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

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**FORM 8-K**

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

**Date of report (Date of earliest event reported): March 25, 2021**

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**HARMONY BIOSCIENCES HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

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**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.)

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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:**

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

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.

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**Item 2.02. Results of Operations and Financial Condition.**

On March 25, 2021, Harmony Biosciences Holdings, Inc. (the “Company”) issued a press release announcing its financial results for the full year and quarter ended December 31, 2020. 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 March 25, 2021, 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 Quarterly Report on Form 10-K for the year ended December 31, 2020 to be 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.

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**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1*	<a href="#">Press release issued by the Company dated March 25, 2021.</a>
99.2*	<a href="#">Investor Presentation dated March 25, 2021.</a>

\* 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: March 25, 2021

By: /s/ John C. Jacobs

John C. Jacobs

President and Chief Executive Officer



**HARMONY BIOSCIENCES REPORTS FOURTH QUARTER AND FULL-YEAR 2020  
FINANCIAL RESULTS AND BUSINESS UPDATES**

*WAKIX® (pitolisant) Total Revenue of \$160 Million for Full-Year 2020; \$56 Million for Fourth Quarter 2020*

*Clinical Utility of WAKIX was Expanded with Additional Approval for Treatment of Cataplexy in Adults with Narcolepsy*

*Enrollment Continues in Phase 2 Trial of Patients with Prader-Willi Syndrome*

*On Track to Initiate Two Additional Clinical Trials with Pitolisant in 2021*

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

PLYMOUTH MEETING, PA, March 25, 2021 — Harmony Biosciences Holdings, Inc. (“Harmony”) (Nasdaq: HRMY), a pharmaceutical company dedicated to developing and commercializing innovative therapies for patients living with rare neurological disorders who have unmet medical needs, today reported its financial results and business updates for the fourth quarter and full year ended December 31, 2020.

**2020 Financial and Business Highlights:**

- Net product revenue of \$56.3 million for the fourth quarter ended December 31, 2020; Full-year net product revenue of \$159.7 million;
- U.S. Food and Drug Administration (FDA) approved expanded use of WAKIX for the treatment of cataplexy in adults with narcolepsy;
- Enrolled first patient in Phase 2 clinical trial of WAKIX for the treatment of excessive daytime sleepiness (EDS) in patients with Prader-Willi Syndrome (PWS);
- Completed upsized initial public offering of 6.15 million shares at a price of \$24.00 per share on August 21, 2020 for gross proceeds of \$147.6 million; and
- Added to the Russell 2000® Index and Russell 3000® Index.

“Harmony achieved many milestones during 2020 and has entered 2021 well positioned to advance our strategic objectives,” stated John C. Jacobs, President and Chief Executive Officer of Harmony Biosciences. “Key to our success was the closing of our initial public offering in August 2020 and the listing of our common stock on the Nasdaq Global Market. These events

elevated Harmony's visibility among investors and provided the financial resources that we believe will allow us to continue to support our commercialization efforts for WAKIX, advance our clinical programs, and pursue the acquisition of additional assets that would be complementary to our existing commercial footprint and core areas of expertise."

Mr. Jacobs added, "With FDA approval of the cataplexy indication for WAKIX and despite the COVID-19 pandemic, WAKIX sales posted double-digit, quarter-over-quarter growth. I am grateful to our employees who met the challenge of achieving these goals during a disruptive global pandemic. Looking ahead, our Phase 2 trial in patients with Prader-Willi Syndrome is actively enrolling patients and our clinical team has made good progress toward the initiation of two additional clinical trials, one in patients with myotonic dystrophy and another in pediatric narcolepsy patients."

#### **Fourth Quarter 2020 Financial Results**

For the three-month period ended December 31, 2020, Harmony reported net product revenue of \$56.3 million, compared to \$6.0 million for the same three-month period in 2019. The increase was primarily due to growing sales of WAKIX, which first became commercially available in November 2019, and the label expansion to include cataplexy in patients with narcolepsy that occurred on October 13, 2020.

For the three-month period ended December 31, 2020, Harmony reported net loss of \$0.2 million, or \$0.00 per diluted share on a U.S. generally accepted accounting principles (GAAP) basis.

