HARMONY BIOSCIENCES



Harmony Biosciences Q3 2020 Financial and Business Update

November 12, 2020

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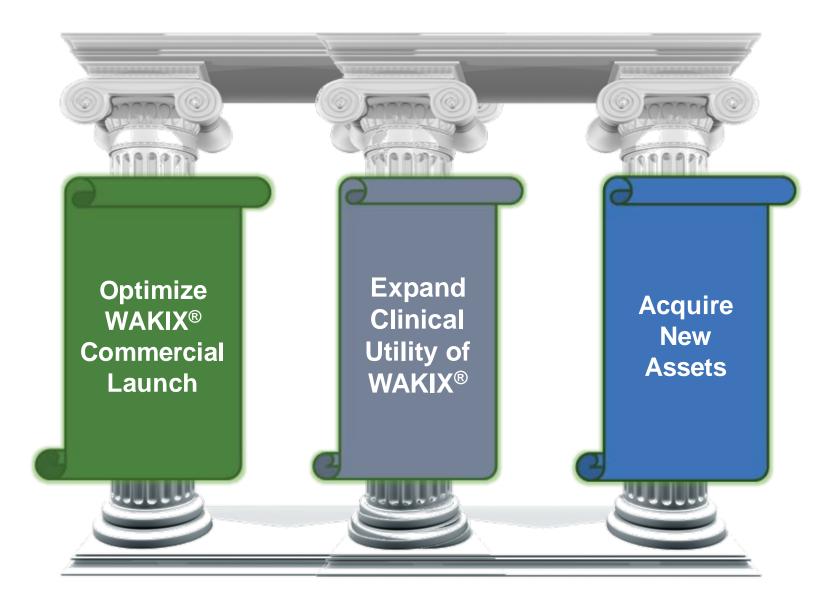
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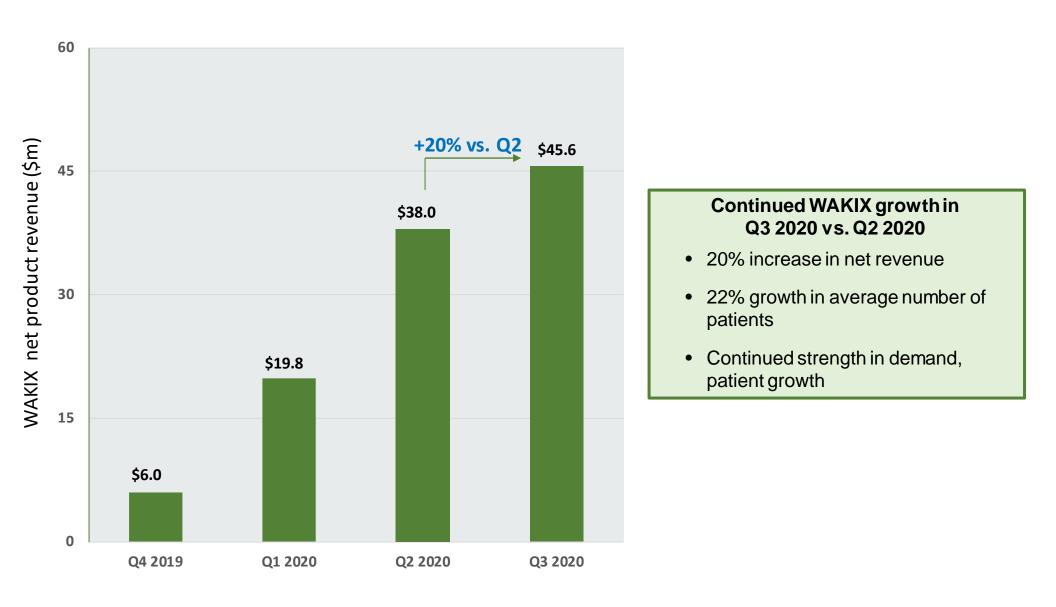
Harmony's Strategy for Growth







