



# Harmony Biosciences Company Overview

February 2024



# Forward-Looking Statements

This presentation includes forward-looking statements within the meaning of the Private Securities Reform Act of 1995. All statements other than statements of historical facts contained in these materials or elsewhere, including statements regarding Harmony Biosciences Holdings, Inc.'s (the "Company") future financial position, business strategy and plans and objectives of management for future operations, should be considered forward-looking statements. Forward-looking statements use words like "believes," "plans," "expects," "intends," "will," "would," "anticipates," "estimates," and similar words or expressions in discussions of the Company's future operations, financial performance or the Company's strategies. These statements are based on current expectations or objectives that are inherently uncertain, especially in light of the Company's limited operating history. These and other important factors discussed under the caption "Risk Factors" in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on February 22, 2024 and its other filings with the SEC could cause actual results to differ materially and adversely from those indicated by the forward-looking statements made in this presentation. While the Company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change.

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# Who We Are



## OUR MISSION

*At Harmony Biosciences, we specialize in developing and delivering treatments for rare neurological diseases that others often overlook. We believe that where empathy and innovation meet, a better life can begin for people living with neurological diseases.*



# Our Journey of Growth

## FOUNDATION

## GROWTH & EXPANSION

2017

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



Founded Harmony Biosciences



2018

Granted Fast Track Status & Breakthrough Therapy Designation for Pitolisant

Filed NDA for Pitolisant



Launched KnowNarcolepsy



2019

FDA Approves WAKIX for EDS in Narcolepsy



IND for Prader-Willi Syndrome (PWS)



2020

Completed Nasdaq IPO (HRMY)

Cataplexy Indication Approved

Initiated PWS Phase 2 POC Trial

IND for Myotonic Dystrophy (DM) Opened



2021

Initiated DM Phase 2 POC Trial

IND for Idiopathic Hypersomnia (IH) Opened



WAKIX Added to AASM Treatment Guidelines



HRMY Added to Nasdaq Biotech Index (NBI)

2022

Initiated IH Phase 3 INTUNE Study



Signed 2022 Agreement with Bioprojet

Achieved Positive Signals in PWS Phase 2 POC Trial

2023

Achieved \$582M in WAKIX Net Revenue

Expanded and Diversified Pipeline with Zynerba Acquisition



Completed IH Phase 3 INTUNE Study

Initiated Share Repurchase Program

Achieved Positive Signals in DM Phase 2 POC Trial

# Strong Momentum in Execution of Our Growth Strategy

## Continued Strong Growth For WAKIX® in Adult Narcolepsy

- FY 2023 WAKIX Net Revenue of \$582.0M **+33% Year-over-Year Growth**
- **~6,150** average number of patients on WAKIX in Q4 2023
- **Continued strong growth** in average number of patients & WAKIX prescriber base
- **Demonstrated durability of the brand** entering year five on the market; **2024 Net Revenue guidance of \$700-\$720M**

## Strong Momentum in Advancing and Expanding the Pipeline

- **FDA granted Priority Review for pediatric narcolepsy sNDA**; PDUFA date of June 21, 2024
- **Meeting with the FDA** to discuss Idiopathic Hypersomnia development program scheduled for March 2024
- **FDA granted Orphan Drug designation** to Pitolisant for PWS; Phase 3 TEMPO study expected to initiate in Q1 24
- **Reported positive topline results** from DM1 Phase 2 POC study in EDS and fatigue
- **Advanced Next-Gen pitolisant based** formulations into the clinic; on track to report pharmacokinetic data in 1H 24
- **Expanded the pipeline and diversified the portfolio** with acquisition of Zynerba; ZYN002 in Phase 3 pivotal trial for Fragile X syndrome and Phase 3 ready for 22q deletion syndrome

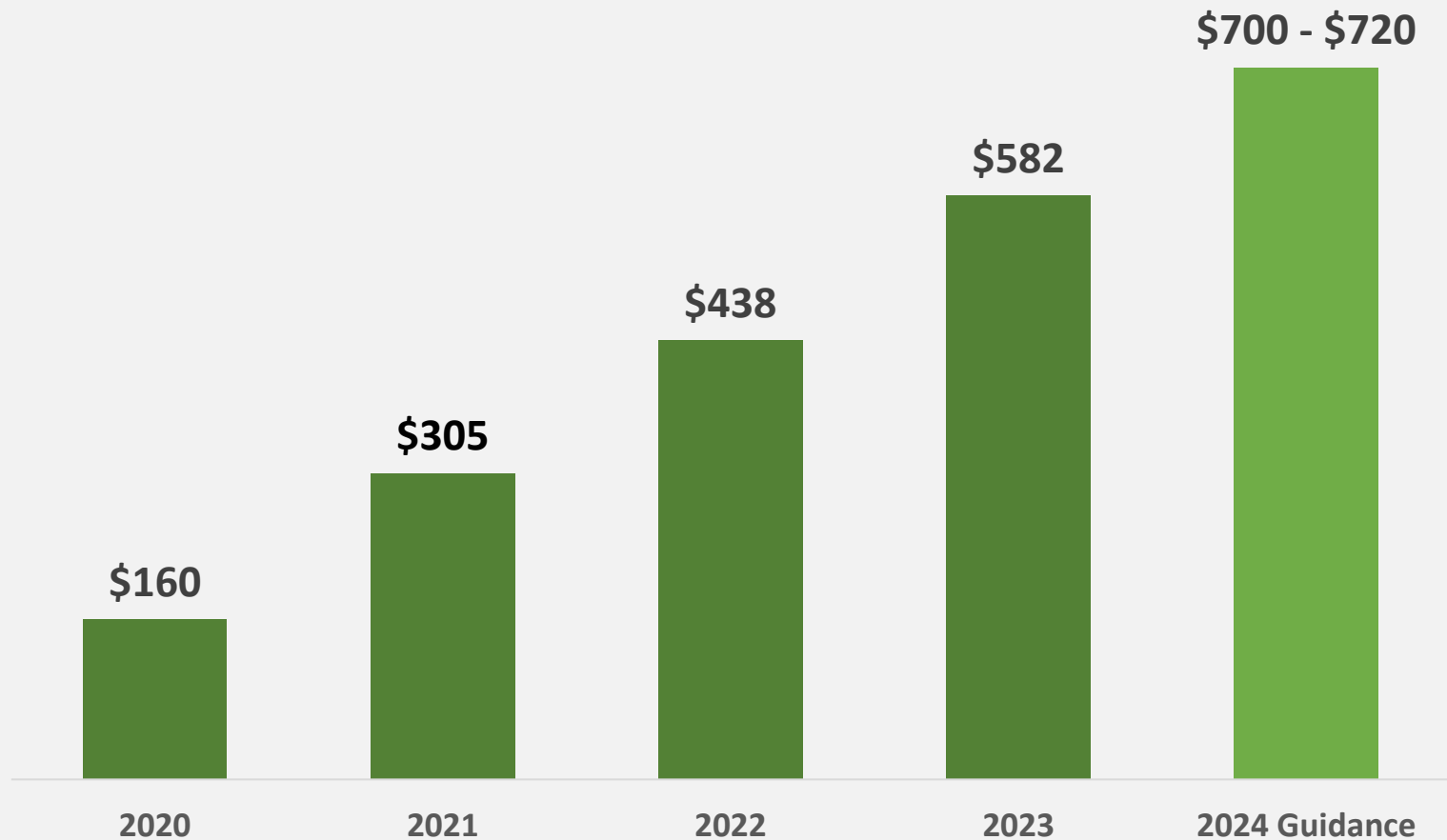
## Disciplined Capital Allocation to Maximize Shareholder Value

