# HARMONY BIOSCIENCES



November 9, 2021



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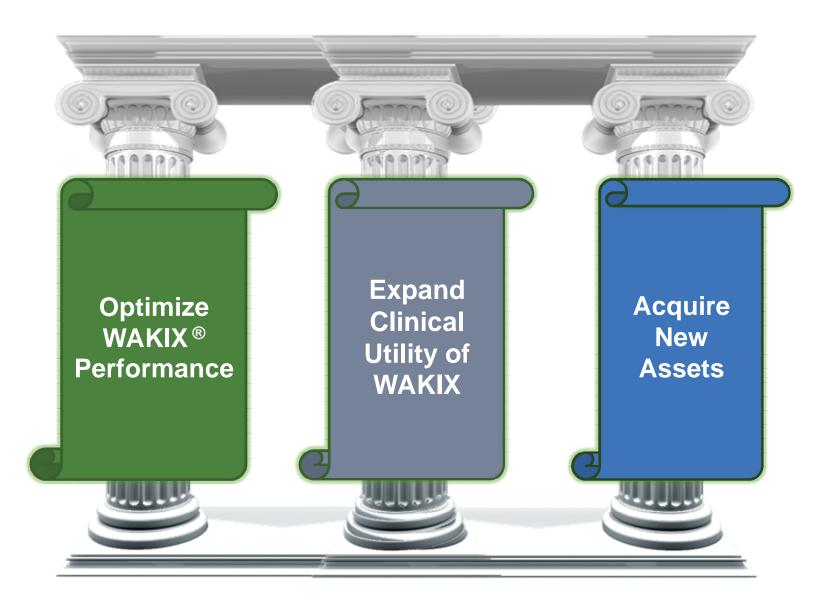
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## Harmony's Strategy for Growth







## Q3 2021 WAKIX Revenue Performance



### Continued Growth with Q3 Revenue of \$80.7M





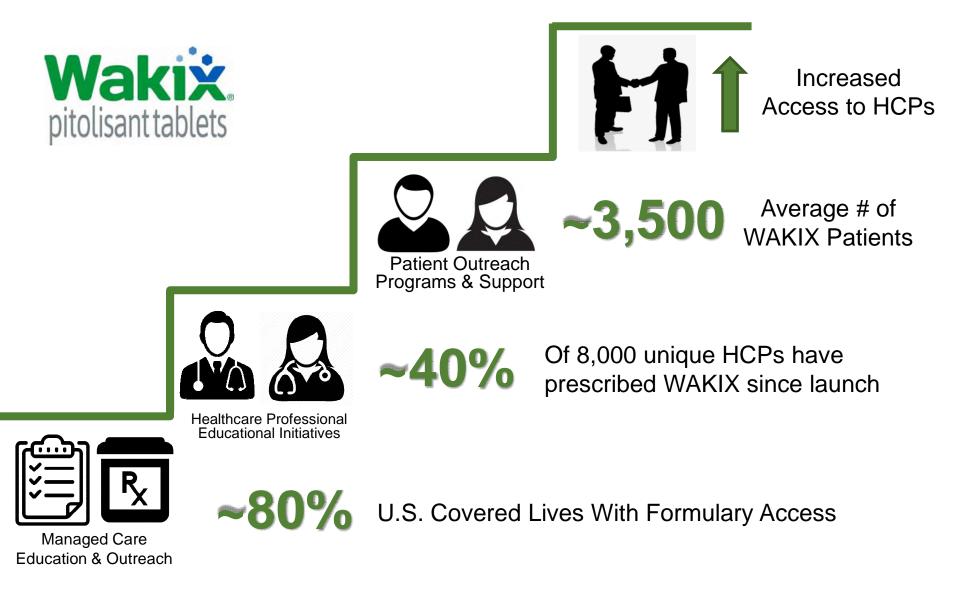
### **Strong Revenue Growth in Q3 2021**

- 9.4% growth Q3 2021 vs. Q2 2021
- 77% growth Q3 2021 vs. Q3 2020
- Continued sequential quarter over quarter growth from launch



