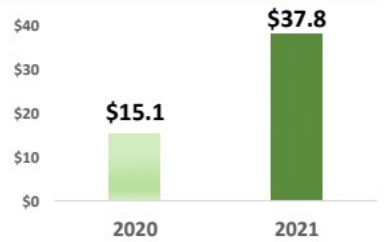


Q4 '21 Non-GAAP Adjusted Net Income¹

\$37.8M



150.3% vs prior year



Cash, Cash Equivalents at 12/31/21

\$234.3M



1. Non-GAAP Adjusted Net Income = EBITDA plus add backs for Stock-based compensation expense, Loss on debt extinguishment and Warrant Expense

Q4 2021 Financial Summary

(In millions, USD)	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Net Product Revenues	\$91.2	\$56.3	\$305.4	\$159.7
Cost of Product Sold	17.8	9.9	55.5	27.7
Total Operating Expenses	\$44.8	\$38.6	\$162.4	\$115.0
R&D Expense	7.5	7.6	30.4	19.5
S&M Expense	19.1	17.5	68.1	55.8
G&A Expense	18.2	13.5	63.9	39.7
Net Income (Loss)	\$22.7	\$(0.2)	\$34.6	\$(36.9)
Cash & cash equivalents			\$234.3	\$228.6

Q4 2021 GAAP vs Non-GAAP Reconciliation



(In millions, USD)	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
GAAP reported net income (loss)	\$22.7	\$(0.2)	\$34.6	\$(36.9)
Interest expense / income	4.2	8.0	24.0	28.2
Taxes	1.8	-	2.8	-
Depreciation	0.1	0.1	0.4	0.4
Amortization	4.6	4.3	18.4	9.8
EBITDA	33.4	12.1	80.2	1.5
Stock-based compensation expense	4.4	2.9	16.1	5.2
Loss on debt extinguishment	-	-	26.1	22.6
Warrant expense	-	-	-	3.1
Non-GAAP adjusted net income	\$37.8	\$15.1	\$122.5	\$32.5
Accumulation of yield on preferred stock	-	-	-	(26.9)
Non-GAAP adjusted net income available to common stockholders	\$37.8	\$15.1	\$122.5	\$5.5
GAAP reported net income (loss) per diluted share	\$0.38	\$(0.00)	\$0.58	\$(24.07)
Non-GAAP adjusted net income per diluted share	\$0.63	\$0.25	\$2.07	\$0.21
Weighted average number of shares of common stock used in non-GAAP diluted per share	60,314,396	59,128,981	59,205,213	26,282,978

Totals may not foot due to rounding





Thank You

February 2022