- **Profitable, cash generating** with **\$425.6M** on the balance sheet as of December 31, 2023
- **Share repurchase program**: Repurchased ~3.2M shares of common stock at an aggregate cost of \$100M during 2023; remaining authorization of \$150M
- **Well positioned** to execute on business development to build out robust pipeline

# Strong Track Record of Commercial Performance

CONFIDENT IN WAKIX BEING A POTENTIAL \$1B+ OPPORTUNITY IN ADULT NARCOLEPSY ALONE WITH THE POTENTIAL TO CONTRIBUTE UP TO AN ADDITIONAL \$1B, IF APPROVED IN OTHER CURRENT PITOLISANT LIFECYCLE MANAGEMENT PROGRAMS

WAKIX ANNUAL NET REVENUE (\$M)



**\$582M**

2023  
Net Revenue

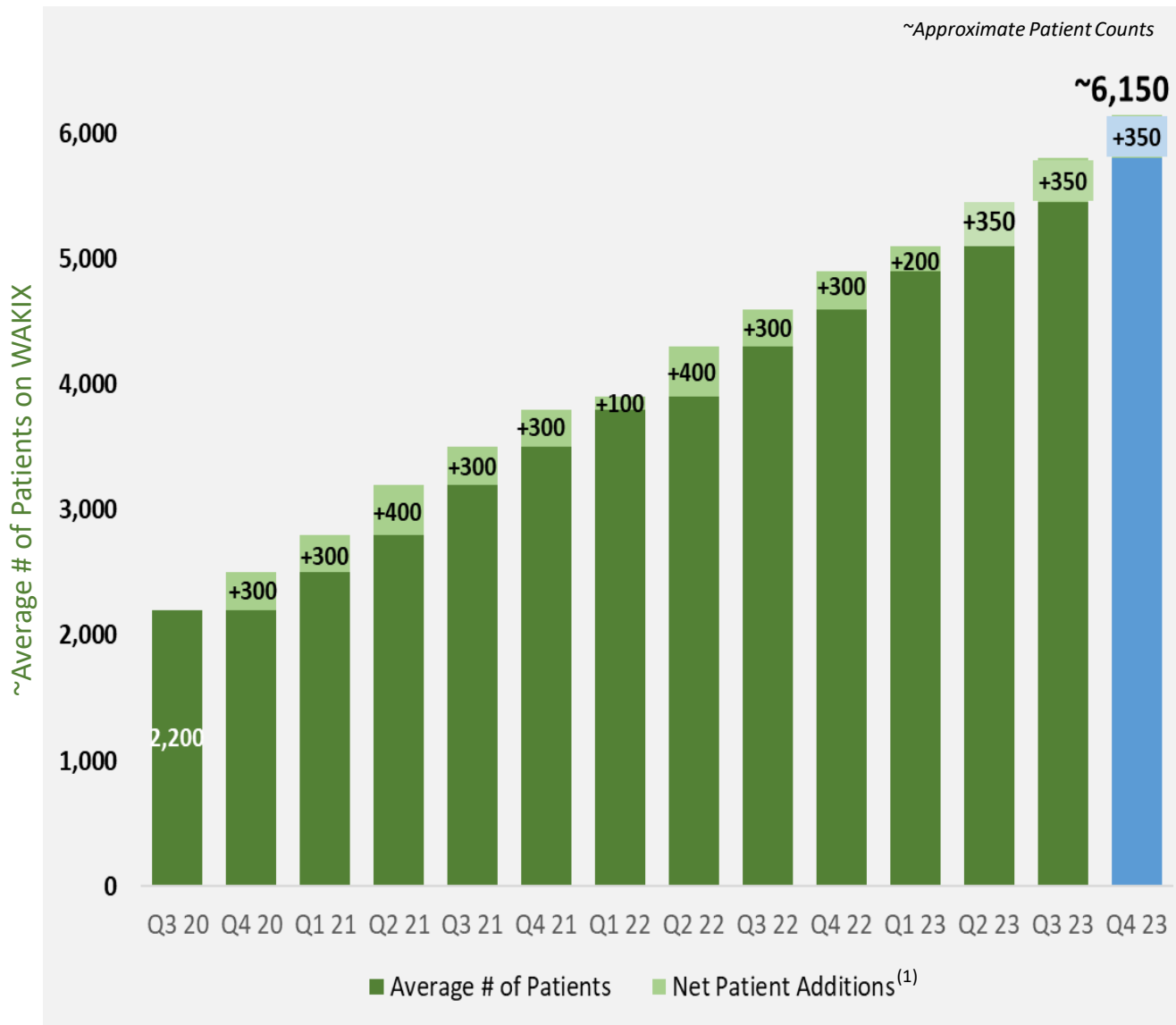
**33% Growth** vs. 2022

**\$700-\$720M**

2024  
Guidance

# Solid Business Fundamentals Driving Growth

## Continued Strong Performance in 2023 - Year 4 of Commercialization



### 2023 Highlights



**More unique prescribers of WAKIX than sodium oxybate**

**Strong market access coverage (~84%) - even with the launch of generic and new oxybate options**

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



## Top Unmet Needs in Narcolepsy

- Need for **non-scheduled treatment options** (low/no abuse potential)
- Need for **more tolerable** treatment regimens
- Need for **more effective** treatment options
- Need for **Novel MOAs** beyond currently available therapies needed
- Need for **less frequently dosed products**; need for once-daily options



## WAKIX Product Profile\*



● First and only FDA-approved **non-scheduled** treatment for narcolepsy

● Established safety & tolerability profile

● Approved for the **treatment of EDS or cataplexy in narcolepsy**

● First in class molecule with a **novel MOA** - The only selective H3 receptor antagonist/inverse agonist approved by the FDA

● **Once-daily** oral tablet administered in the morning upon waking

● **Not a stimulant** - no evidence of drug tolerance or withdrawal symptoms

● Can be used as **monotherapy** or administered **concomitantly** with other narcolepsy treatments (modafinil and sodium oxybate)

