



Harmony Biosciences Company Overview

August 2022



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Corporate Highlights



(NASDAQ: HRMY) Founded in 2017



Commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological diseases as well as patients living with other neurological diseases who have unmet medical needs

WAKIX® (pitolisant), Harmony's first commercial product, was approved in August of 2019

Opportunity to expand existing ~\$2.3B* narcolepsy market with WAKIX

- First-in-class molecule with a novel mechanism of action (MOA)
- Approved for treatment of EDS or cataplexy in adult patients with narcolepsy
- Only FDA-approved non-scheduled treatment option for narcolepsy
- Differentiated product profile including convenient, once-daily dosing
- *"Portfolio in a Product"* opportunity due to unique MOA

Source: 2021 Net Sales based on US Market: Generics-based on IMS Data Nov 2021 MAT and internal factoring of narcolepsy use; Sodium oxybate, Sunosi based on Q4 2021 Jazz Earning call

Our Journey

Significant Milestones Achieved Since Inception

2017

2018

2019

2020

2021

Secured Exclusive U.S.
License for WAKIX®
from Bioprojet



Narcolepsy IND accepted

Fast Track Status &
Breakthrough Therapy
Designation granted for
pitolisant

NDA for WAKIX filed



Launched
KnowNarcolepsy



Deployed Medical
Science Liaison Team

FDA approval of
WAKIX (August)



WAKIX Launched
(November)



IND for Prader-Willi
Syndrome (PWS)
accepted



\$160M Net Sales in
First Year of Launch

Approval of
cataplexy indication

Initiated PWS Phase
2 POC clinical trial

IND for Myotonic
Dystrophy (DM)
accepted



Quarter over quarter
growth since launch



Initiated DM Ph2 trial

IND for Idiopathic
Hypersomnia (IH) accepted

Strategic financing deal
with Blackstone

Blackstone

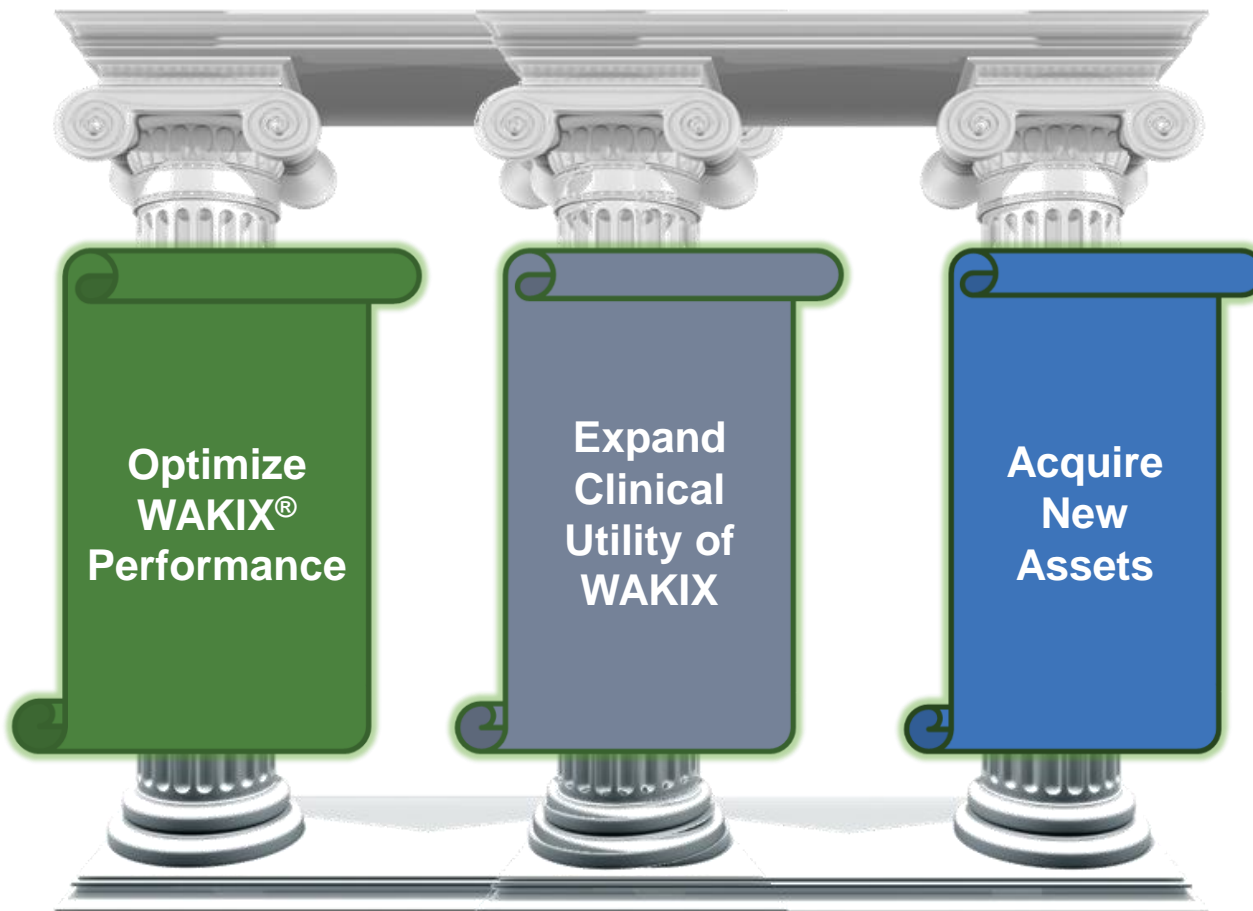
WAKIX added to AASM
treatment guidelines



HRMY added to S&P600
Small cap and NASDAQ
Biotech index

Harmony's Strategy for Growth

Three-Pillar Growth Strategy



Designed to support long term, sustainable growth for Harmony

- Continued performance with WAKIX in narcolepsy
- Expand the utility of WAKIX beyond narcolepsy
- Acquire new assets to expand our portfolio beyond WAKIX

Harmony's Three Pillar Strategy for Growth

A Year of Opportunity in 2022

Optimize WAKIX® Performance

Continued growth and performance with WAKIX is anticipated due to strong underlying demand, positive feedback from both the HCP and Patient communities and the large and growing market opportunity in narcolepsy

Expand Clinical Utility of WAKIX

Four Clinical Programs Underway







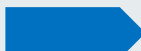
- Phase 2 POC trial in Prader-Willi Syndrome (TL data in Q4 2022)
- Phase 2 POC trial in Myotonic Dystrophy (TL data anticipated 2023)
- Phase 3 registrational trial in Idiopathic Hypersomnia (INTUNE Study)
- Phase 3 trial in pediatric narcolepsy (completed by Bioprojet)

Acquire New Assets

Dedicated business development team focused on acquiring new assets in rare/orphan neurological diseases and/or other neurological diseases where we can leverage our expertise and infrastructure

HBS-102: first new product beyond WAKIX acquired in 2021

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 (IH)							Trial initiated 1H 2022
Prader-Willi Syndrome (PWS)							Top line data Q4 2022
Myotonic Dystrophy (DM)							Top line data 2023
HBS-102							
Prader-Willi Syndrome (PWS)							Pre-clinical POC 2022

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

(2) Bioprojet conducted pediatric narcolepsy trial



1 Adult Narcolepsy Commercial Opportunity & Launch Performance



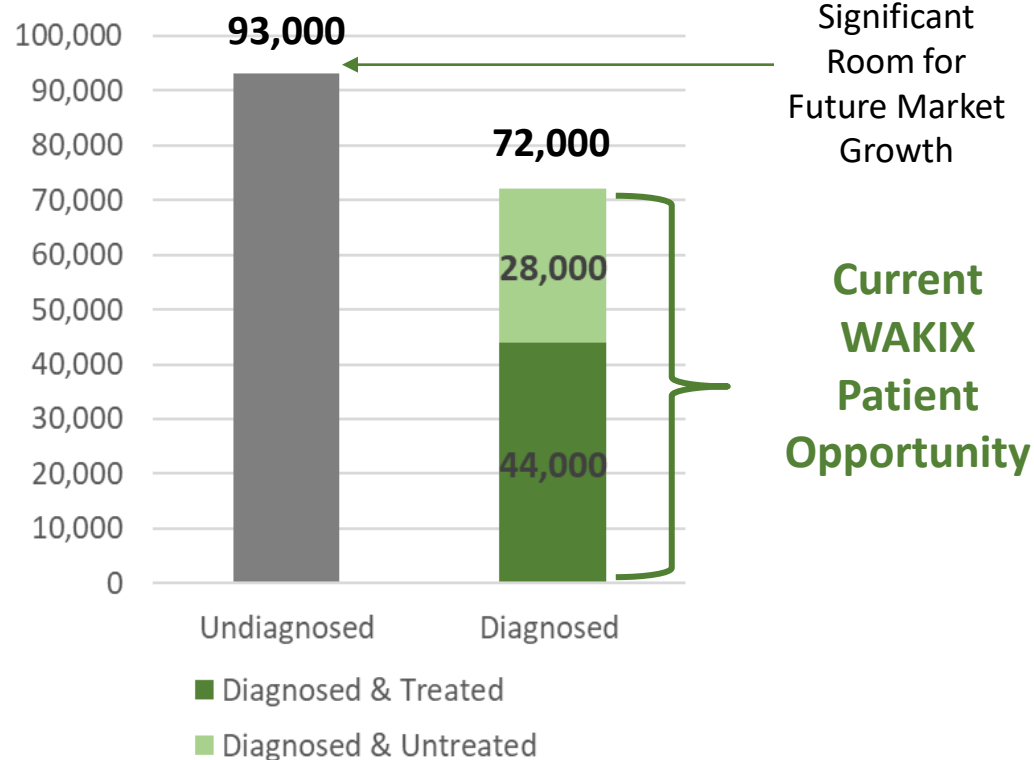
Significant Value Opportunity in Narcolepsy Market

People Living With Narcolepsy in the U.S.