For the three-month period ended December 31, 2020 and 2019, a comparison of total operating expenses is not meaningful and not included in this commentary as WAKIX did not become commercially available for the treatment of EDS in adult patients with narcolepsy until November 2019.

#### **Full Year 2020 Financial Results**

For the twelve-month period ended December 31, 2020, net product revenue grew to \$159.7 million, compared to \$6.0 million during the same twelve-month period in 2019. The increase was primarily due to growing sales of WAKIX following the drug's initial FDA approval in November 2019 as a treatment for EDS in adult patients with narcolepsy and the label expansion in October 2020 to include cataplexy in adult patients with narcolepsy.

For the twelve-month period ended December 31, 2020, total operating expenses were \$115.0 million compared to \$150.3 million for the same twelve-month period in 2019. The decrease was primarily driven by a decrease in R&D expenses related to payment of a \$50 million milestone to Bioprojet, partially offset by an increase in sales and marketing and general and administrative expenses related to the commercial launch of WAKIX.

For the twelve-month period ended December 31, 2020, Harmony reported a net loss of \$36.9 million, or \$2.48 per diluted share on a GAAP basis. For the same period, non-GAAP adjusted

net income was \$32.5 million, and after deducting \$26.9 million of accumulation of yield on preferred stock, non-GAAP adjusted net income available to common stockholders was \$5.5 million, or \$0.21 per diluted share. Reconciliations of applicable GAAP measures to non-GAAP adjusted information are included at the end of this press release.

As of December 31, 2020, Harmony had cash and cash equivalents of \$228.6 million compared to \$24.5 million for the same period in 2019.

## **2020 Select Business Highlights**

### **Initial Public Offering**

On August 21, 2020, Harmony completed an upsized initial public offering of 6.15 million primary shares of common stock at \$24.00 per share, which began trading on the Nasdaq Global Market under the ticker symbol “HRMY”. The gross proceeds, before deducting any discounts, commissions or expenses, were \$147.6 million. Goldman Sachs, Jefferies and Piper Sandler managed the deal.

### **FDA Approved New Indication for WAKIX**

On October 13, 2020, the FDA approved WAKIX for the treatment of cataplexy in adult patients with narcolepsy. This approval expands the label for WAKIX and broadens its clinical utility for healthcare professionals managing adult patients living with narcolepsy. In August 2019, the FDA approved WAKIX as the first treatment for EDS associated with narcolepsy that is not scheduled as a controlled substance by the U.S. Drug Enforcement Administration.

### **Advances in WAKIX Clinical Programs**

On December 15, 2020 Harmony enrolled the first patient in a Phase 2 randomized, double-blind, placebo-controlled trial for EDS in patients with PWS, a rare genetic condition. The trial is designed to evaluate the safety and efficacy of WAKIX for EDS and other symptoms (behavioral, cognitive dysfunction) in patients with PWS. Harmony expects to report top-line results in first half of 2022.

In December 2020, Harmony submitted an Investigational New Drug (IND) application to the FDA to evaluate pitolisant in patients with myotonic dystrophy (DM). The IND opened in January 2021 and Harmony is on-track to initiate a Phase 2 trial in patients with DM the first half of 2021.

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

We are hosting our fourth quarter and full-year 2020 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 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 5049024. A replay will be accessible until April 1, 2021 by dialing (855) 859-2056 (domestic) or +1 (404) 537-3406 (international).

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## **Non-GAAP Financial Measures**

In addition to our GAAP results, we provide certain non-GAAP metrics including adjusted net income and adjusted net income per share. We believe that the presentation of these measures 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 on-going 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 are not meant to 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 its non-GAAP financial measures; and we may in the future cease to exclude items that it has historically excluded for purposes of its 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. WAKIX is a selective histamine 3 (H<sub>3</sub>) receptor antagonist/inverse agonist. The mechanism of action of WAKIX is unclear; however its efficacy could be mediated through its activity at H<sub>3</sub> receptors, thereby increasing the synthesis and release of histamine, a wake promoting neurotransmitter. WAKIX was designed and developed by Bioprojet Société Civile de Recherche (Bioprojet). 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.