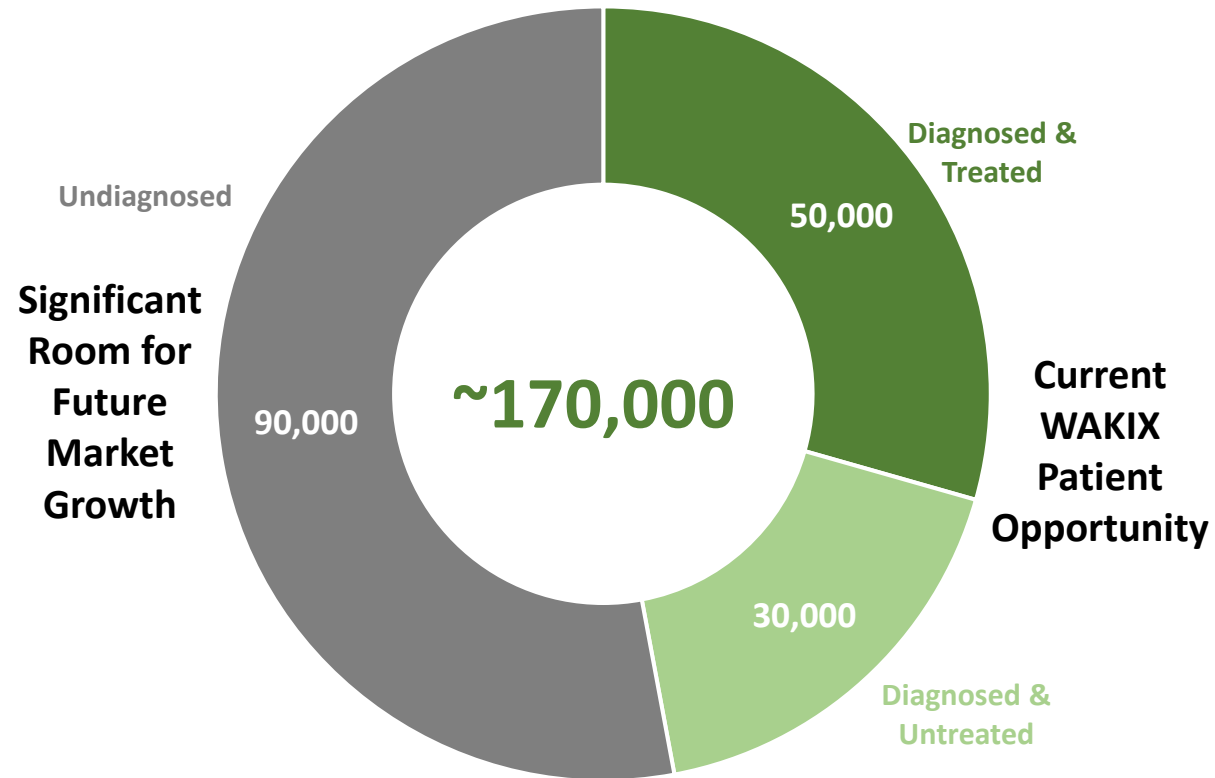
\* Based on FDA approved product labeling

Source: Harmony ATU, July 2018 (n=286); Versta Research, Know Narcolepsy Survey ("Know Narcolepsy"), October 2018; Unmet needs listed in descending order of importance stated by combined HCP and patient audience responses.



# Narcolepsy: Significant Remaining Market Opportunity

## People Living With Narcolepsy in the U.S.



Current Market Size<sup>1</sup>

**~\$2.5B 2022**

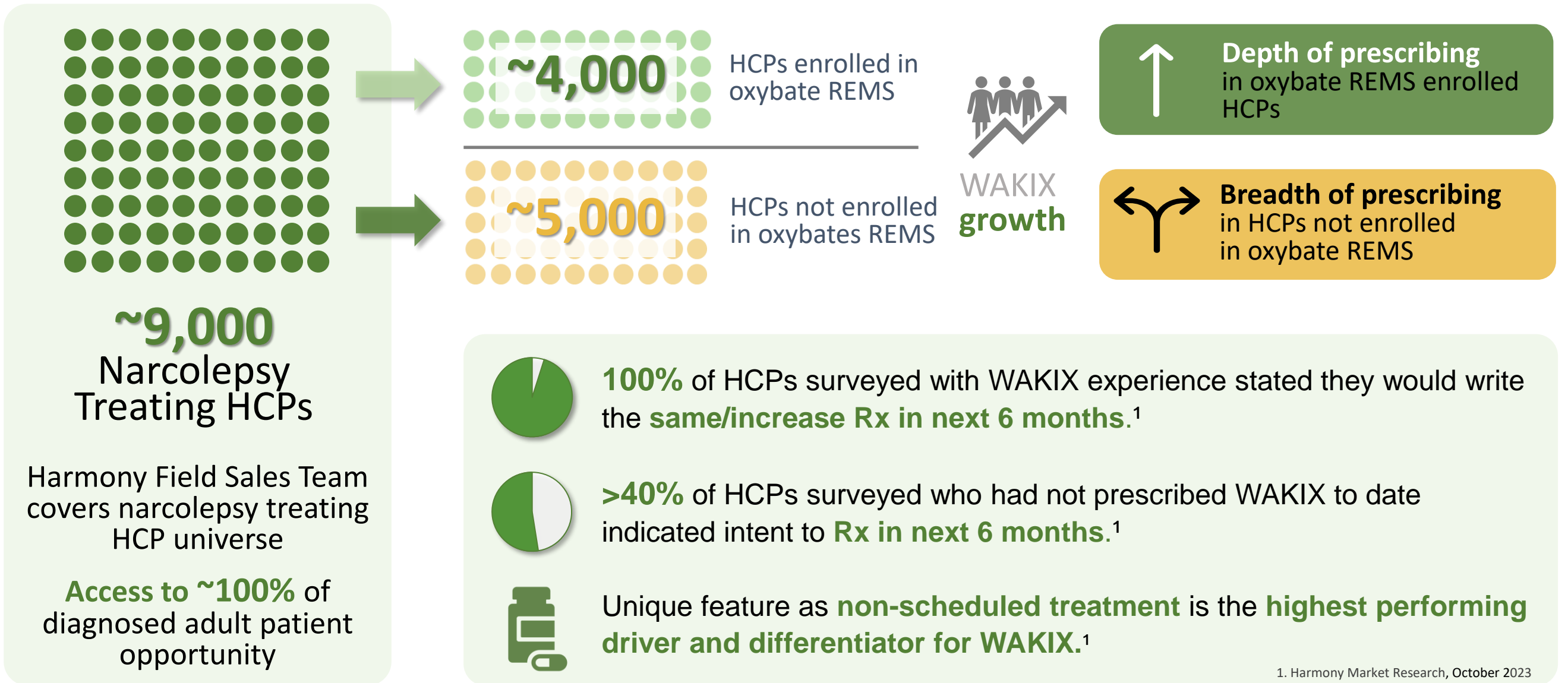
Estimated Total Market Opportunity<sup>2</sup>