165,000

Significant Market Opportunity¹

~\$2.3B 2021



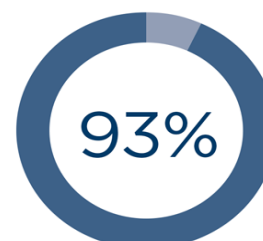
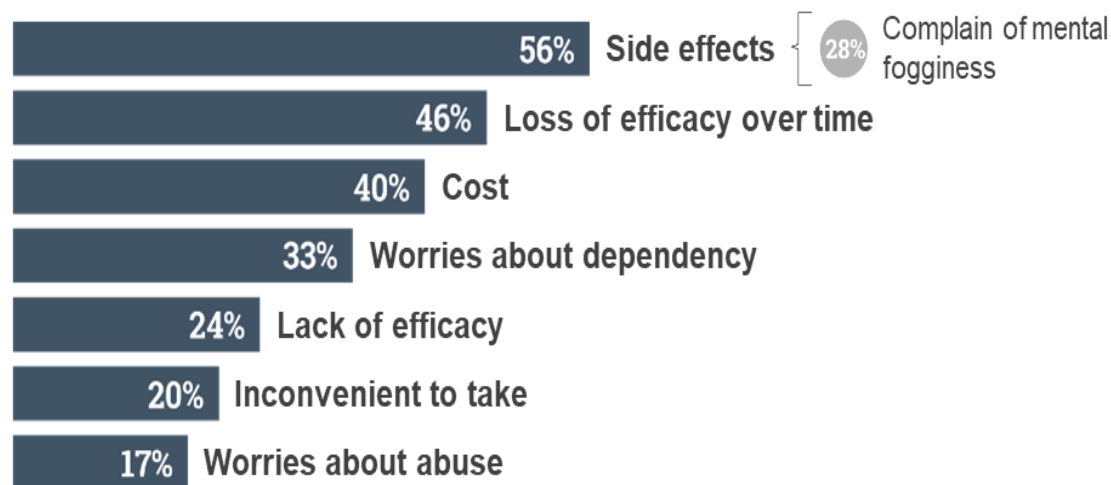
Factors contributing to continue market growth

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

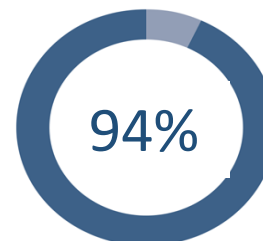
Source: 1. 2021 Net Sales based on US Market: Generics-based on IMS Data Nov 2021 MAT and internal factoring of narcolepsy use; Sodium oxybate, Sunosi based on Q4 2021 Jazz Earning call

Market Research Supports the Need for Novel Treatment Options for People Living with Narcolepsy

Patient survey¹ of 200 **people living with narcolepsy** showed:

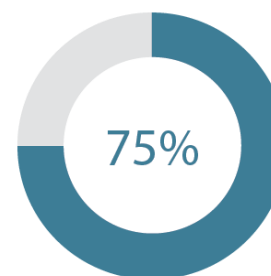


Expressed frustrations with narcolepsy medications



Believed they needed new treatment options

A retrospective, electronic chart review of 97 treated narcolepsy patients conducted at Rush University Medical Center found the majority of patients reported unresolved symptoms even while on treatment²



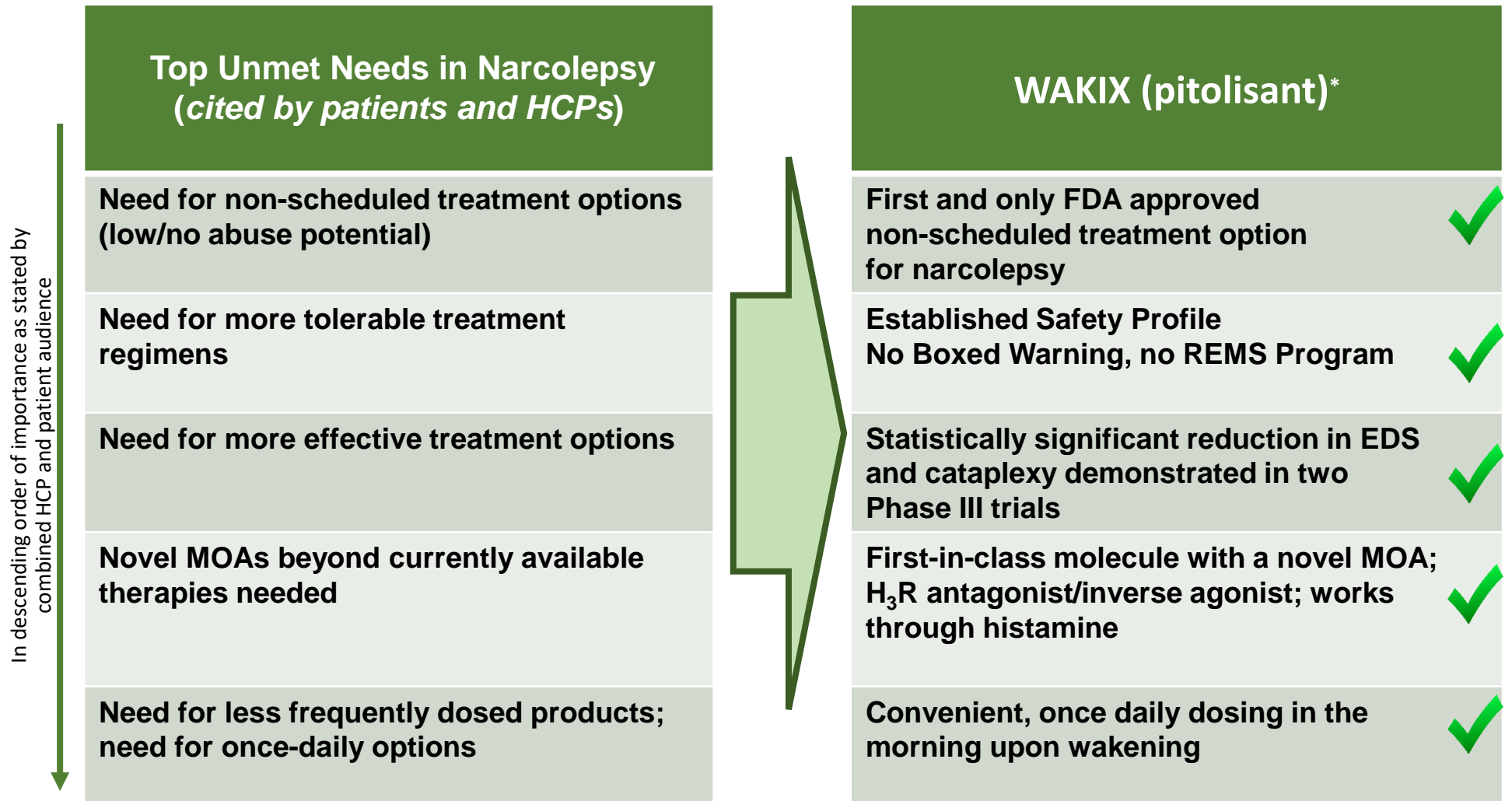
Patients reported having residual symptoms that disrupt their life even while on current medications

Sources: 1. Versta Research, Know Narcolepsy Survey ("Know Narcolepsy"), October 2018; 2. McCullough et al. Novel Treatments Options in Narcolepsy. SLEEP Meeting 2019 Abstract

- ***First in class molecule with a novel MOA***
 - The only selective H3 receptor antagonist/inverse agonist approved by the FDA
- ***First and only FDA-approved non-scheduled treatment for narcolepsy***
- **Not a stimulant - no evidence of drug tolerance or withdrawal symptoms**
- **Can be used as a monotherapy or administered concomitantly with other narcolepsy treatments (modafinil and sodium oxybate)**
- **Once-daily oral tablet administered in the morning upon waking**