## **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.



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## 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 (35% and twice placebo) for WAKIX were insomnia (6%), nausea (6%), and anxiety (5%). Other adverse reactions that occurred at 32% 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 FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### **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 Biosciences, please visit the company's website: [www.harmonybiosciences.com](http://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; 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; and 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; 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 March 25, 2021, 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.**  
**CONSOLIDATED**  
**STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(In thousands except share and per share data)  
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Net product revenues	\$ 56,288	\$ 5,995	\$ 159,742	\$ 5,995
Cost of product sold	9,918	1,577	27,738	1,577
Gross profit	46,370	4,418	132,004	4,418
Operating expenses:				
Research and development	7,618	5,276	19,448	69,595
Sales and marketing	17,526	16,841	55,824	44,318
General and administrative	13,466	15,995	39,746	36,409
Total operating expenses	38,610	38,112	115,018	150,322
Operating income (loss)	7,760	(33,694)	16,986	(145,904)
Loss on debt extinguishment	—	—	(22,639)	—
Other expense, net	—	—	(3,071)	—
Interest expense, net	(7,966)	(2,747)	(28,220)	(6,073)
Loss before income taxes	(206)	(36,441)	(36,944)	(151,977)
Income taxes	—	—	—	—
Net loss and comprehensive loss	\$ (206)	\$ (36,441)	\$ (36,944)	\$ (151,977)
Accumulation of dividends on preferred stock	—	(9,575)	(26,904)	(35,231)
Net loss available to common stockholders	\$ (206)	\$ (46,016)	\$ (63,848)	\$ (187,208)
NET LOSS PER SHARE:				
Basic	\$ (0.00)	\$ (5.92)	\$ (2.48)	\$ (24.07)
Diluted	\$ (0.00)	\$ (5.92)	\$ (2.48)	\$ (24.07)
Weighted average number of shares of common stock - basic	56,889,460	7,778,453	25,772,419	7,777,441
Weighted average number of shares of common stock - diluted	56,889,460	7,778,453	25,772,419	7,777,441

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

	December 31, 2020	December 31, 2019
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 228,631	\$ 24,457
Trade receivables, net	22,176	4,255
Inventory, net	3,823	1,088
Prepaid expenses	6,959	1,436
Other current assets	1,302	261
Total current assets	<u>262,891</u>	<u>31,497</u>
<b>NONCURRENT ASSETS:</b>		
Property and equipment, net	938	1,330
Restricted cash	750	750
Intangible asset, net	162,343	72,185
Other noncurrent assets	152	941
Total noncurrent assets	<u>164,183</u>	<u>75,206</u>
<b>TOTAL ASSETS</b>	<u>\$ 427,074</u>	<u>\$ 106,703</u>
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
<b>CURRENT LIABILITIES:</b>		
Trade payables	\$ 2,556	\$ 6,360
Accrued compensation	8,942	7,917
Accrued expenses	122,727	5,500
Other current liabilities	314	115
Total current liabilities	<u>134,539</u>	<u>19,892</u>
<b>NONCURRENT LIABILITIES:</b>		
Deferred rent	212	287
Long term debt, net	194,250	97,946
Other noncurrent liabilities	893	163
Total noncurrent liabilities	<u>195,355</u>	<u>98,396</u>
<b>TOTAL LIABILITIES</b>	<u>329,894</u>	<u>118,288</u>
<b>COMMITMENTS AND CONTINGENCIES (Note 9)</b>		
<b>CONVERTIBLE PREFERRED STOCK</b>		
Convertible preferred stock, net of placement costs		
Series A convertible preferred stock - \$1.00 stated value; 0 shares and 286,000,000 shares authorized at December 31, 2020 and 2019, respectively; 0 shares and 285,000,000 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	348,203
Series B convertible preferred stock - \$1.25 stated value; 0 shares and 8,030,000 shares authorized at December 31, 2020 and 2019, respectively; 0 shares and 8,000,000 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	12,023
Series C convertible preferred stock - \$1.96 stated value; 0 shares and 25,600,000 shares authorized at December 31, 2020 and 2019, respectively; 0 shares and 25,510,205 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	51,051
<b>STOCKHOLDERS' EQUITY (DEFICIT):</b>		
Preferred stock - \$0.00001 par value; 10,000,000 shares and 0 shares authorized at December 31, 2020 and 2019, respectively; 0 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	—
Common stock—\$0.00001 par value; 500,000,000 shares and 423,630,000 shares authorized at December 31, 2020 and 2019, respectively; 56,890,569 shares and 7,787,470 issued and outstanding at December 31, 2020 and 2019, respectively	1	—
Additional paid in capital	585,374	—
Accumulated deficit	<u>(488,195)</u>	<u>(422,862)</u>
<b>TOTAL STOCKHOLDERS' EQUITY (DEFICIT)</b>	<u>97,180</u>	<u>(422,862)</u>
<b>TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)</b>	<u>\$ 427,074</u>	<u>\$ 106,703</u>