## Driving Growth Through Our Launch For WAKIX Q3 2021 Performance

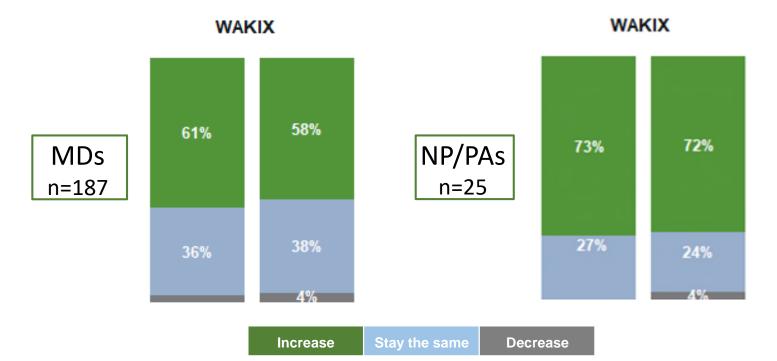






# The Majority of HCPs (MDs & NP/PAs) Stated They Expect to Increase Future Use of WAKIX<sup>®</sup> in Both Type 1 & Type 2 Patients





Top Reasons For Increasing Future Use of WAKIX					
To minimize use of stimulants	61%				
Impact on EDS (Excessive Daytime Sleepiness) or improved alertness	58%				
Non-scheduled treatment (not a controlled substance)	51%				
Impact on cataplexy	48%				
Novel mechanism of action	47%				

Source: Harmony Market Research (total n=212); Q: MD-Type 1=172 respondents, Type 2=177 respondents; NP/PA=22 respondents, July 2021



# AASM Treatment Guideline on Central Disorders of Hypersomnolence



**Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline** Kiran Maski, MD, MPH; Lynn Marie Trotti MD, MSc; Suresh Kotagal, MD; Robert R Auger MD; James A Rowley MD; Sarah D Hashmi, MBBS, MSc, MPH; Nathaniel F Watson, MD, MSc

#### Table 2—Summary of recommended interventions in adult populations.

Intervention	Strength of Decommondation	Critical Outcomes Showing Clinically Significant Improvement*					
	Strength of Recommendation	Excessive Daytime Sleepiness Cataplex		Disease Severity	Quality of Life		
Narcolepsy							
Modafinil	Strong	1		~	<		
Pitolisant	Strong	1	~	~			
Sodium Oxybate	Strong	1	~	~			
Solriamfetol	Strong	1		~	<		
Armodafinil	Conditional	1		1			
Dextroamphetamine	Conditional	1	~				
Methylphenidate	Conditional			1			

\*Accident risk and work/school performance/attendance were critical outcomes; however, no data were available. V Critical outcomes showing clinically significant improvement.

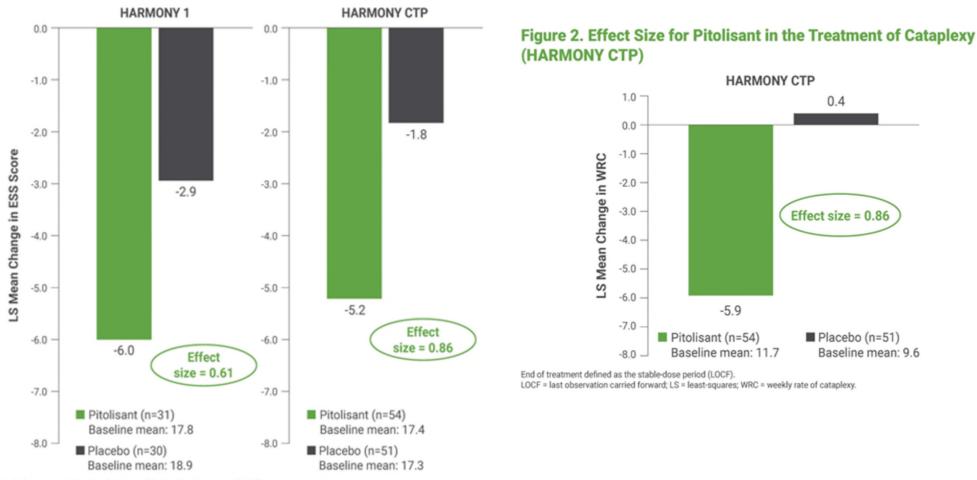
Adapted from: Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2021;17(9):1881–1893. https://doi.org/10.5664/jcsm.9328.\_Copyright American Academy of Sleep Medicine. Reproduced with permission.



## **New Data for WAKIX Presented at SLEEP 2021**



#### Figure 1. Effect Size for Pitolisant in the Treatment of Excessive Daytime Sleepiness (HARMONY 1, HARMONY CTP)



End of treatment defined as the mean of the last 2 assessments (LOCF).

ESS = Epworth Sleepiness Scale; LOCF = last observation carried forward; LS = least-squares.