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

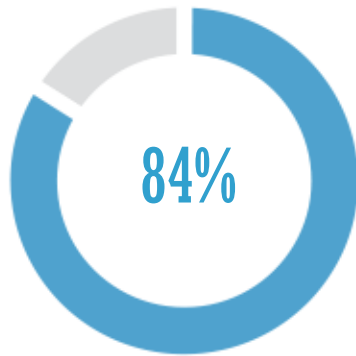


* Based on FDA approved product labeling

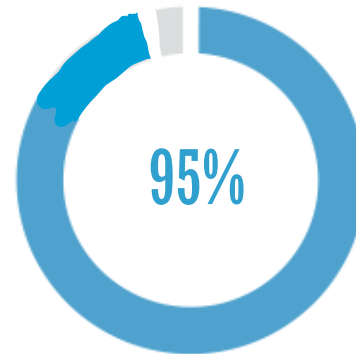
Source: Harmony ATU, July 2018 (n=286); Versta Research, Know Narcolepsy Survey ("Know Narcolepsy"), October 2018

HCP Insights Demonstrate Future Growth Opportunity for WAKIX® in Adult Narcolepsy

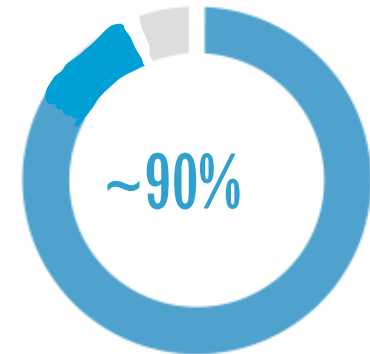
Key Findings from HCP Market Research:



Significant unmet need and WAKIX offers a unique treatment option for patients



WAKIX is effective for treatment of EDS and 90% effective for cataplexy



Expecting to prescribe the same or increase their use of WAKIX in more patients in the future

- WAKIX is being **well received by patients**
- WAKIX is **appropriate for the vast majority** of narcolepsy patients
 - **Patient opportunity increased since the approval for the cataplexy indication**

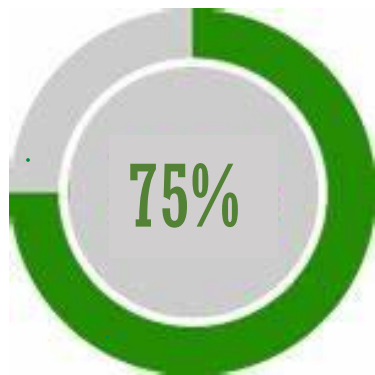
Demonstrates the overall benefit/risk profile, broad clinical utility to narcolepsy patients

Source: Harmony Market Research conducted with 50 narcolepsy treating HCPs, April 2021 (n=50)

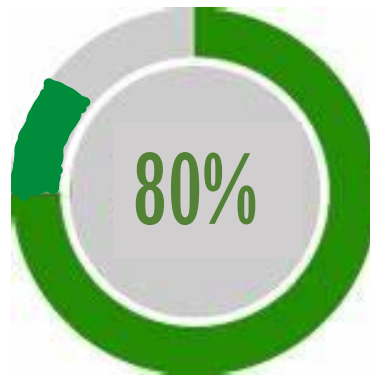
Patient Insights Also Demonstrate Future Growth Opportunity for WAKIX®

Key Findings from Patient Market Research:

- Patients communicated an **overall good experience with WAKIX**
- **Better experience in learning about and accessing the medication** than other narcolepsy treatments



Patient's **interest in WAKIX is strong** and has increased since the cataplexy indication



Likely to tell other people living with narcolepsy about WAKIX

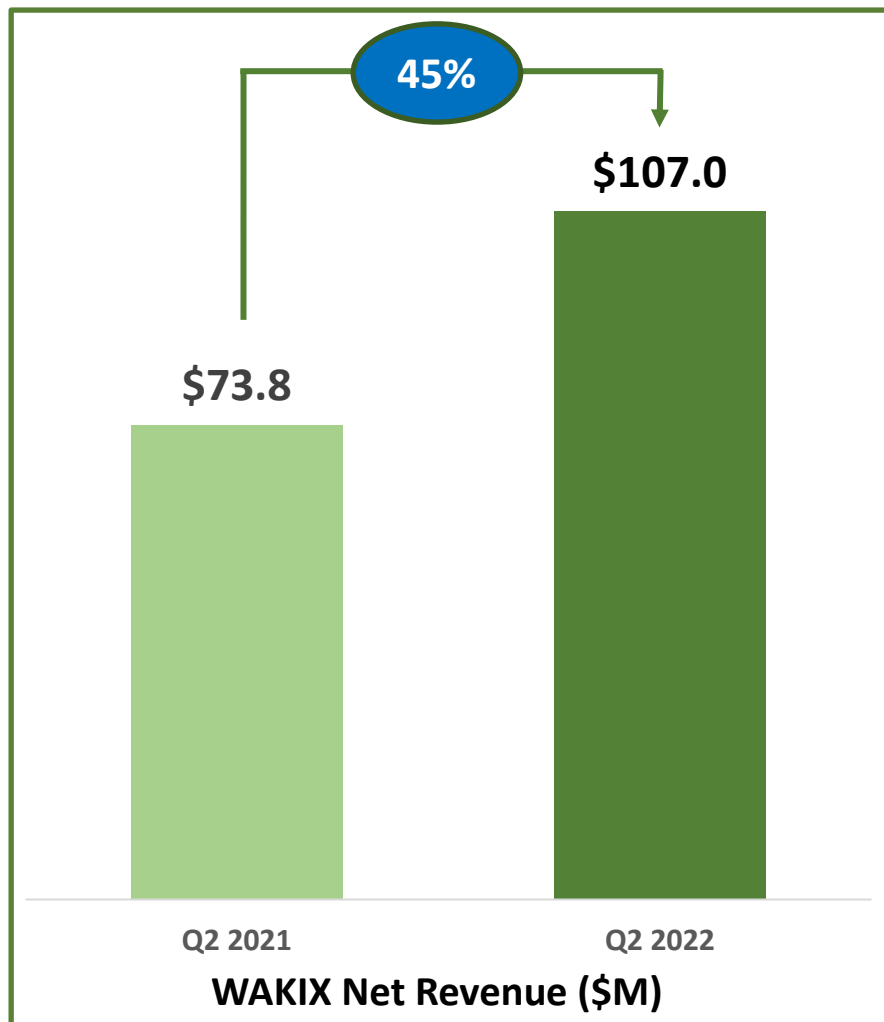


WAKIX users **expect to continue to take WAKIX**

Source: Harmony Market Research conducted with 30 narcolepsy patients with WAKIX experience, April 2021 (n=30)

Q2 2022 WAKIX® Net Revenue Performance

Q2 2022 Net Revenue of \$107.0M



2Q21	1Q22	2Q22	Δ 2Q22 vs. 1Q22	Δ 2Q22 vs. 2Q21
\$73.8	\$85.3	\$107.0	25%	45%

Strong Revenue Growth

- 45% growth Q2 2022 vs. Q2 2021
- 25% growth Q2 2022 vs. Q1 2022
- Strong momentum in top line prescription demand and new patient starts

