## HARMONY BIOSCIENCES



August 10, 2021



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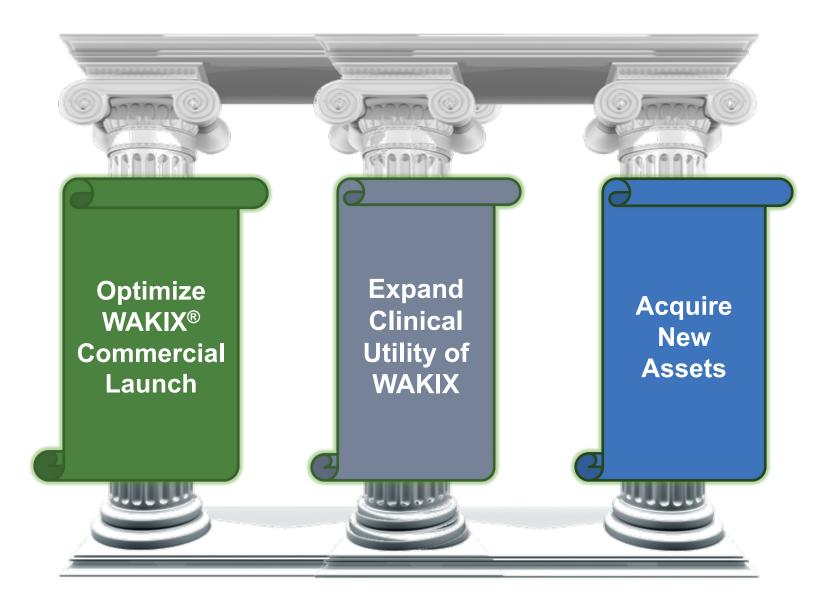
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#### Harmony's Strategy for Growth



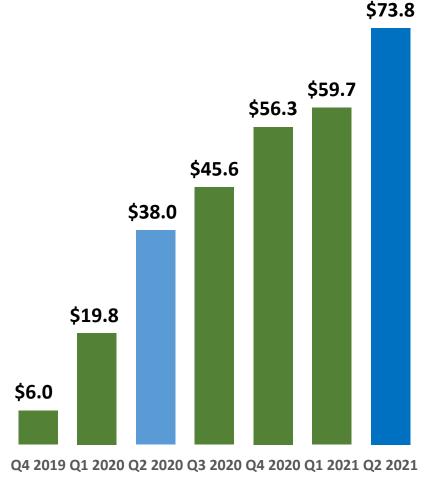




## **Q2 2021 WAKIX Revenue Performance**



#### Continued Growth with Q2 Revenue of \$73.8M



#### WAKIX Net Revenue (\$m)



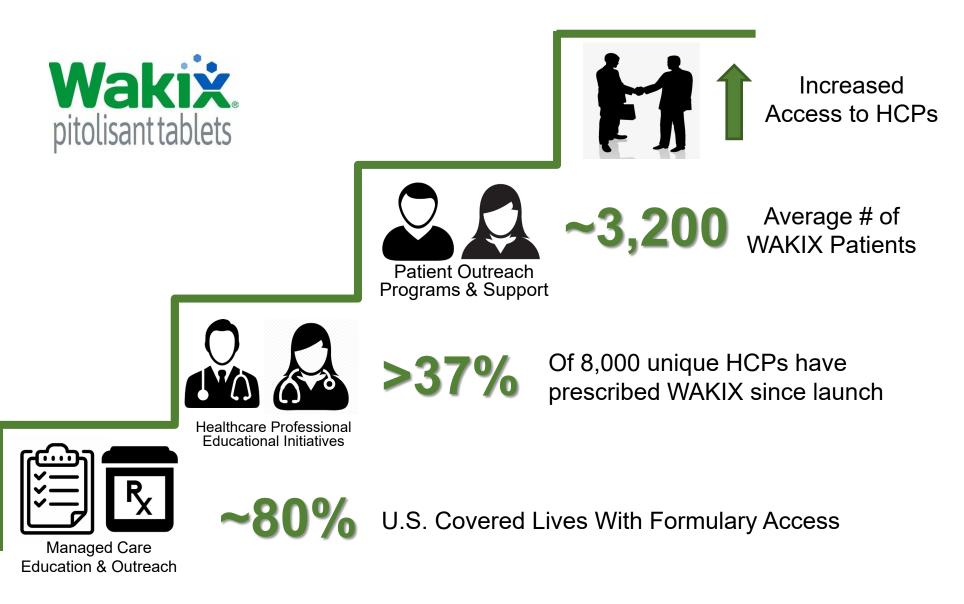
2Q20	1Q21	2Q21	2Q21 vs. 1Q21	2Q21 vs. 2Q20	
\$38.0	\$59.7	\$73.8	23.6%	94%	