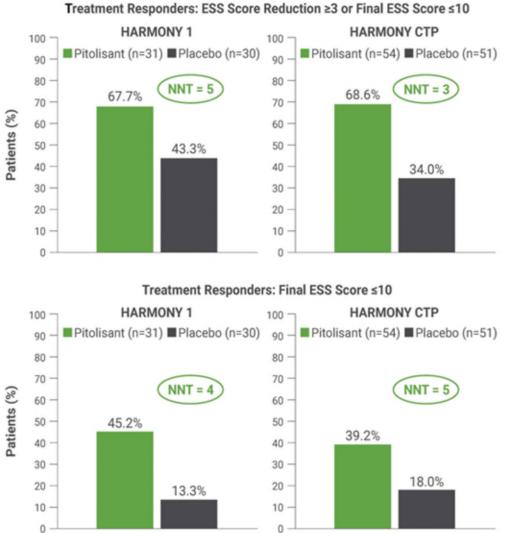


Assessment of the Clinical Impact of Pitolisant on Excessive Daytime Sleepiness and Cataplexy in Adults with Narcolepsy. Meskill GM et al. Poster presentation at SLEEP, June 10 – 13, 2021.

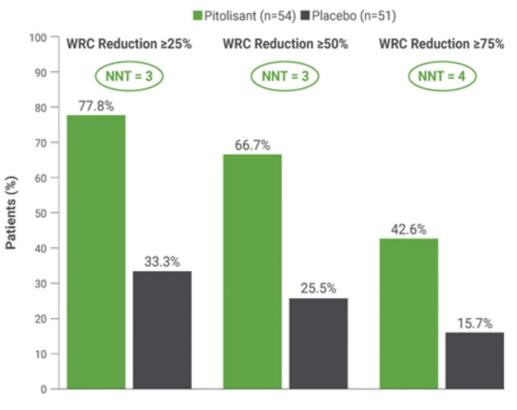
## New Data for WAKIX Presented at SLEEP 2021



#### Figure 3. NNT for Pitolisant in the Treatment of Excessive Daytime Sleepiness (HARMONY 1, HARMONY CTP)



## Figure 4. NNT for Pitolisant in the Treatment of Cataplexy (HARMONY CTP)



Baseline mean WRC: pitolisant, 11.7; placebo, 9.6. NNT = number needed to treat; WRC = weekly rate of cataplexy.

Baseline mean ESS scores in HARMONY 1: pitolisant, 17.8; placebo, 18.9 and HARMONY CTP: pitolisant, 17.4; placebo, 17.3. ESS = Epworth Sleepiness Scale.



Assessment of the Clinical Impact of Pitolisant on Excessive Daytime Sleepiness and Cataplexy in Adults with Narcolepsy. Meskill GM et al. Poster presentation at SLEEP, June 10 - 13, 2021.

## **Harmony Pipeline**



Product / Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Regulatory Filing <sup>1</sup>	Marketed Product	Upcoming Milestones
<b>WAKIX</b> ®							
EDS in Narcolepsy (Adults)							
Cataplexy in Narcolepsy (Adults)							
Pitolisant							
Narcolepsy (Pediatrics) <sup>2</sup>							
Prader-Willi Syndrome (PWS)							Top line data 1H2022
Myotonic Dystrophy (DM)							Top line data 2H2O22
HBS-102							
Other Neurological Diseases							

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

2. Current trial being conducted by Bioprojet.





### **Historical Financials**







	Three Months Ended September 30,				
		2021	2020		
Net Product Revenues	\$	80.7	\$	45.6	
Cost of Product Sold		14.6		7.9	
Total Operating Expenses	\$	45.1	\$	27.3	
R&D Expense		11.7		4.2	
S&M Expense		16.5		12.6	
G&A Expense		16.9		10.5	
Net (Loss) Income	\$	(9.6)	\$	1.9	
Cash & cash equivalents	\$	189.7			



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



	Three Months Ended September,			
		2021	2020	
GAAP reported net (loss) income	\$	(9.6)	\$	1.9
Interest expense / income		5.4		6.9
Taxes		(0.9)		
Depreciation		0.1		0.1
Amortization		4.6		1.9
EBITDA		(0.4)		10.8
Stock-based compensation expense		4.7		1.3
Loss on debt extinguishment		26.1		
Warrant expense				1.5
Non-GAAP adjusted net income		30.4		13.7
Accumulation of yield on preferred stock				(6.0)
Non-GAAP adjusted net income (loss) available to common stockholders	\$	30.4	\$	7.7
GAAP reported net loss per diluted share	\$	(0.17)	\$	(0.14)
Non-GAAP adjusted net income per diluted share	\$	0.51	\$	0.25
Weighted average number of shares of common stock used in non-GAAP diluted per share	59,270,603 30,212,959		0,212,959	

Totals may not foot due to rounding