Driving Growth Through Our Launch For WAKIX®

Q2 2022 Performance



~75% In-Person
Access to HCPs



Patient Outreach
Programs & Support

~4,300 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

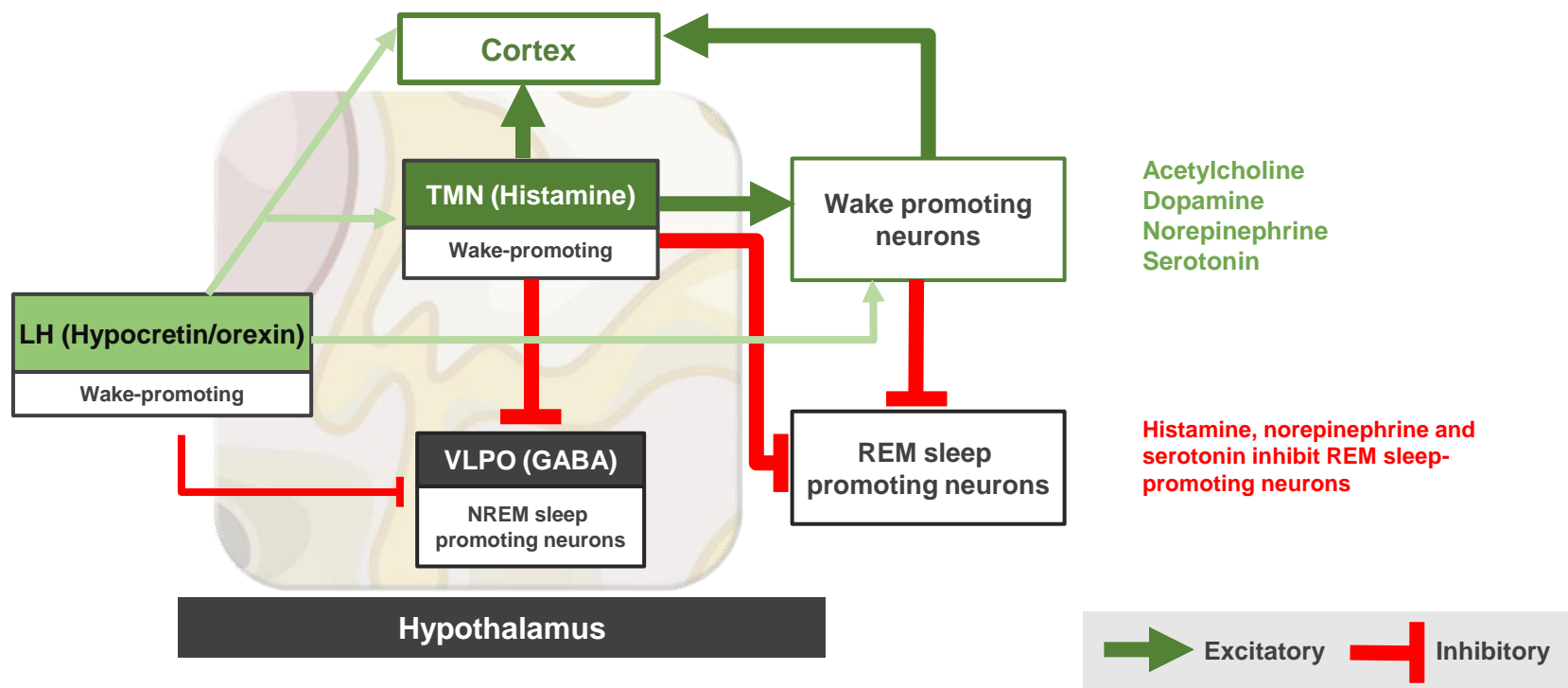


2 WAKIX[®] (pitolisant) Clinical Overview



Pitolisant: First-in-Class Molecule; Novel Mechanism of Action

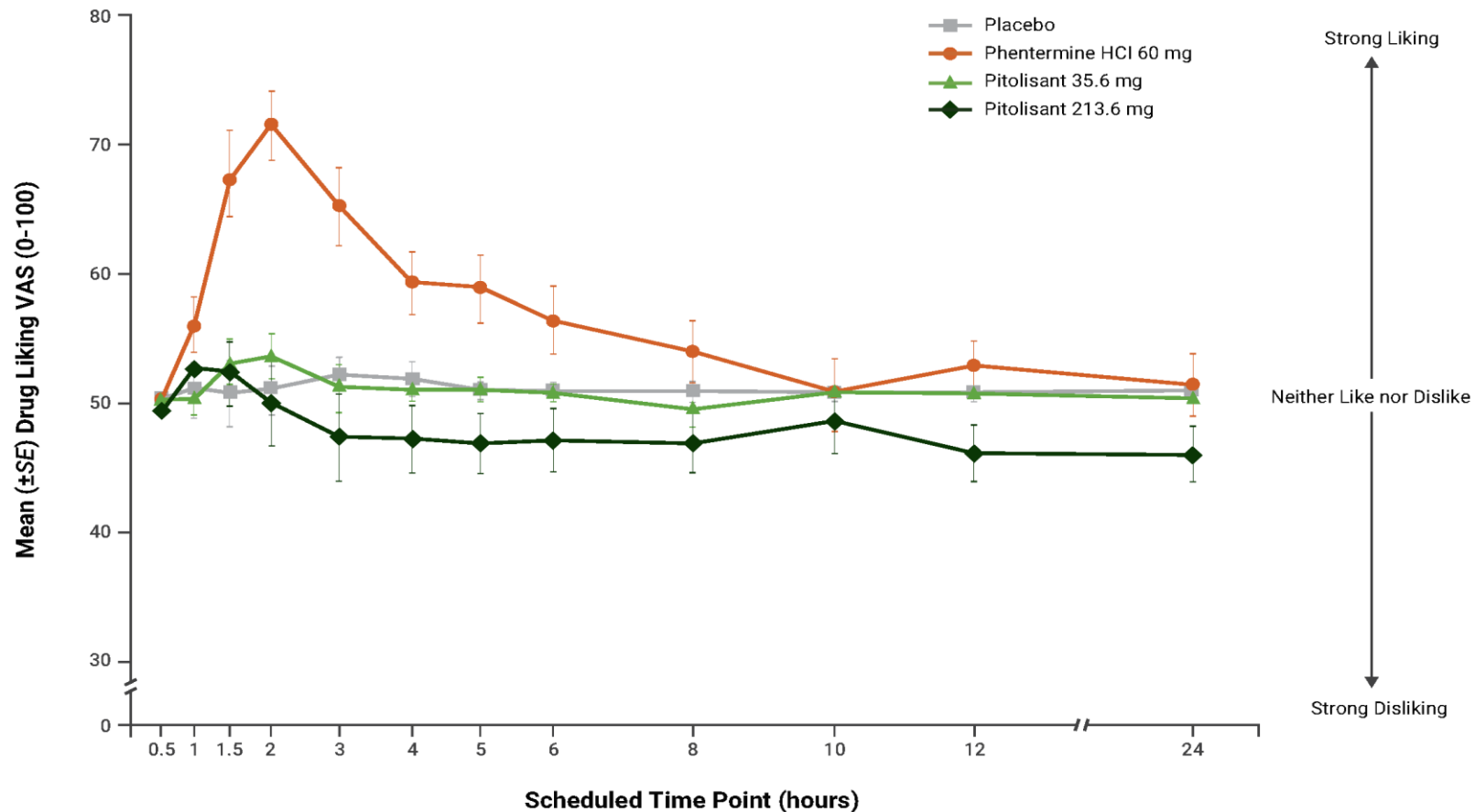
- **Pitolisant** - Potent, highly selective histamine 3 (H_3) receptor antagonist/inverse agonist
 - Increases histaminergic transmission in the brain
 - Activates other wake promoting neurotransmitters (dopamine, norepinephrine, serotonin, acetylcholine)
 - Does not increase dopamine in the nucleus accumbens (consistent with its lack of abuse potential)
- Role of **histamine** in sleep-wake state stability (**3 H's**)



WAKIX® Phase 3 Clinical Development Program

Name of Study Study Design	Number of Patients	Maximum Dose; % at that Dose	Primary Objective	Results
HARMONY 1 Randomized, double-blind, placebo and active control; patients with narcolepsy ± cataplexy; 8 weeks of treatment	N = 95	35.6 mg; 61%	Assess change in Epworth Sleepiness Scale (ESS) score from baseline to final visit	-6.0 for WAKIX compared to -2.9 for placebo (treatment effect -3.1; p=0.022)
HARMONY 1bis Randomized, double-blind, placebo and active control; patients with narcolepsy ± cataplexy; 8 weeks of treatment	N = 166	17.8 mg 76%	Assess change in ESS score from baseline to final visit	-5.0 for WAKIX compared to -2.8 for placebo (treatment effect -2.2; p=0.030)
HARMONY CTP Randomized, double-blind, placebo control; patients with narcolepsy and cataplexy; 7 weeks of treatment	N = 106	35.6 mg 65%	Assess change in Weekly Rate of Cataplexy (WRC)	WRC decreased 75% for WAKIX compared to 38% for placebo (rate ratio 0.51; p<0.0001)
HARMONY 3 Long-term, open-label, real-world trial; ≥1 year of treatment	N = 104	35.6 mg 88%	Long-term safety	Safety/tolerability profile consistent with that seen in the RCTs
Human Abuse Potential Study Randomized, double-blind, active & placebo-controlled, 4-way crossover study	N = 43	35.6 mg & 213.6 mg; phentermine 60 mg (active control)	Assess drug liking	WAKIX demonstrated a statistically significant and clinically relevant reduction in drug liking compared to phentermine (p<0.0001)

Clinical HAP Study – WAKIX® Showed Significantly Lower Maximum Drug Liking Compared to Schedule IV Stimulant



- Significant reduction in maximal drug liking for both doses of WAKIX compared to phentermine ($P < 0.0001$)
- Same pattern seen on key secondary endpoints of Overall Drug Liking and Take Drug Again – significant reduction for both doses of WAKIX compared to phentermine ($P < 0.0001$)
- Responses to both doses of WAKIX were similar to placebo

WAKIX® : Safety & Tolerability Profile

- 1,513 patients treated with WAKIX in clinical development program
- 303 patients in clinical trials for narcolepsy: 172 treated with WAKIX for up to 8 weeks in placebo-controlled trials