**~\$5B by 2030**

### Growth Drivers

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

# Prescriber Dynamics Support Continued WAKIX® Growth in Adult Narcolepsy

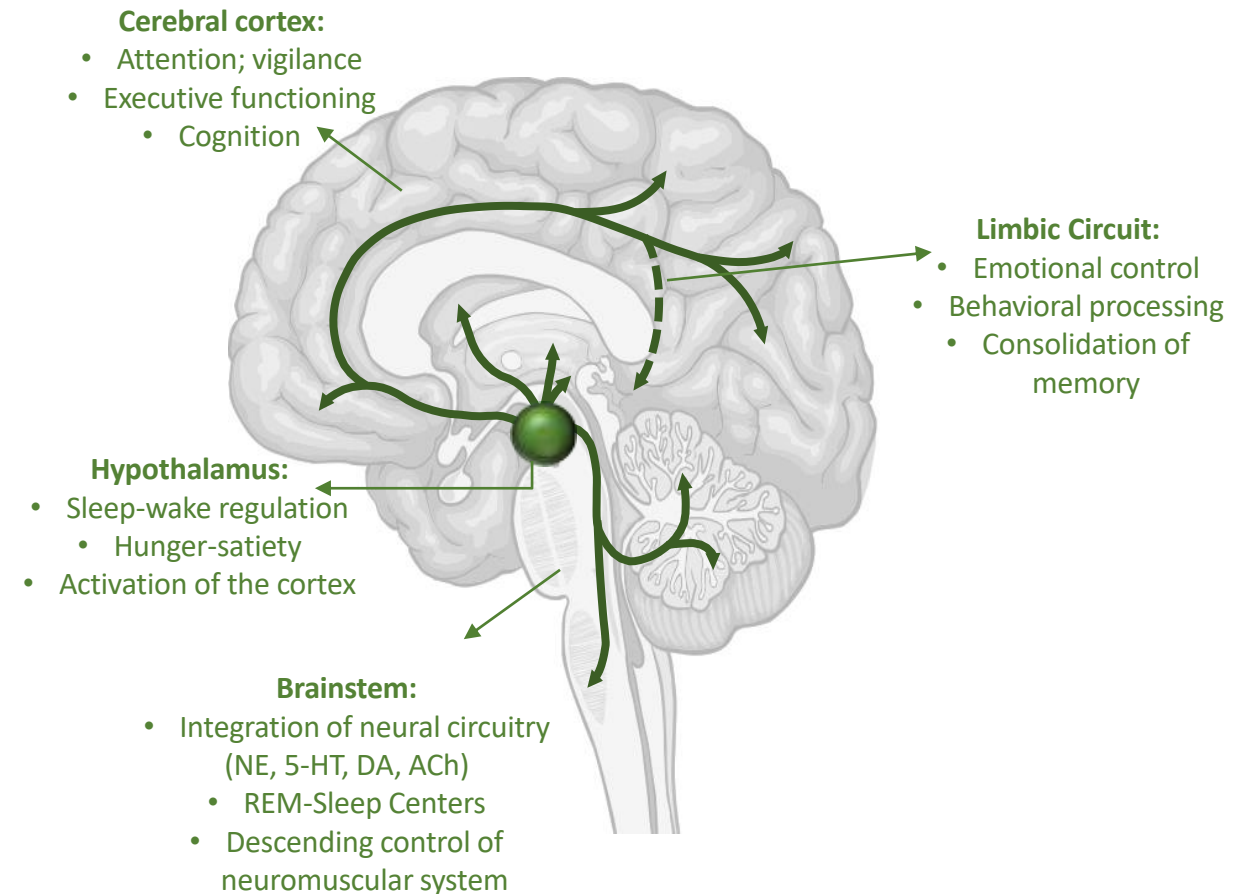


# Pitolisant: *Portfolio In a Product Opportunity*

*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 H<sub>3</sub> receptors throughout the CNS
- Limited H<sub>3</sub> receptor populations outside the CNS
- Proven clinical efficacy of pitolisant for EDS

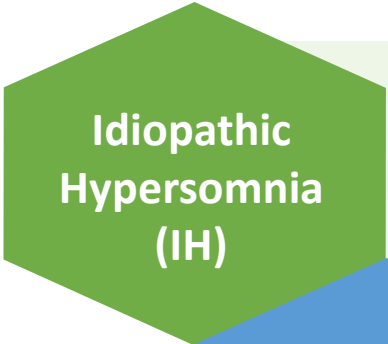
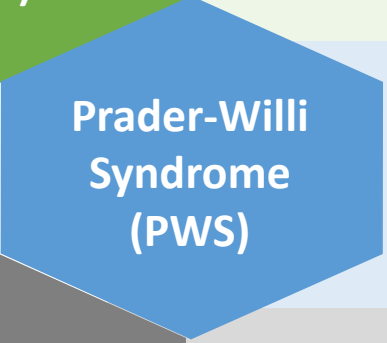
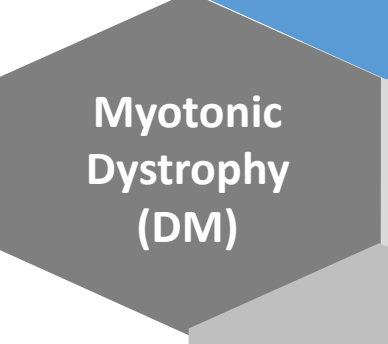
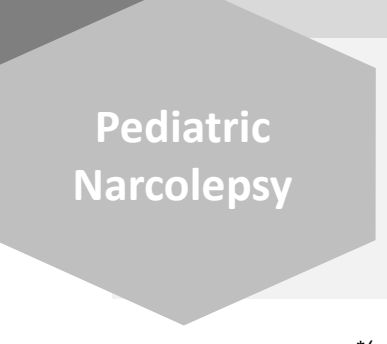


# Development Pipeline: Continues to Grow

Product / Indication	Pre-IND	Phase 1	Phase 2	Phase 3	Regulatory Filing	Marketed Product	Milestone
<b>WAKIX®</b>							
EDS in Narcolepsy (Adults)							
Cataplexy in Narcolepsy (Adults)							
<b>Pitolisant</b>							
Pediatric Narcolepsy <sup>(1)</sup>							PDUFA Date June 21, 2024
Idiopathic Hypersomnia (IH)							FDA Meeting March 2024
Prader-Willi Syndrome (PWS)							Initiate Ph3 Trial 1Q2024
Myotonic Dystrophy (DM)							Positive Topline Data 4Q2023
Next Gen Pitolisant Formulations							PK Data 1H2024
<b>ZYN002 (Cannabidiol Gel)</b>							
Fragile X Syndrome (FXS)							Topline Data Mid-2025
22q11.2 Deletion Syndrome (22q)							Ph 3 Prep Ongoing
<b>HBS-102</b>							
PWS							Preclinical POC Data 1H2024

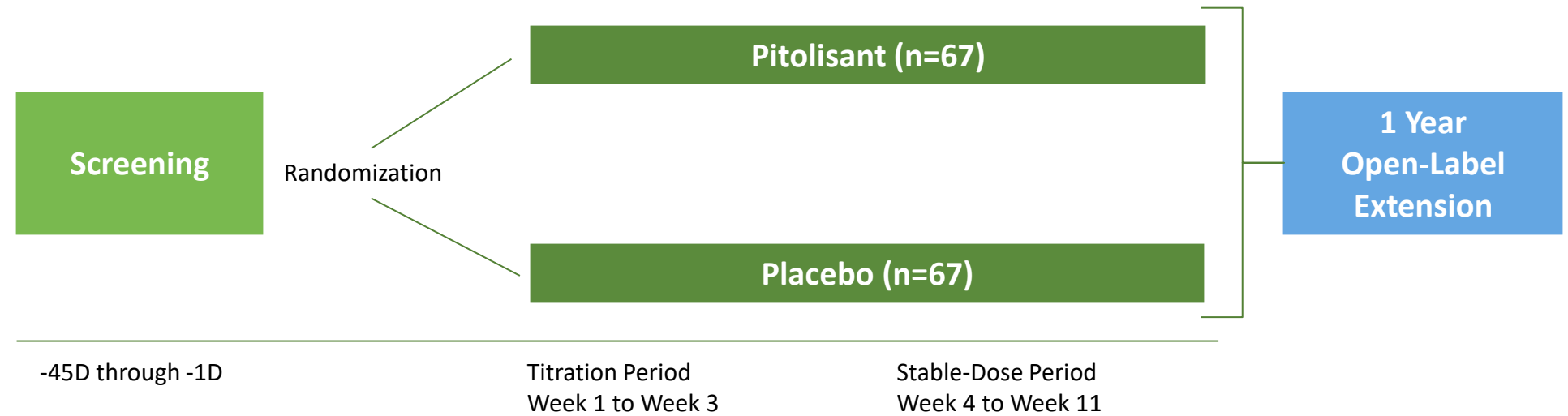
# Advancing our Pitolisant Lifecycle Management Programs