#### Strong Revenue Growth in Q2 2021

- 23.6% growth Q2 2021 vs. Q1 2021
- Over 90% growth Q2 2021 vs. Q2 2020
- Continued sequential quarter over quarter growth from launch

#### Driving Growth Through Our Launch For WAKIX Q2 2021 Performance







#### **Core Attributes of WAKIX Product Profile Align with Existing Unmet Needs in Narcolepsy**



## Top Unmet Needs in Narcolepsy (cited by patients and HCPs)

Need for non-scheduled treatment options (low/no abuse potential)

Need for more tolerable treatment regimens

Need for more effective treatment options

Novel MOAs beyond currently available therapies needed

Need for less frequently dosed products; need for once-daily options

#### WAKIX (pitolisant)\*

First and only FDA approved non-scheduled treatment option for narcolepsy

Established Safety Profile No Boxed Warning, no REMS Program

Statistically significant reduction in EDS and cataplexy demonstrated in two Phase III trials

First-in-class molecule with a novel MOA; H<sub>3</sub>R antagonist/inverse agonist; works through histamine

Convenient, once daily dosing in the morning upon wakening

\* Based on FDA approved product labeling

Source: Harmony ATU, July 2018 (n=286); Versta Research, Know Narcolepsy Survey ("Know Narcolepsy"), October 2018



## **Harmony Development Pipeline**





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

2. Current trial being conducted by Bioprojet.

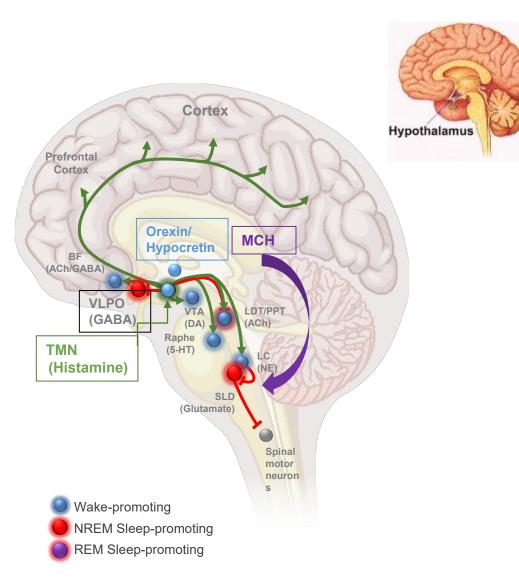
3. Phase 1 PK data available from studies conducted in the UK.



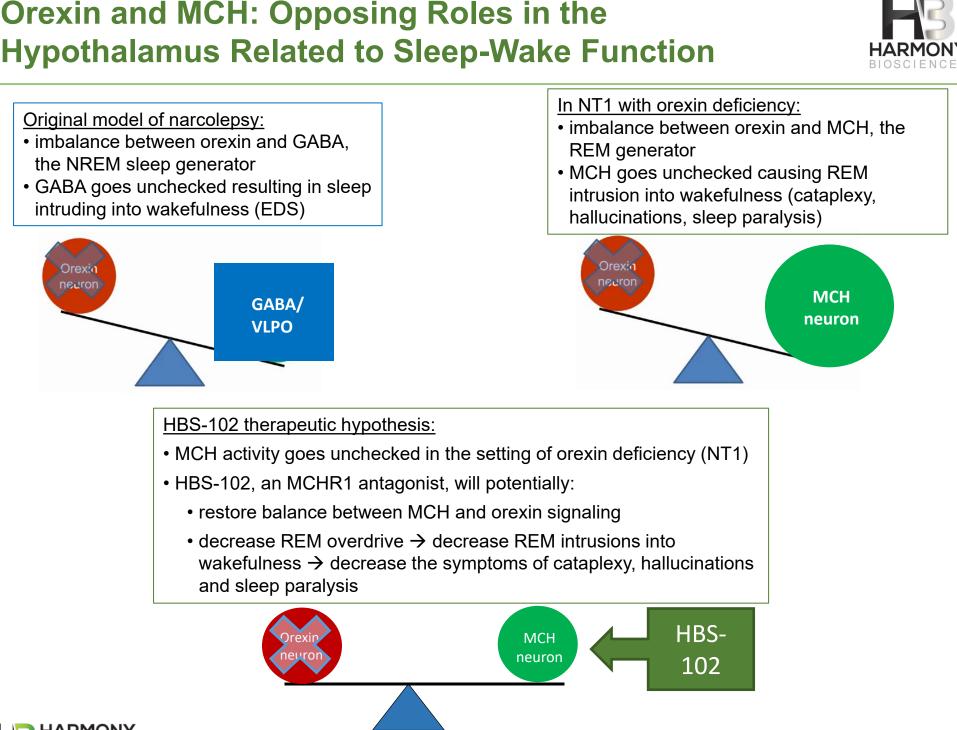
#### **Control Centers for Sleep-Wake Centered in the Hypothalamus (HT)**