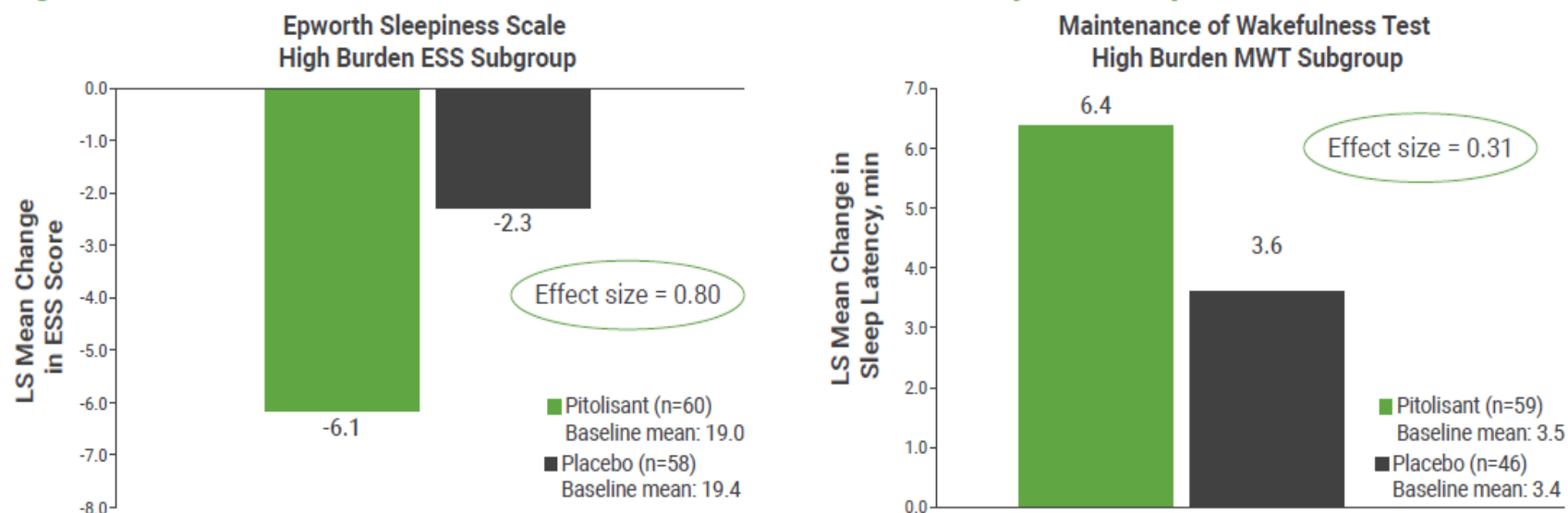
Most Common Adverse Reactions With WAKIX (occurring in ≥5% of patients and twice the rate of placebo)

Adverse Reaction	Pitolisant (n=152)	Placebo (n=114)
Insomnia	6%	2%
Nausea	6%	3%
Anxiety	5%	1%

- In trials in which WAKIX was directly compared with placebo, 6 of 152 patients (3.9%) who received WAKIX discontinued due to an adverse event compared to 4 of 114 (3.5%) who received placebo
- Long-term safety of WAKIX was assessed in a 12-month open-label study (HARMONY 3) in patients with narcolepsy (N=102)
 - Safety results were consistent with those recorded in the randomized controlled trials

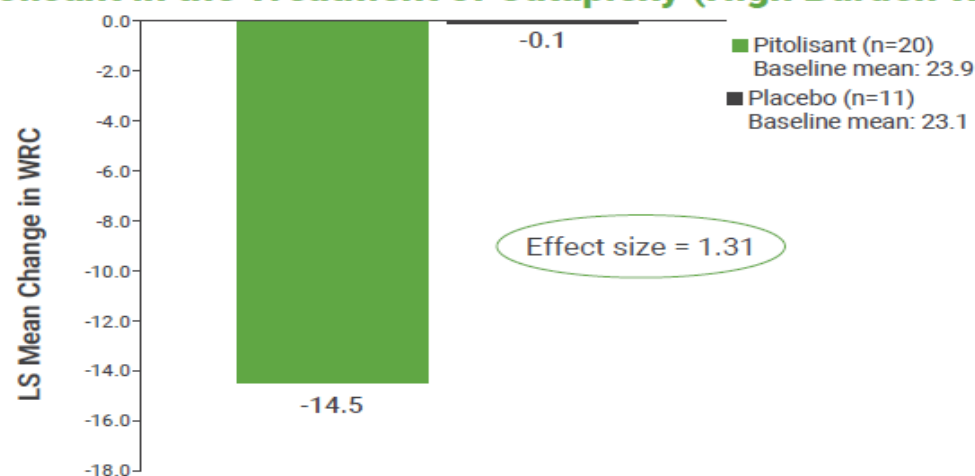
Data for WAKIX® Presented at SLEEP 2022

Figure 1. Effect Size for Pitolisant in the Treatment of Excessive Daytime Sleepiness



Effect size assessed using Cohen's *d*. End of treatment defined as the last postbaseline assessment (LOCF). Postbaseline MWT: pitolisant, n=54; placebo, n=42. ESS = Epworth Sleepiness Scale; LOCF = last observation carried forward; LS = least-squares; MWT = Maintenance of Wakefulness Test.

Figure 2. Effect Size for Pitolisant in the Treatment of Cataplexy (High Burden WRC Subgroup)



Effect size assessed using Cohen's *d*. End of treatment defined as the stable dosing period (LOCF). LOCF = last observation carried forward; LS = least-squares; WRC = weekly rate of cataplexy.

Data for WAKIX® Presented at SLEEP 2022

Figure 3. NNT for Pitolisant in the Treatment of Excessive Daytime Sleepiness (High Burden ESS Subgroup)

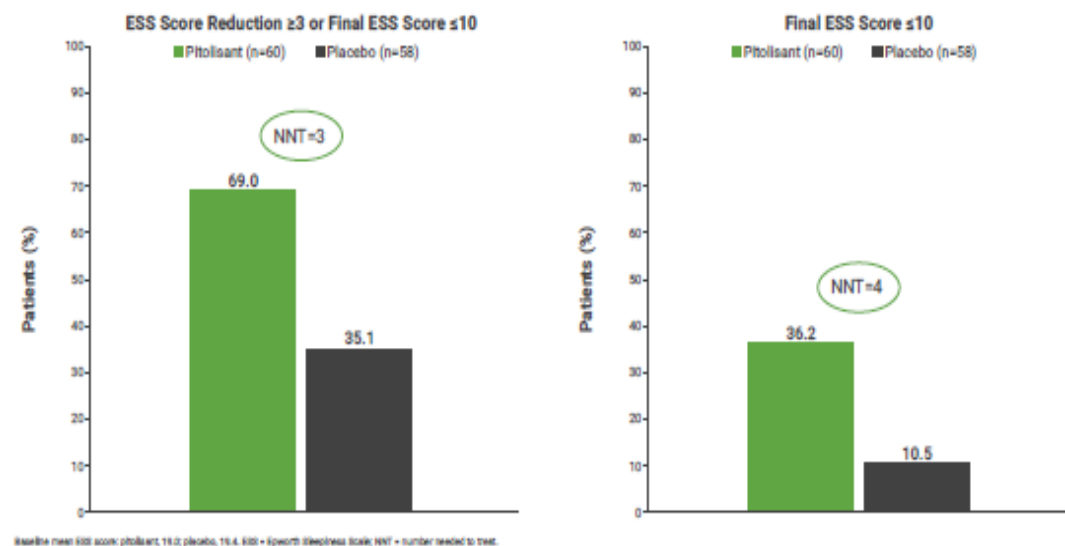


Figure 4. NNT for Pitolisant in the Treatment of Cataplexy (High Burden WRC Subgroup)

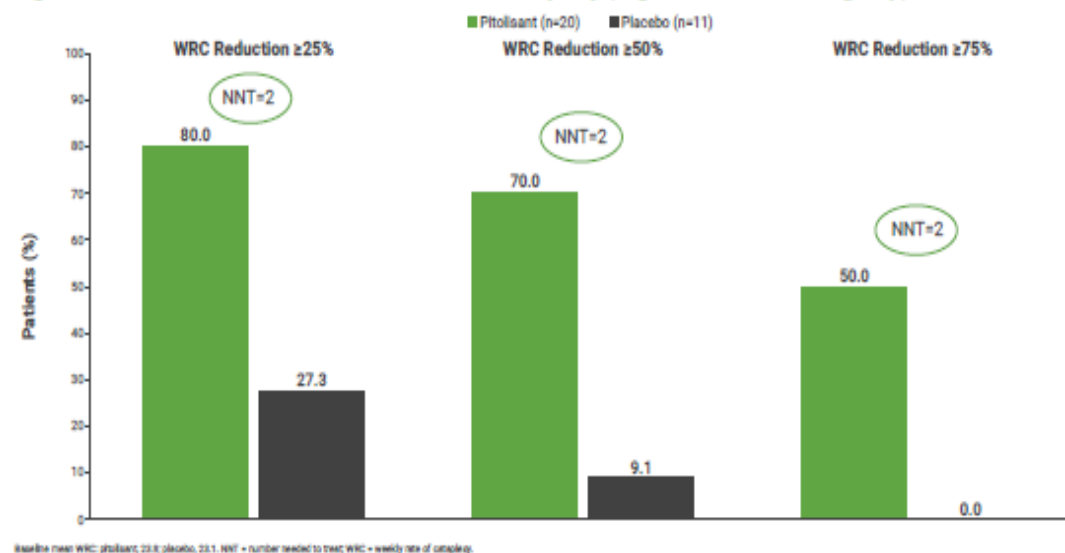
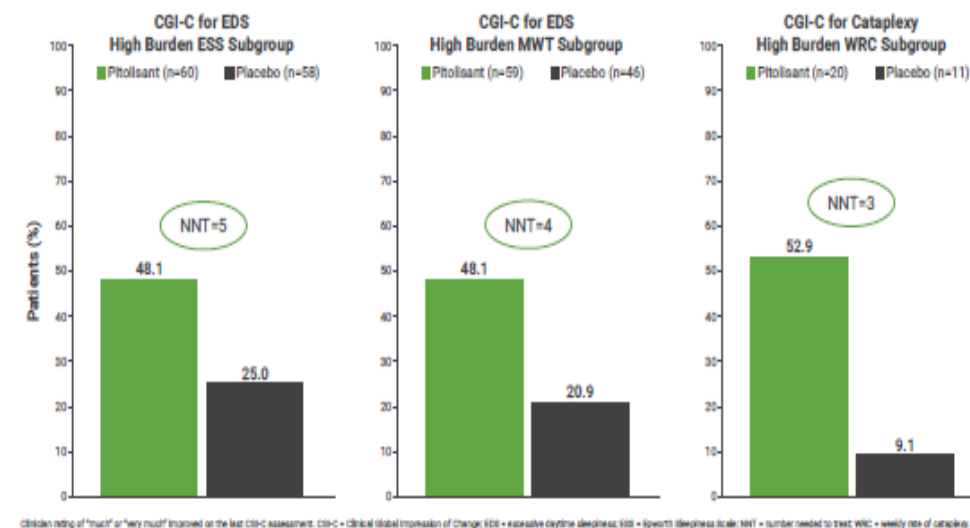