## Patient Opportunity Represents >100K Diagnosed Patients

	Data / Proof Point	Patient Opportunity	Catalyst / Timing
 <p>Idiopathic Hypersomnia (IH)</p>	<ul style="list-style-type: none"> <li>83% Responder Rate*</li> <li>9.4 pt. Reduction in EDS as measured by ESS in OLTP</li> </ul>	<p>~40,000 Diagnosed Patients<sup>1</sup></p>	<p>FDA Meeting March 2024 Update Q1 24 Earnings Call</p>
 <p>Prader-Willi Syndrome (PWS)</p>	<ul style="list-style-type: none"> <li>Clinically meaningful improvements seen in EDS and behavioral symptoms</li> </ul>	<p>~20,000 Diagnosed Patients<sup>2</sup></p>	<p>Phase 3 Study Initiation Q1 24</p>
 <p>Myotonic Dystrophy (DM)</p>	<ul style="list-style-type: none"> <li>Clinically meaningful improvements seen in EDS and fatigue symptoms</li> </ul>	<p>~40,000 Diagnosed Patients<sup>3</sup></p>	<p>Review of Data Ongoing Update in Q2 24</p>
 <p>Pediatric Narcolepsy</p>	<ul style="list-style-type: none"> <li>Positive Phase 3 study</li> <li>Approval in EU for EDS and cataplexy in age 6 and older</li> </ul>	<p>~4,000 Diagnosed Patients</p>	<p>Granted Priority Review PDUFA Date June 21, 2024</p>

\*(>=3 points improvement in ESS) ; OLTP = open label treatment period

# TEMPO: Global Phase 3 Trial of Pitolisant in PWS



## Trial Design:

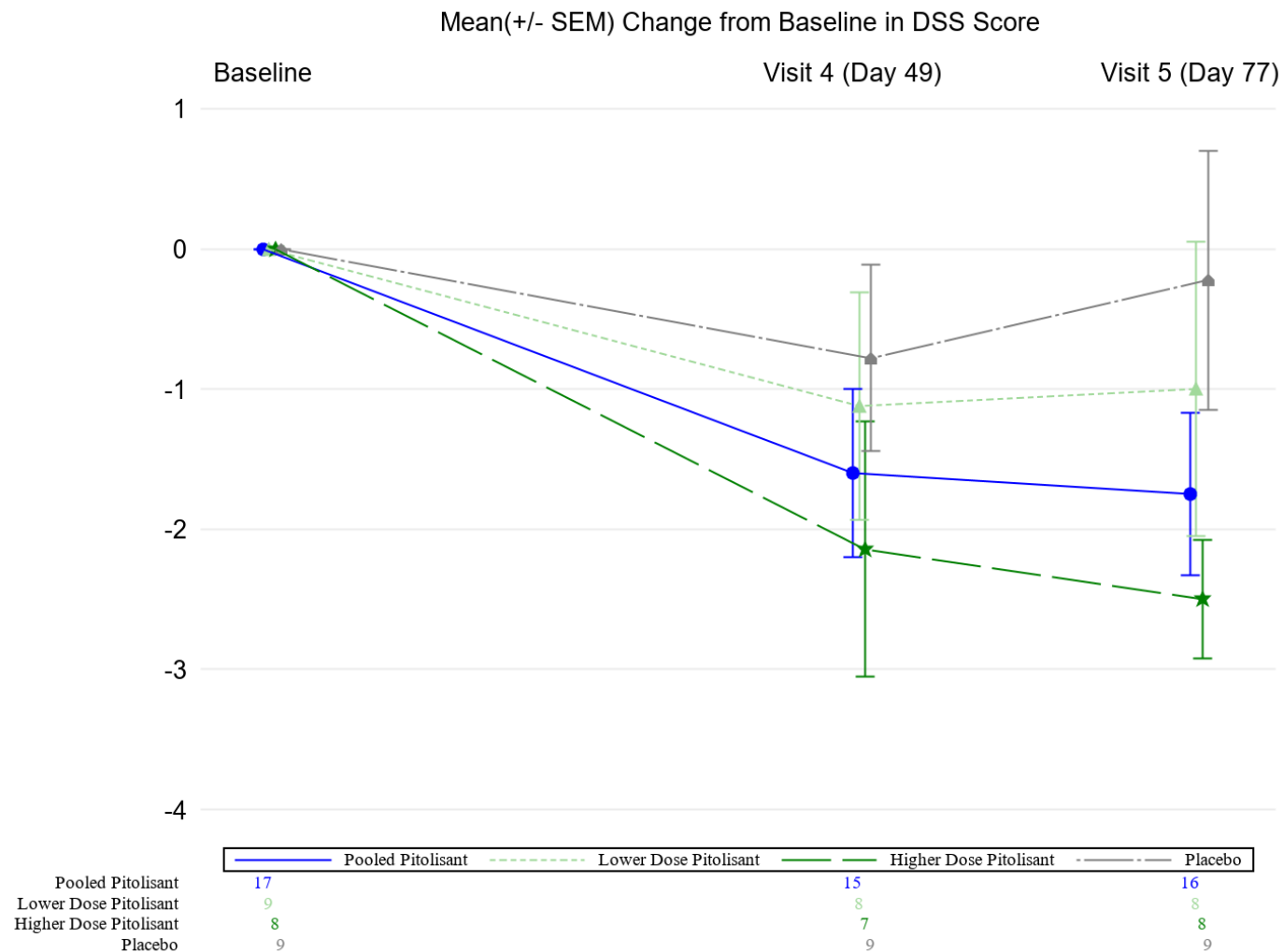
- Randomized, double-blind, placebo-controlled, parallel-group study
- 1:1 pitolisant : placebo
- 134 patients; ages 6 and older

## Objectives / Endpoints:

- **Primary objective:** to evaluate the efficacy of pitolisant on EDS in patients with PWS
- **Primary endpoint:** change in severity of EDS as measured by PROMIS-SRI T-score from Baseline to the end of the Double-Blind Treatment Period (Day 77)
- **Secondary objectives:** to evaluate the efficacy of pitolisant on irritability, hyperphagia and behavioral problems in PWS
- **Secondary endpoints:** ABC-C Irritability domain, HQ-CT, ABC-C Other domains

# DM1 Phase 2 POC Study Topline Data

## Change in Daytime Sleepiness Scale (DSS) from Baseline to End of Treatment Period



## Topline Data Highlights

- **Clinically meaningful signal in EDS (DSS, ESS and CGI-S)**
- **Clinically meaningful signal in Fatigue (FSS)**
  - Mean change from baseline of -0.86 and -0.36 for high-dose and low-dose pitolisant, respectively, compared to -0.13 for placebo
- **A clear and consistent dose-response** was demonstrated across the efficacy outcomes
- **Well tolerated** with an overall safety/tolerability profile consistent with the known profile of pitolisant
- **Next Steps:** Evaluate full data set and assess opportunity. Potentially pivot to next-gen formulations of pitolisant to advance program