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
<b>GAAP reported loss</b>	\$ (207)	\$ (36,439)	\$ (36,944)	\$ (151,977)
Non-GAAP adjustments:				
Interest expense	7,967	2,747	28,220	6,073
Taxes	—	—	—	—
Depreciation	100	95	394	395
Amortization	4,283	1,850	9,843	2,815
<b>EBITDA</b>	12,143	(31,747)	1,513	(142,694)
Additional non-GAAP adjustments:				
Stock-based compensation expense	2,924	8,805	5,190	9,909
Loss on debt extinguishment	—	—	22,639	—
Warrant expense	—	—	3,109	—
Non-GAAP adjusted net income (loss)	15,067	(22,942)	32,451	(132,785)
Accumulation of dividends on preferred stock	—	(9,575)	(26,904)	(35,231)
Non-GAAP net income (loss) available to common stockholders	\$ 15,067	\$ (32,517)	\$ 5,547	\$ (168,016)
<b>GAAP reported net loss per diluted share</b>	<b>\$ (0.00)</b>	<b>\$ (5.92)</b>	<b>\$ (2.48)</b>	<b>\$ (24.07)</b>
Non-GAAP adjusted net income (loss) per diluted share	\$ 0.25	\$ (4.18)	\$ 0.21	\$ (21.60)
Weighted average number of shares of common stock used in non-GAAP diluted per share	59,128,981	7,778,453	26,982,978	7,777,441

**Harmony Biosciences Investor Contact:**

Lisa Caperelli  
610-608-0215  
[lcaperelli@harmonybiosciences.com](mailto:lcaperelli@harmonybiosciences.com)

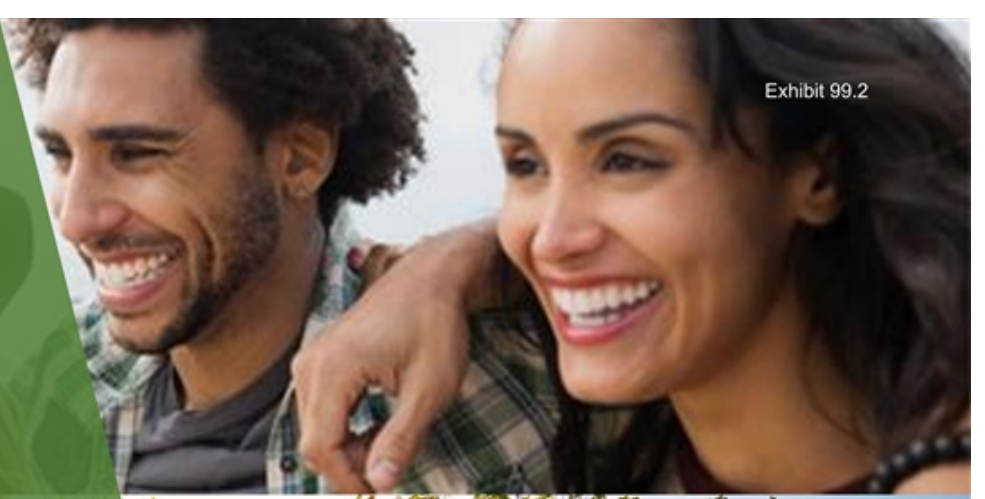
**Harmony Biosciences Media Contact:**

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# Harmony Biosciences Q4 & FY 2020 Financial and Business Update