Figure 5. Clinical Global Impression of Change for Excessive Daytime Sleepiness and Cataplexy



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 Recommendation	Critical Outcomes Showing Clinically Significant Improvement*			
		Excessive Daytime Sleepiness	Cataplexy	Disease Severity	Quality of Life
Narcolepsy					
Modafinil	Strong	✓		✓	✓
Pitolisant	Strong	✓	✓	✓	
Sodium Oxybate	Strong	✓	✓	✓	
Solriamfetol	Strong	✓		✓	✓
Armodafinil	Conditional	✓		✓	
Dextroamphetamine	Conditional	✓	✓		
Methylphenidate	Conditional			✓	

*Accident risk and work/school performance/attendance were critical outcomes; however, no data were available. ✓ 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.



3 Life Cycle Management for Pitolisant

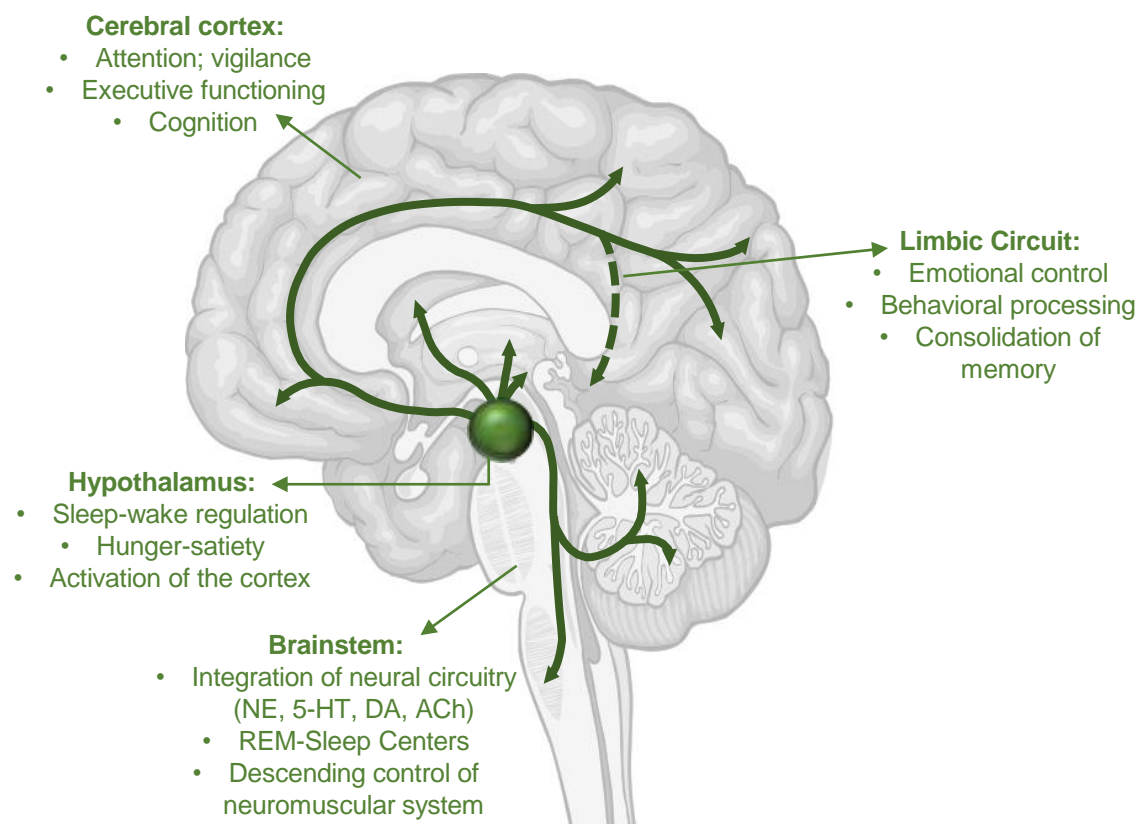


Pitolisant: *Portfolio in a Product Opportunity*

Pitolisant has a unique MOA with potential for multiple additional indications in rare neurological disease patient populations with unmet medical needs

Mechanism-based approach to drug development and LCM studies based on:

- Role of histamine in normal physiologic functioning
- Role of histamine in disorders of orexin deficiency
- Location of H₃ receptors throughout the CNS
- Limited H₃ receptor populations outside the CNS
- Proven clinical efficacy of pitolisant for EDS



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)	<div></div>						
Cataplexy in Narcolepsy (Adults)	<div></div>						
Pitolisant							
Pediatric Narcolepsy ⁽²⁾	<div></div>						Trial completed
Idiopathic Hypersomnia (IH)	<div></div>						Trial initiated 1H 2022
Prader-Willi Syndrome (PWS)	<div></div>						Top line data Q4 2022
Myotonic Dystrophy (DM)	<div></div>						Top line data 2023
HBS-102							
Prader-Willi Syndrome (PWS)	<div></div>						Pre-clinical POC 2022

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

(2) Bioprojet conducted pediatric narcolepsy trial

Pitolisant: Key Clinical Programs & Rationale



Idiopathic Hypersomnia (IH)

- Rare, chronic, neurological disease characterized by EDS despite sufficient or long sleep; other key features include sleep inertia after waking and impaired cognition, attention, and alertness¹⁻⁵
- Like narcolepsy, another central disorder of hypersomnolence
- Estimated number of diagnosed patients in U.S. currently about 30,000 to 40,000⁶
- Only one approved treatment for patients with IH



Prader-Willi Syndrome (PWS)

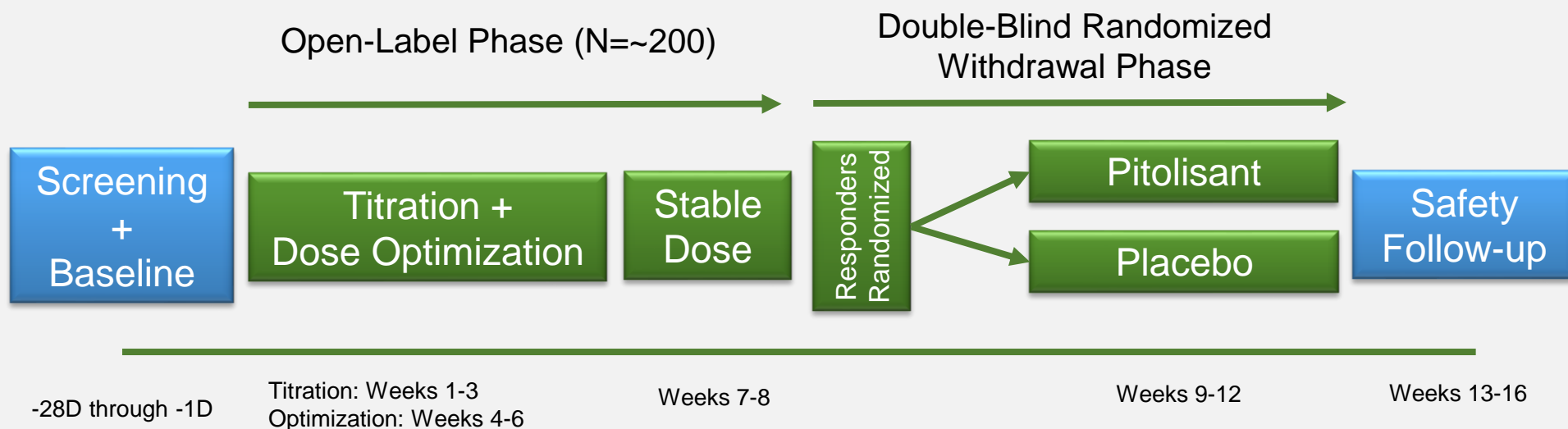
- Rare, genetic multi-system, neurodevelopmental disorder characterized by hypothalamic dysfunction
- Decreased hypocretin levels in some patients^{7,8}
- ~15,000-20,000 patients in U.S. and more than 50% have EDS⁷
- No approved treatments for EDS in patients with PWS; unmet medical need