# Extending the Pitolisant Franchise With Next-Gen Formulations

Anticipate Data in First Half of 2024

## Next-Gen Formulation 1

- **Opportunity:** Fast to market strategy for narcolepsy within WAKIX lifecycle
- **Formulation:** Modified formulation with potential clinical differentiation
- **Program:** Abbreviated development program
- **Status:** Phase 1 PK study initiated in Q4 23; data available in 1H 24

## Next-Gen Formulation 2

- **Opportunity:** Extend franchise beyond 2040, with potential for new IP and opportunity to explore additional indications
- **Formulation:** Enhanced formulation designed to deliver an optimized PK profile and a higher dosage strength
- **Program:** Full development program
- **Status:** Pilot PK study initiated in Q4 23; data available in 1H 24



# ZYN002: Potential New Therapeutic Option For Rare Neuropsychiatric Disorders

- First and only **pharmaceutically-manufactured synthetic cannabidiol**
- Another *Portfolio in a Product* opportunity
- **Two late-stage programs**: Phase 3 for Fragile X syndrome and Phase 3 ready for 22q11.2 deletion syndrome
- **Contains no THC**; potential to be non-scheduled
- **Patent protected** permeation-enhanced gel for **transdermal delivery**; benefit over oral cannabidiol products include:
  - Lower incidence of GI side effects (nausea, vomiting, diarrhea)
  - Avoids first pass metabolism
- **Well tolerated** safety profile with over 750 patients treated with ZYN002 in Phase 2/3 studies for various indications; some patients with exposure to ZYN-002 for over 6 years
- Patent protection through at least **2040** for the treatment of FXS

**RECONNECT**

# Diversifying Our Portfolio Beyond Sleep/Wake

## Fragile X Syndrome (FXS) ~80K U.S. Patients

- Rare neuropsychiatric disorder; leading known cause of inherited intellectual disability and autism spectrum disorder
- Mutation of the FMR1 gene causes endocannabinoid system (ECS) dysregulation
  - Easily identified mutation manifests as multiple CGG repeats on FMR1 (complete methylation usually >200 repeats)
  - Resulting in cognitive, social, and behavioral symptoms
- No FDA approved treatments

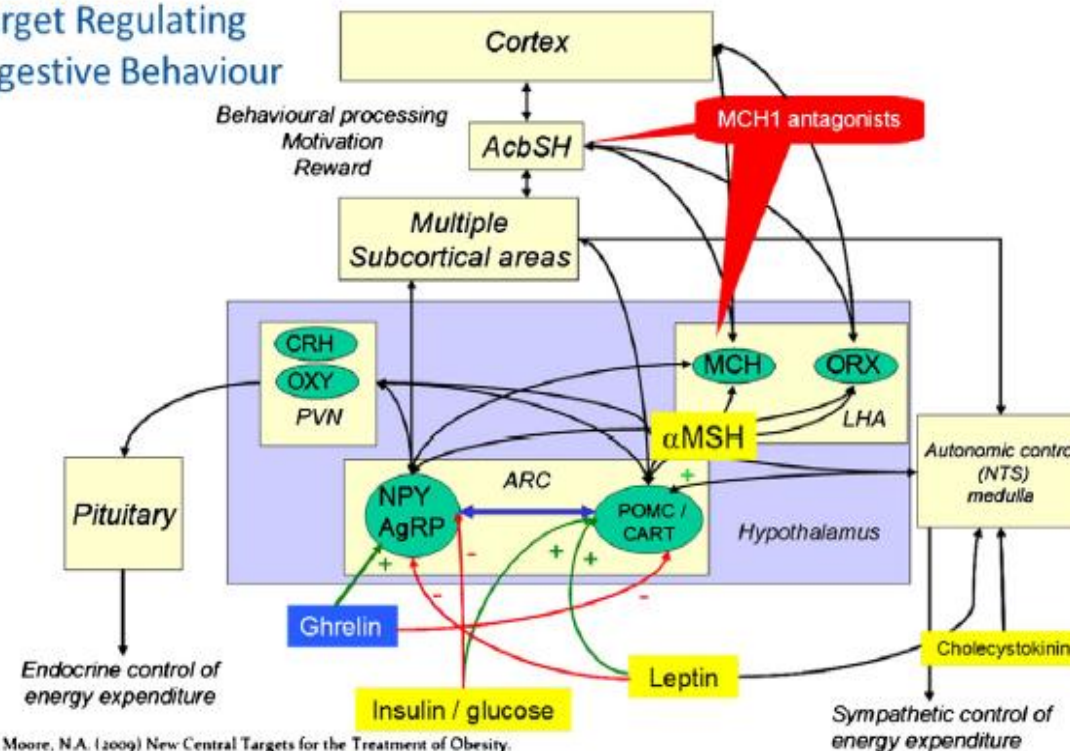
## 22q11.2 Deletion Syndrome (22q) ~80K U.S. Patients

- Rare genetic disorder due to microdeletion at q11.2 on chromosome 22
- Midline abnormalities affecting palate, face, heart and other organs; surgically corrected in infancy
- Behavioral symptoms and learning disabilities common
  - Early onset of neuropsychiatric symptoms such as anxiety, social avoidance, disrupts development and quality of life
- No FDA approved treatments

# 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

## MCH<sub>1</sub>: 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.

# Disciplined Capital Allocation to Maximize Shareholder Value

PROFITABILITY AND CASH GENERATION PROVIDES  
FINANCIAL STRENGTH AND FLEXIBILITY FOR CAPITAL DEPLOYMENT



## Business Development

- **High priority** to build out pipeline, diversify portfolio, and drive long-term growth
- **Dedicated BD team** and internal capabilities across clinical development, regulatory affairs, commercial launch and execution
- **Focus on rare neurological disease assets** and other rare disease assets with unmet medical needs
- **Preference for late-stage assets** but open to early-stage assets with strategic fit

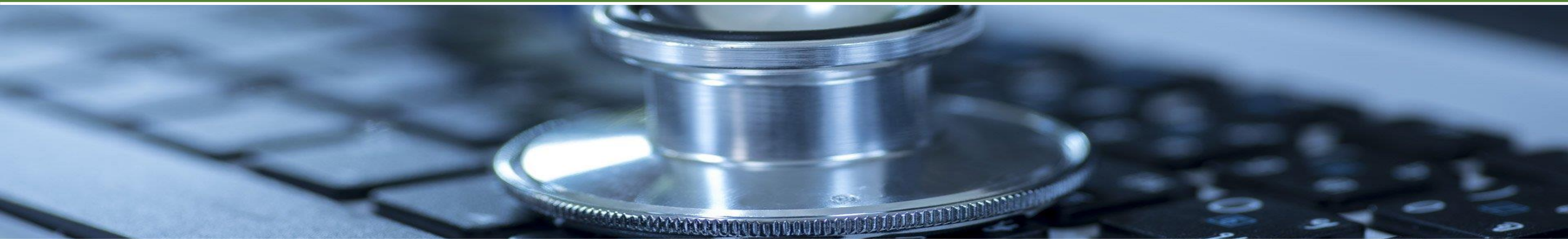


## Capital Return

- Initiated share repurchase program in August of 2023
- Repurchased **~3.2M** shares of common stock at an aggregate cost of **\$100M** during 2023
- Remaining program authorization of **\$150M**
- Opportunistic approach to **maximize shareholder value**