- Main mediators of wakefulness and sleep/wake state stability:
  - orexin/hypocretin (produced in the lateral HT)
  - histamine (produced in the TMN, also located in the HT)
- Main driver of NREM sleep:
  - GABA (produced in the VLPO in the HT)
- Main generator of REM sleep:
  - Melanin concentration hormone (MCH) (produced in a diffuse network of neurons in the lateral HT interspersed amongst the orexin neurons)









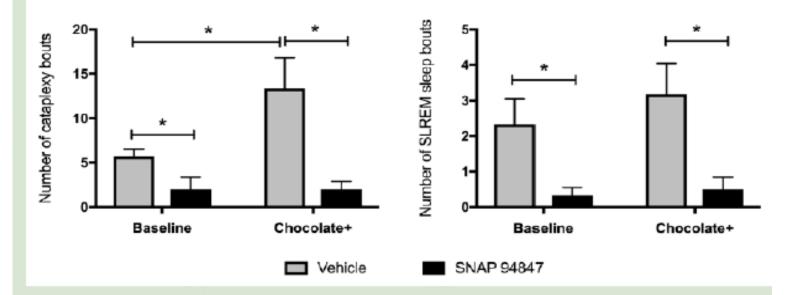
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#### **Pre-clinical POC for MCHR1 Antagonism**



#### **Preclinical Evidences**

 MCHR-1 antagonist, SNAP 94847, almost completely eliminated cataplexy & SLREM in orexin KO mice<sup>1</sup>, a translational cataplexy model.



 MCH neuron activity positively correlated with the number of cataplexy bouts in orexin KO mice<sup>2</sup>

SLREM: short latency transitions into REM sleep (a feature of NT1)





### **HBS-102: Next Steps**



- Demonstrate preclinical POC with HBS-102 in orexin knockout mouse model
- Prepare IND then submit to FDA
- Initiate Phase 2a proof of concept study once IND opens

# Become a leading rare neurological disease company with an innovative product portfolio

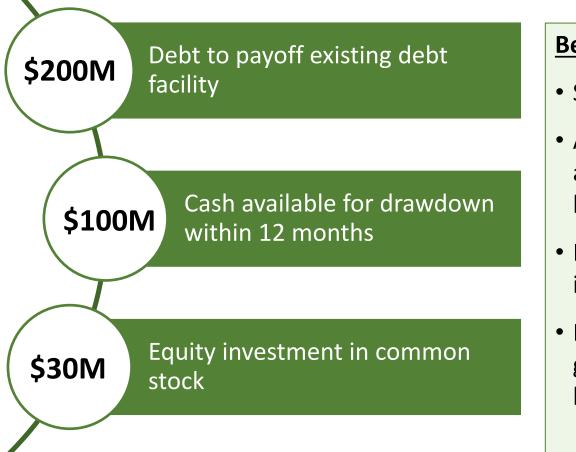
Committed to advancing breakthrough science and addressing unmet medical needs



## **Strategic Financing Collaboration** Blackstone



\$330M of financing and growth capital from Blackstone enables Harmony to expand portfolio of assets in rare, neurological diseases



#### **Benefits to Harmony**

- Strengthens balance sheet
- Access to additional capital to acquire complementary assets to build our product pipeline
- Lower interest cost reduces annual interest expense by ~\$10M
- Equity investment from premier, global investment firm with leading life sciences capabilities





		Three Months Ended June 30,		
		2021		2020
Net Product Revenues	\$	73.8	\$	38.0
Cost of Product Sold		12.7		6.4
Total Operating Expenses		37.8	\$	24.2
R&D Expense		6.5		4.2
S&M Expense		17.0		12.4
G&A Expense		14.3		7.6
Net Income available to common stockholders (Loss)		14.1	\$	(10.5)
Cash & cash equivalents		159.7		

Totals may not foot due to rounding



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



	Three Months Ended June 30,			ded	
		2021		2020	
GAAP reported net income (loss)		14.1	\$	(0)	
Interest expense / income		7.2		6.9	
Taxes		2.0			
Depreciation		0.1		0.1	
Amortization		4.6		1.9	
EBITDA		28.0		8.9	
Stock-based compensation expense		3.8		0.6	
Loss on debt extinguishment					
Warrant expense				0.4	
Non-GAAP adjusted net income (loss)		31.9		9.9	
Accumulation of yield on preferred stock				(10.4)	
Non-GAAP adjusted net income (loss) available to common stockholders		31.9	\$	(0.5)	
GAAP reported net loss per diluted share		0.24	\$	(1.34)	
Non-GAAP adjusted net income (loss) per diluted share	\$	0.54	\$	(0.07)	
Weighted average number of shares of common stock used in non-GAAP diluted per share		58,592,876		7,805,848	

Totals may not foot due to rounding



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#### **Thank You**

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