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)
- Decreased hypocretin levels in some patients^{9,10, 12}
- ~160,000 people in the US with genetic defect for DM1; of those, ~50% symptomatic and of those, ~50% diagnosed (~40,000 patients)¹³
- No approved treatments for DM; significant unmet medical need

INTUNE Study: Phase 3 Registrational Trial of Pitolisant in Idiopathic Hypersomnia



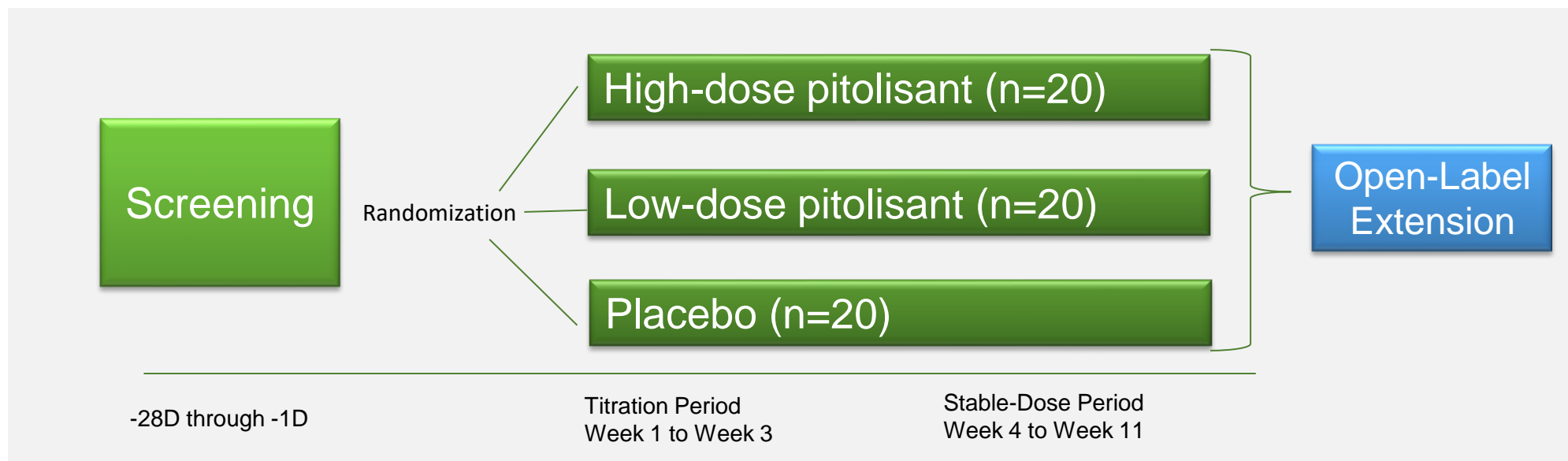
Trial Design:

- 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
- ~60 - 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

PWS: Phase 2 Clinical POC Trial of Pitolisant



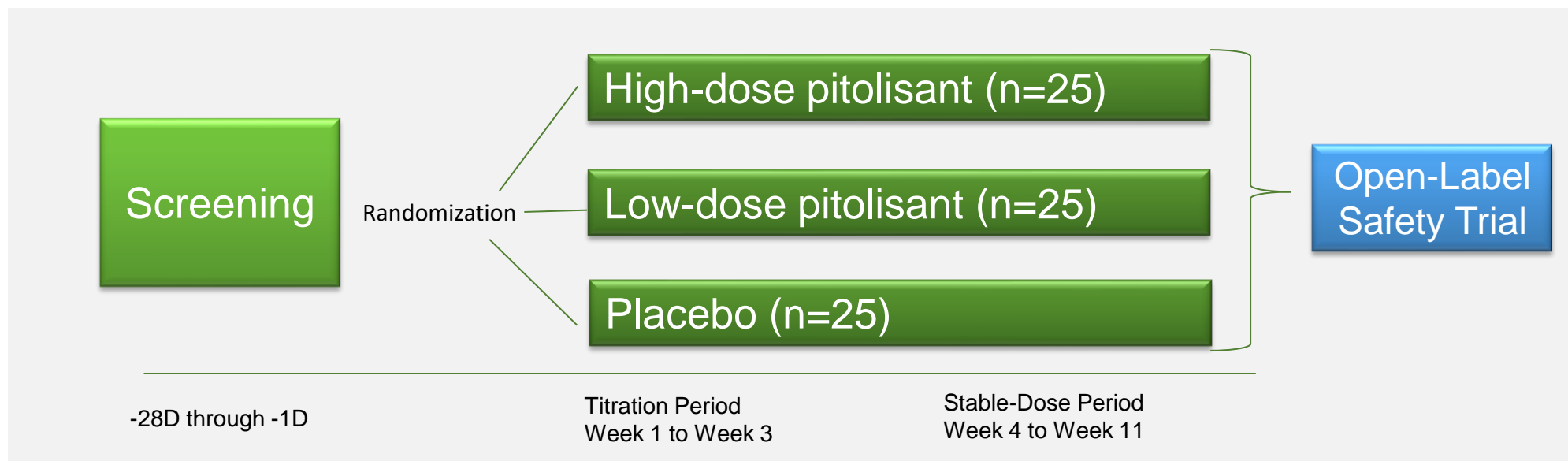
Trial Design:

- Randomized, double-blind, placebo-controlled, parallel-group study
- ~60 patients; ages 6 – 65
- 15 clinical trial sites

Objectives:

- Primary objective: to evaluate the safety and efficacy of pitolisant compared with placebo in treating EDS in patients with PWS
- Secondary objectives: caregiver assessment of severity based on EDS; clinician assessment of severity based on PWS symptoms; behavioral assessments; cognitive function; caregiver burden; long-term safety and effectiveness in patients with PWS

DM1: Phase 2 Clinical POC Trial of Pitolisant



Trial Design:

- Randomized, double-blind, placebo-controlled, parallel-group study
- ~75 patients; ages 18 – 65
- ~20 clinical trial sites

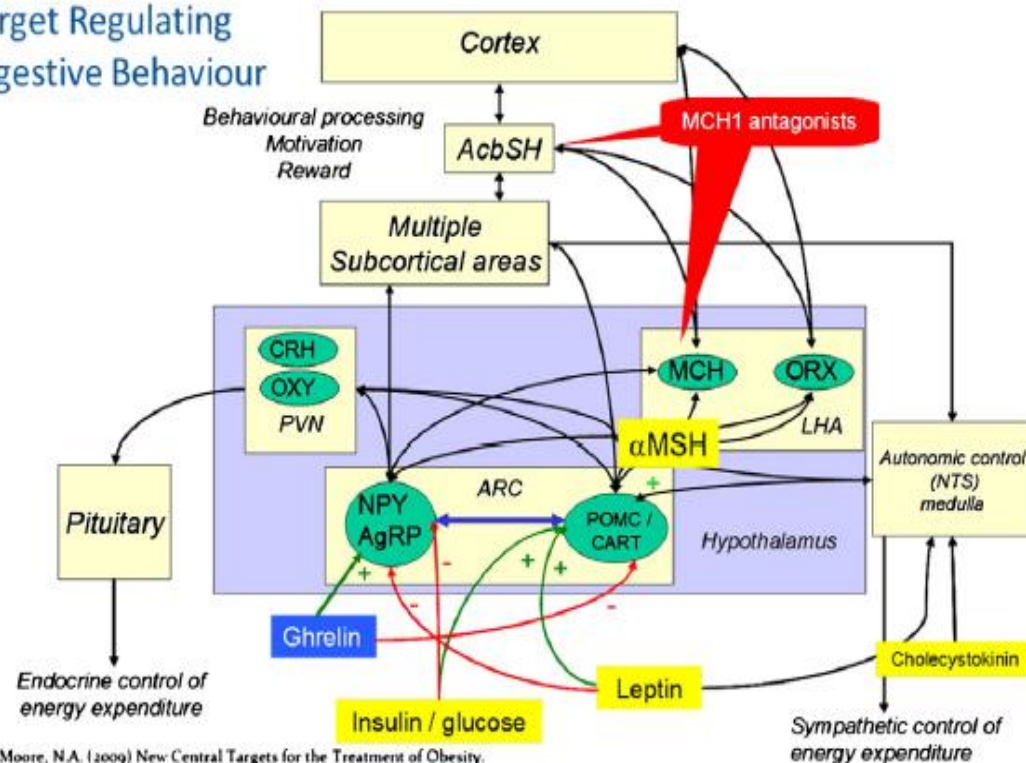
Objectives:

- Primary objective: to evaluate the safety and efficacy of pitolisant compared with placebo in treating EDS in patients with DM1
- Secondary objectives: to assess the impact of pitolisant on fatigue, cognitive function, patient assessment of overall disease burden, clinician assessment of overall disease severity, and long-term safety and effectiveness in patients with DM1

HBS-102: Preclinical POC Study in PWS

- Melanin Concentrating Hormone (MCH) neurons are located in the hypothalamus and function as a key control center of feeding behavior and energy metabolism
- HBS-102 is an MCH receptor-1 (MCHR1) antagonist and this class of compounds has been shown to mediate the activity of MCH neurons
- Preclinical POC study planned to assess the effects of the MCHR1 antagonist HBS-102 on hyperphagia, weight gain and other metabolic parameters in a preclinical model (SNORD 116 KO mouse model) of PWS

MCH₁: A Central Target Regulating Ingestive Behaviour



Sargent, B.J., Moore, N.A. (2009) New Central Targets for the Treatment of Obesity.
British Journal of Clinical Pharmacology. 68 852-860.