March 25, 2021





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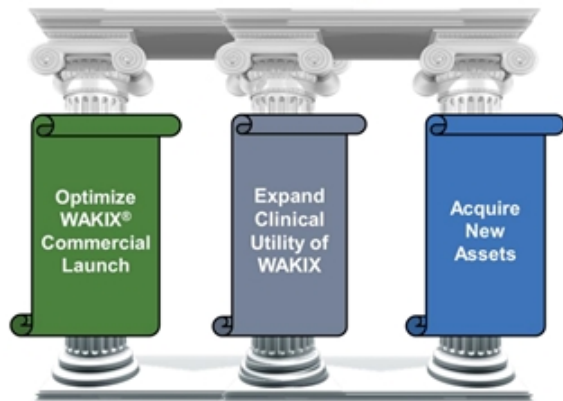
This presentation includes information related to market opportunity as well as cost and other estimates obtained from internal analyses and external sources. The internal analyses are based upon management's understanding of market and industry conditions and have not been verified by independent sources.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



- Commercial-stage US Pharma company focused on treatments for patients living with rare, neurological disorders who have unmet medical needs
- Opportunity to expand existing \$2B narcolepsy market with WAKIX® (pitolisant)
  - First-in-class molecule with a novel mechanism of action (MOA)
  - Approved for treatment of EDS and cataplexy in adult patients with narcolepsy
  - Only FDA-approved non-scheduled treatment option for narcolepsy
  - Differentiated product profile
  - Convenient, once-daily dosing
  - \$160M net revenues in 2020
- WAKIX Life Cycle Management opportunities
  - *Portfolio-in-a-product* opportunity with pitolisant
  - Novel MOA supports mechanism-based approach to LCM drug development
  - New indications being pursued in additional rare neurological disease patient populations
- Strong financial position



## Harmony's Three Pillars of Growth Strategy



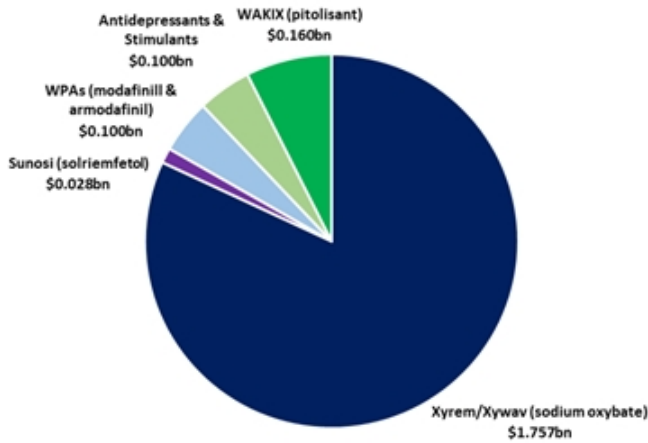
## 2020 Achievements

- ✓ Raised \$147M in IPO
- ✓ Added to Russell 2000 and 3000 Indices
- ✓ WAKIX generated \$160M in first full year of sales
- ✓ Received FDA approval for cataplexy indication
- ✓ Enrolled first patient in Phase 2 trial in patients with Prader-Willi Syndrome
- ✓ Submitted IND for Myotonic Dystrophy development program
- ✓ Data presentations at medical conferences