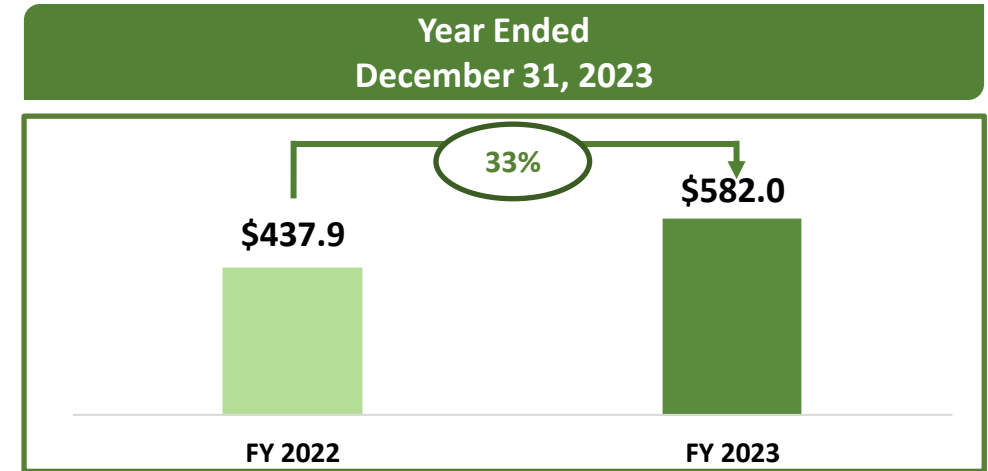
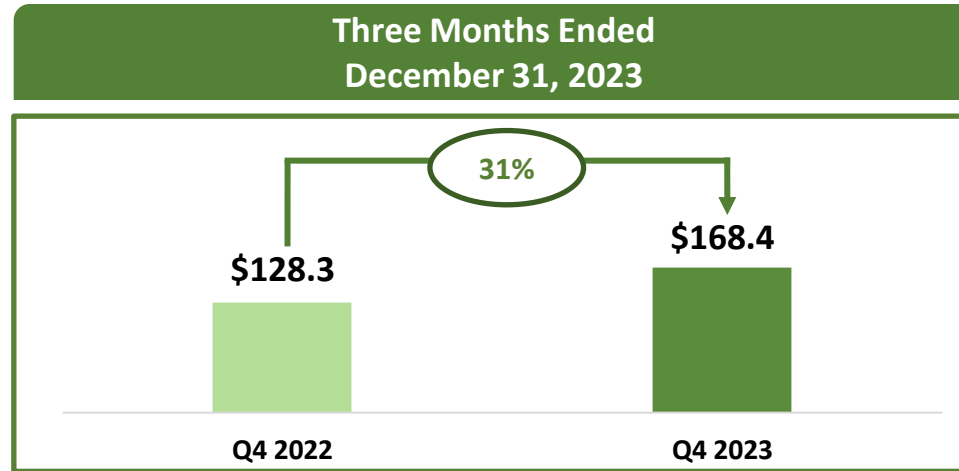
## FINANCIALS



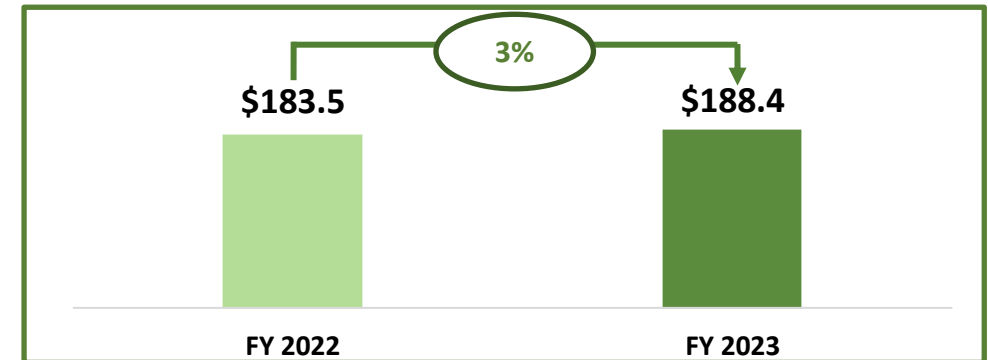
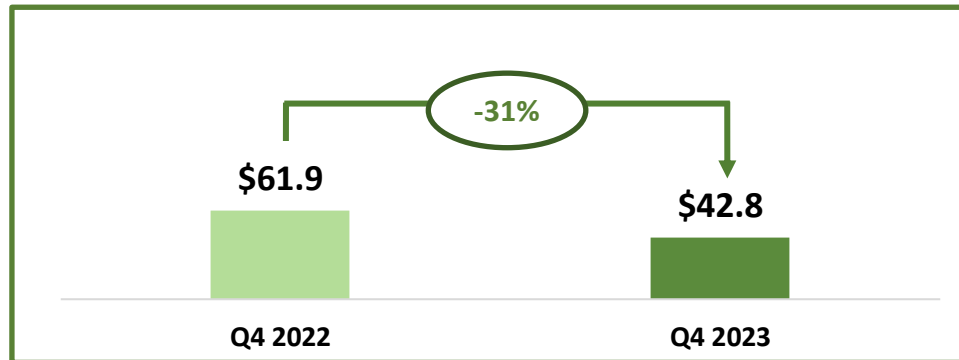
# Financial Highlights

(In millions, USD)

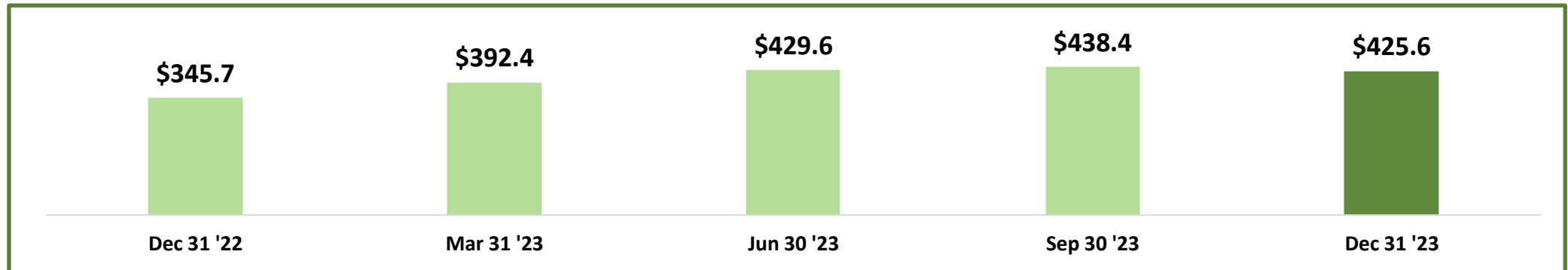
**Net Product Revenue**



**Non-GAAP Adjusted Net Income<sup>(1)</sup>**



**Cash, Cash Equivalents & Investment Securities**



(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

# Financial Summary

<i>(In millions, USD)</i>	Three Months Ended December 31,		% Change	Year Ended December 31,		% Change
	2023	2022		2023	2022	
Totals may not foot due to rounding						
<b>Net Product Revenue</b>	<b>\$168.4</b>	<b>\$128.3</b>	<b>31%</b>	<b>\$582.0</b>	<b>\$437.9</b>	<b>33%</b>
Cost of Product Sold	43.2	26.9	61%	121.2	83.5	45%
<b>Total Operating Expenses</b>	<b>\$85.1</b>	<b>\$53.8</b>	<b>58%</b>	<b>\$268.8</b>	<b>\$234.2</b>	<b>15%</b>
R&D Expense <sup>(1)</sup>	30.3	10.1	NM	76.1	70.9	7%
S&M Expense	26.9	21.1	28%	97.4	79.3	23%
G&A Expense <sup>(2)</sup>	27.9	22.6	23%	95.3	84.0	13%
<b>Net Income</b>	<b>\$26.6</b>	<b>\$48.5</b>	<b>(45%)</b>	<b>\$128.9</b>	<b>\$181.5</b>	<b>(29%)</b>
<b>Cash, cash equivalents &amp; investment securities</b>				<b>\$425.6</b>	<b>\$345.7</b>	<b>23%</b>