4 Acquire New Assets (Business Development)



Harmony Business Development

Objective

We intend to evolve Harmony into a leading pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological diseases as well as patients living with other neurological diseases who have unmet medical needs

Focus

To achieve this, building upon our success with WAKIX®, we intend to acquire a portfolio of rare/orphan neurology assets and/or assets in other neurological diseases;

- Where we can leverage our existing expertise and infrastructure
 - Have potential synergies with WAKIX and our current footprint
-

Timeline

We are beginning this journey early in our company history, so we can take the time to be thoughtful in what we acquire and flexible in the types of deals we will consider

Capabilities

We have a dedicated BD team focused on this initiative, and the internal capabilities to develop assets from very early stage through to commercialization in the neurology arena because of our experience in clinical development, regulatory affairs and commercial launch and execution



5 Historical Financials

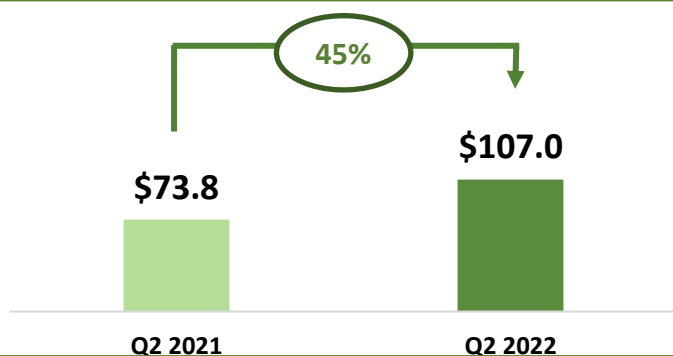


Financial Highlights

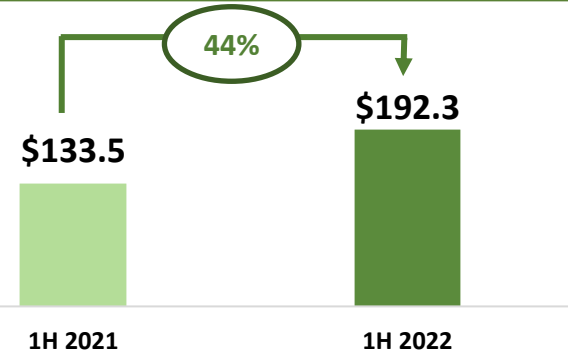
(In millions, USD)

Net Product Revenues

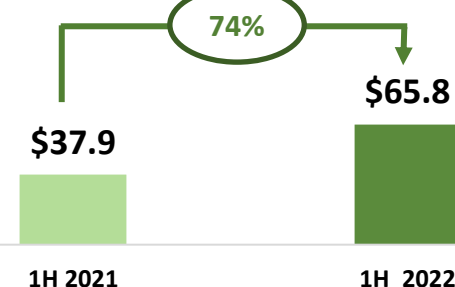
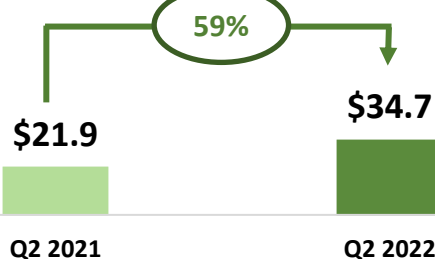
Three Months Ended
June 30, 2022



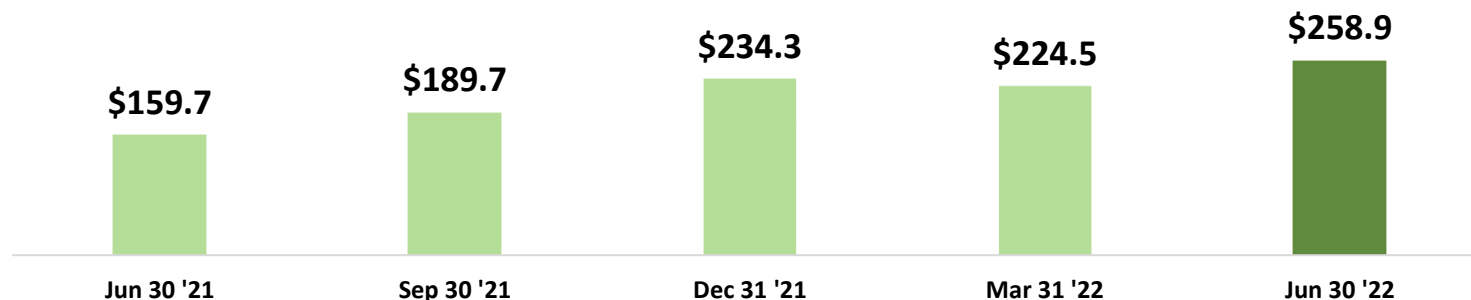
Six Months Ended
June 30, 2022



Non-GAAP Adjusted Net Income⁽¹⁾



Cash, Cash Equivalents & Investments



(1) Non-GAAP Adjusted Net Income= GAAP Net Income excluding non-cash interest expense, depreciation, amortization, stock-based compensation, other non-operating items and tax effect of these items

Q2 2022 Financial Summary

(In millions, USD)	Three Months Ended June 30,		% Change
	2022	2021	
Net Product Revenues	\$107.0	\$73.8	45%
Cost of Product Sold	18.9	12.7	49%
Total Operating Expenses	\$55.0	\$37.8	45%
R&D Expense	12.7	6.5	95%
S&M Expense	20.2	17.0	18%
G&A Expense	22.2	14.3	55%
Net Income	\$23.5	\$14.1	67%
Cash, cash equivalents & investments	\$258.9		

Totals may not foot due to rounding

Q2 2022 GAAP vs Non-GAAP Reconciliation

(In millions, USD)	Three Months Ended June 30,	
	2022	2021
GAAP net income	\$23.5	\$14.1
Non-cash interest expense ⁽¹⁾	0.4	0.7
Depreciation	0.1	0.1
Amortization ⁽²⁾	6.0	4.6
Stock-based compensation expense	7.4	3.8
Income tax effect related to Non-GAAP adjustments ⁽³⁾	(2.7)	(1.5)
Non-GAAP adjusted net income	\$34.7	\$21.9
GAAP net income per diluted share	\$0.39	\$0.24
Non-GAAP adjusted net income per diluted share	\$0.57	\$0.37
Weighted average number of shares of common stock used in non-GAAP diluted per share	60,922,672	58,592,876

Totals may not foot due to rounding

(1) Includes amortization of deferred finance charges

(2) Includes amortization of intangible assets related to WAKIX

(3) Calculated using the reported effective tax rate for the periods presented



6 Summary



Summary



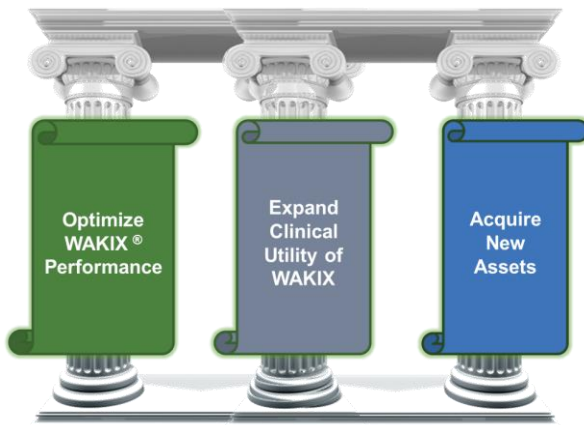
(NASDAQ: HRMY) Founded in 2017



Commercial-stage pharmaceutical company focused on developing and commercializing innovative therapies for patients living with rare neurological diseases as well as patients living with other neurological diseases who have unmet medical needs

WAKIX® (pitolisant), Harmony's first commercial product, was approved in August of 2019

Three-Pillar Growth Strategy



We Anticipate 2022 to Be Our Best Year Yet

- Continued growth with WAKIX in narcolepsy
- Advancement of our clinical trials in IH, PWS and DM
- Our dedicated team will be seeking additional assets to expand our portfolio beyond WAKIX and HBS-102 with additional rare/orphan neurology and/or other neurology assets where we can leverage our expertise and infrastructure



Thank You

August 2022