# Significant Adult Narcolepsy Market Value Opportunity

**~\$2.1B**

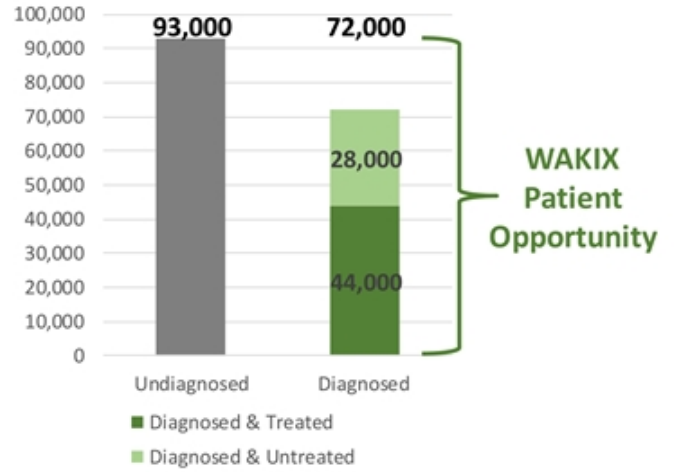
Net Sales



U.S. Narcolepsy Market (2020)

**165,000**

People Living With Narcolepsy in the U.S.



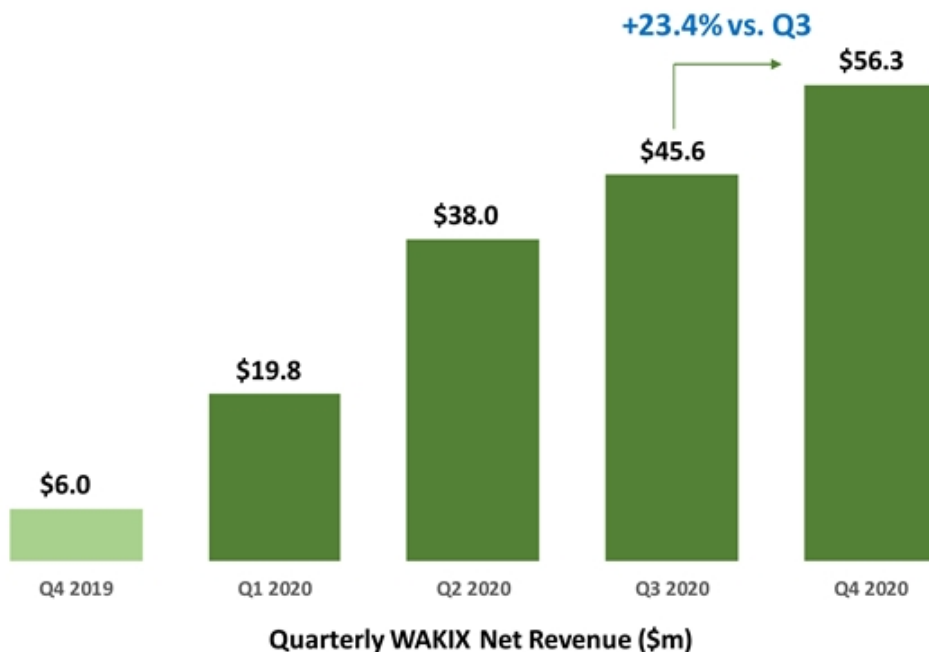
## Factors contributing to market growth

- Growth in diagnosis rates in recent years
- Increased investment in education
- Introduction of new entries
- Low satisfaction with traditional treatment options

# 2020 WAKIX Revenue Performance



Continued Growth with Q4 Revenue of \$56.3M



# Driving Growth Through Our Launch For WAKIX Q4 2020 Performance



**~2,500**  
Average # of  
WAKIX Patients



Expanded Virtual  
Engagement Programs



Healthcare Professional  
Educational Initiatives

**>2,400** Unique HCP Prescribers  
Since Launch



Managed Care  
Educational & Outreach

**~80%** U.S. Covered Lives With Formulary Access



# Multiple Opportunities for Pitolisant



Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Regulatory Filing <sup>1</sup>	Marketed Product	Upcoming Milestones
<b>APPROVED INDICATIONS</b>							
EDS in Adult Patients with Narcolepsy	[Green arrow spanning Pre-IND to Phase 3]						
Cataplexy in Adult Patients with Narcolepsy	[Green arrow spanning Pre-IND to Phase 3]						
<b>LABEL EXPANSION IN NARCOLEPSY</b>							
Pediatric Narcolepsy <sup>2</sup>	[Light green arrow spanning Pre-IND to Phase 2]						Initiation of Phase 3 trial 2H2021; top line data 1H2023
<b>NEW INDICATIONS</b>							
Prader-Willi Syndrome (PWS)	[Blue arrow spanning Pre-IND to Phase 2]						Top line data 1H2022
Myotonic Dystrophy	[Blue arrow spanning Pre-IND to Phase 1]						Initiation of Phase 2 trial 1H2021; top line data 2H2022

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

2. Current trial being conducted by Bioprojet. We plan to initiate a Phase 3 clinical trial in 2H2021 in pursuit of pediatric indications for both EDS and cataplexy as well as pediatric exclusivity.