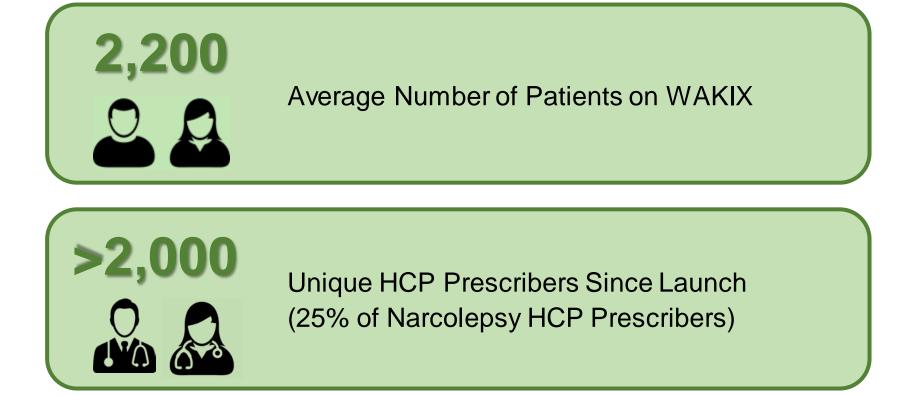
WAKIX[®] Net Product Revenue Q3 Net Product Revenue of \$45.6M, 20% Increase over Q2 2020





Q3 2020 WAKIX® Launch Performance Metrics







Targeted Account Lives Being Covered Positively (~182M Lives)



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_3R 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



Development Pipeline for Pitolisant



Indication	Pre-IND ¹	Phase 1	Phase 2	Phase 3	Regulatory Filing²	Marketed Product	Upcoming Milestones		
APPROVED INDICATIONS									
EDS in Adult Patients with Narcolepsy									
Cataplexy in Adult Patients with Narcolepsy									
LABEL EXPANSION IN NARCOLEPSY									
Pediatric Narcolepsy ³							Initiation of Phase 3 trial 2H2021; top line data 1H2023		
NEW INDICATIONS									
Prader-Willi Syndrome (PWS)							Initiation of Phase 2 trial 2H2020; top line data 1H2022		
Myotonic Dystrophy							Initiation of Phase 2 trial 1H2021; top line data 2H2022		

1. For each potential new indication, we do not anticipate being required to conduct additional preclinical studies or studies enabling an IND beyond those studies that are already included in the New Drug Application for WAKIX. Additional preclinical studies were not required to open the IND for PWS.

2. Includes New Drug Applications and supplemental New Drug Applications.

3. 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.



Current LCM Programs for Pitolisant: Scientific Rationale



Prader-Willi Syndrome

- Rare, genetic multi-system disease characterized by hypothalamic dysfunction; decreased hypocretin levels in some patients^{1,2}
- ~15-20,000 patients in US and more than 50% have EDS due to sleepwake state instability of central origin and other factors¹
- Primary endpoint is EDS; secondary outcomes: behavioral symptoms and cognitive function; exploratory endpoint in hyperphagia
- No approved treatments for EDS in PWS and significant unmet medical need

Myotonic Dystrophy

- Rare, genetic multi-system disease; myotonia and progressive muscle weakness hallmark symptoms; EDS most common non-muscular symptom (~80% - 90% of patients)^{3,4}
- Two forms: DM1 (~140,000 patients in US) more common than DM2 (~3 29,000 US patients); earlier onset and more severe symptoms in DM1 compared to DM2 ^{3,4}
- EDS and fatigue second only to muscle weakness in symptom prevalence and impact; decreased hypocretin levels ^{3,4}
- No approved treatments and significant unmet medical need

^{1.} Camfferman, Sleep Medicine Reviews, 2008; 2. Omokawa et al, American Journal of Medical Genetics, 2015; 3. Dauvilliers et al, Sleep Medicine Reviews, 2012; 4. Hagerman et al, Muscle Nerve, 2019



Q3 2020 Selected Financial Results



In millions, USD

	Three Months Ended September 30,		Nine Months Ended September 30,		
	2020	2019	2020	2019	
Net Product Revenues	\$45.6		\$103.5		
Cost of Products Sales	<u>7.9</u>		<u>17.8</u>		
Gross profit	37.7		85.6		
Total Operating Expenses	<u>\$27.3</u>	<u>\$29.8</u>	<u>\$76.4</u>	<u>\$112.2</u>	
R&D Expense	4.2	4.3	11.8	62.3 ¹	
S&M Expense	12.6	12.9	38.3	27.5	
G&A Expense	10.5	12.6	26.3	22.4	
Net Income (Loss)	\$1.9	\$(31.9)	\$(36.7)	\$(115.5)	
Cash & cash equivalents	\$221.7				



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Thank You

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