# Prader-Willi Syndrome (PWS)



Rare, genetic multi-system disease characterized by hypothalamic dysfunction; decreased hypocretin levels in some patients<sup>1,2</sup>



~15,000-20,000 patients in U.S. and more than 50% have Excessive Daytime Sleepiness (EDS) due to sleep-wake state instability of central origin and other factors<sup>1</sup>



Other symptoms include behavioral issues and cognitive impairment which could be related to, or exacerbated by, EDS



No approved treatments for EDS in patients with PWS and significant unmet medical need



Phase 2 clinical trial initiated in 2020; top-line results anticipated in 1H 2022



## A disorder of hypothalamic dysfunction<sup>1,2</sup>

- Abnormalities have been found in the hypothalamus in patients with PWS
- Many of the features of PWS are the result of hypothalamic dysfunction (growth hormone deficiency, hypogonadism, hyperphagia, sleep-wake abnormalities)



## The hypothalamus regulates sleep-wake state stability via hypocretin and histamine<sup>3,4,5</sup>

- Decreased levels of hypocretin have been found in patients with PWS<sup>6,7</sup>
- Mouse models of PWS (MAGEL2 & SNORD116) have demonstrated impaired hypocretin systems and sleep-wake state instability<sup>8,9,10</sup>



## Pitolisant increases histamine levels in the brain and has demonstrated significant improvement in EDS in adult patients with narcolepsy

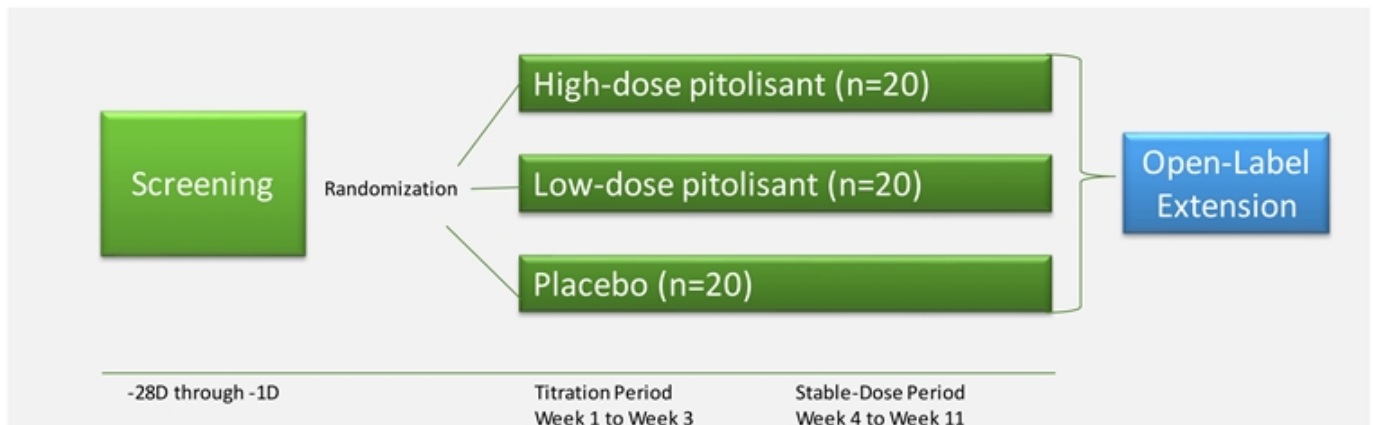


## Studies have suggested potential role of histamine and benefit of pitolisant in attention, vigilance, and cognitive function<sup>11,12</sup>

- Preliminary evidence from both animal and human studies
- Further studies are needed in patients with PWS



# Phase 2 Clinical Trial of Pitolisant in Patients with PWS: Trial Design



## **Trial Design:**

- Randomized, double-blind, placebo-controlled, parallel-group followed by open-label extension
- ~60 – 70 patients; ages 6 – 65
- Randomized-Controlled Phase
  - 11-week treatment period: 3-week titration period followed by 8-weeks of stable dosing
- Open-label extension planned to run throughout development program



**Primary Objective:** To evaluate the safety and efficacy of pitolisant compared to placebo in treating EDS in patients with PWS



**Secondary Objectives - Impact of pitolisant on:**

- Caregiver assessment of severity based on EDS
- Clinician assessment of severity based on overall PWS symptoms
- Behavioral assessments
- Cognitive function
- Caregiver burden
- Long-term safety and effectiveness



**Exploratory Objectives – Impact of pitolisant on:**

- ESS-CHAD as rated by caregivers
- Hyperphagia as measured by the HQCT
- Ghrelin levels

# Myotonic Dystrophy (DM)



Rare, genetic multi-system disease; myotonia and progressive muscle weakness hallmark symptoms; EDS most common non-muscular symptom (~80% - 90% of patients)<sup>1,2</sup>



Two forms: DM1 (~140,000 US patients) more common than DM2 (~3,000 - 29,000 US patients); earlier onset and more severe symptoms in DM1 patients compared to DM2<sup>1,2</sup>



EDS and fatigue second only to muscle weakness in symptom prevalence and impact; impaired cognitive function another prominent symptom; decreased hypocretin levels in some patients<sup>1,2</sup>



No approved treatments and significant unmet medical need



IND open; on-track to initiate Phase 2 clinical trial in 1H 2021

## FY 2020 Financial Summary *(in millions, USD)*



	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
<b>Net Product Revenues</b>	\$ 56.3	\$ 6.0	\$ 159.7	\$ 6.0
<b>Total Operating Expenses</b>	\$ 38.6	\$ 38.1	\$ 115.0	\$ 150.3
R&D Expense	7.6	5.3	19.4	69.6
S&M Expense	17.5	16.8	55.8	44.3
G&A Expense	13.5	16.0	39.7	36.4
<b>Net Income (Loss)</b>	\$ (0.2)	\$ (36.4)	\$ (36.9)	\$ (152.0)
<b>Cash &amp; cash equivalents</b>			\$ 228.6	

Totals may not foot due to rounding

## GAAP vs Non-GAAP Reconciliation *(in millions, USD)*



	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
<b>GAAP reported net loss</b>	<b>\$ (0.2)</b>	<b>\$ (36.4)</b>	<b>\$ (36.9)</b>	<b>\$ (152.0)</b>
Interest expense / income	8.0	2.7	28.2	6.1
Taxes				
Depreciation	0.1	0.1	0.4	0.4
Amortization	4.3	1.9	9.8	2.8
EBITDA	12.1	(31.7)	1.5	(142.7)
Stock-based compensation expense	2.9	8.8	5.2	9.9
Loss on debt extinguishment			22.6	
Warrant expense			3.1	
Non-GAAP adjusted net income (loss)	15.1	(22.9)	32.5	(132.8)
Accumulation of yield on preferred stock		(9.6)	(26.9)	(35.2)
Non-GAAP adjusted net income (loss) available to common stockholders	\$ 15.1	\$ (32.5)	\$ 5.5	\$ (168.0)
<b>GAAP reported net loss per diluted share</b>	<b>\$ (0.00)</b>	<b>\$ (5.92)</b>	<b>\$ (2.48)</b>	<b>\$ (24.07)</b>
Non-GAAP adjusted net income (loss) per diluted share	\$ 0.25	\$ (4.18)	\$ 0.21	\$ (21.60)
<b>Weighted average number of shares of common stock used in non-GAAP diluted per share</b>	<b>59,128,981</b>	<b>7,778,453</b>	<b>26,982,978</b>	<b>7,777,441</b>

Totals may not foot due to rounding







Thank You



March 25, 2021