NM denotes not meaningful % change

(1) Includes one-time Zynerva transaction related costs of \$6.0M for the three months and year ended December 31, 2023

(2) Includes one-time Zynerva transaction related costs of \$3.8M for the three months and year ended December 31, 2023

# GAAP vs NON-GAAP Reconciliation

<i>(In millions, USD)</i>	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Totals may not foot due to rounding				
<b>GAAP net income</b>	<b>\$26.6</b>	<b>\$48.5</b>	<b>\$128.8</b>	<b>\$181.5</b>
Non-cash interest expense <sup>(1)</sup>	0.2	0.4	3.2	1.7
Depreciation	0.2	0.1	0.5	0.4
Amortization <sup>(2)</sup>	6.0	6.0	23.8	23.0
Stock-based compensation expense	8.9	7.7	31.2	26.9
Transaction related costs <sup>(3)</sup>	9.8	-	9.8	-
Loss on debt extinguishment	-	-	9.8	-
Licensing fees and milestone payments <sup>(4)</sup>	-	-	0.8	30.0
Valuation allowance release	-	-	-	(74.5)
Income tax effect related to Non-GAAP adjustments <sup>(5)</sup>	(8.8)	(0.7)	(19.6)	(5.4)
<b>Non-GAAP adjusted net income</b>	<b>\$42.8</b>	<b>\$61.9</b>	<b>\$188.4</b>	<b>\$183.5</b>
<b>GAAP net income per diluted share</b>	<b>\$0.45</b>	<b>\$0.79</b>	<b>\$2.13</b>	<b>\$2.97</b>
<b>Non-GAAP adjusted net income per diluted share</b>	<b>\$0.73</b>	<b>\$1.01</b>	<b>\$3.12</b>	<b>\$3.00</b>
Weighted average number of shares of common stock used in non-GAAP diluted per share	58,853,292	61,620,712	60,372,397	61,097,045

(1) Includes amortization of deferred finance charges.

(2) Includes amortization of intangible asset related to WAKIX.

(3) Includes costs associated with the acquisition of Zynerba in October 2023. There were \$2.3M of IPR&D charges and \$3.7M of severance recorded in research and development expenses and \$3.8M of severance recorded in general and administrative expenses.

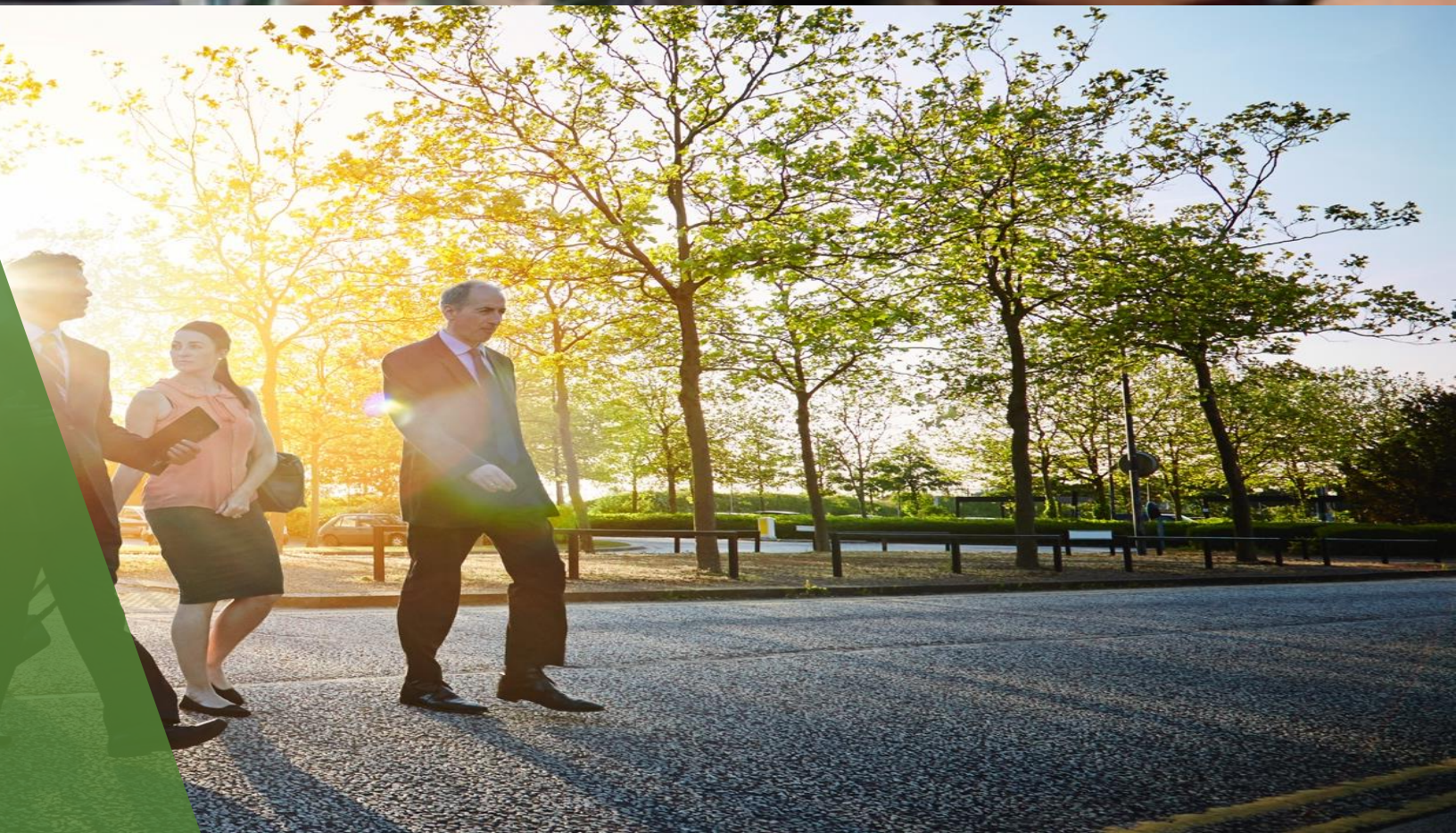
(4) Includes a \$0.8M milestone payment related to HBS-102 preclinical milestone in March 2023 and \$30M licensing fee incurred upon closing the 2022 Licensing and Commercialization Agreement with Bioprojet in August 2022.

(5) Calculated using the reported effective tax rate for the periods presented less impact of valuation allowance release and discrete items.



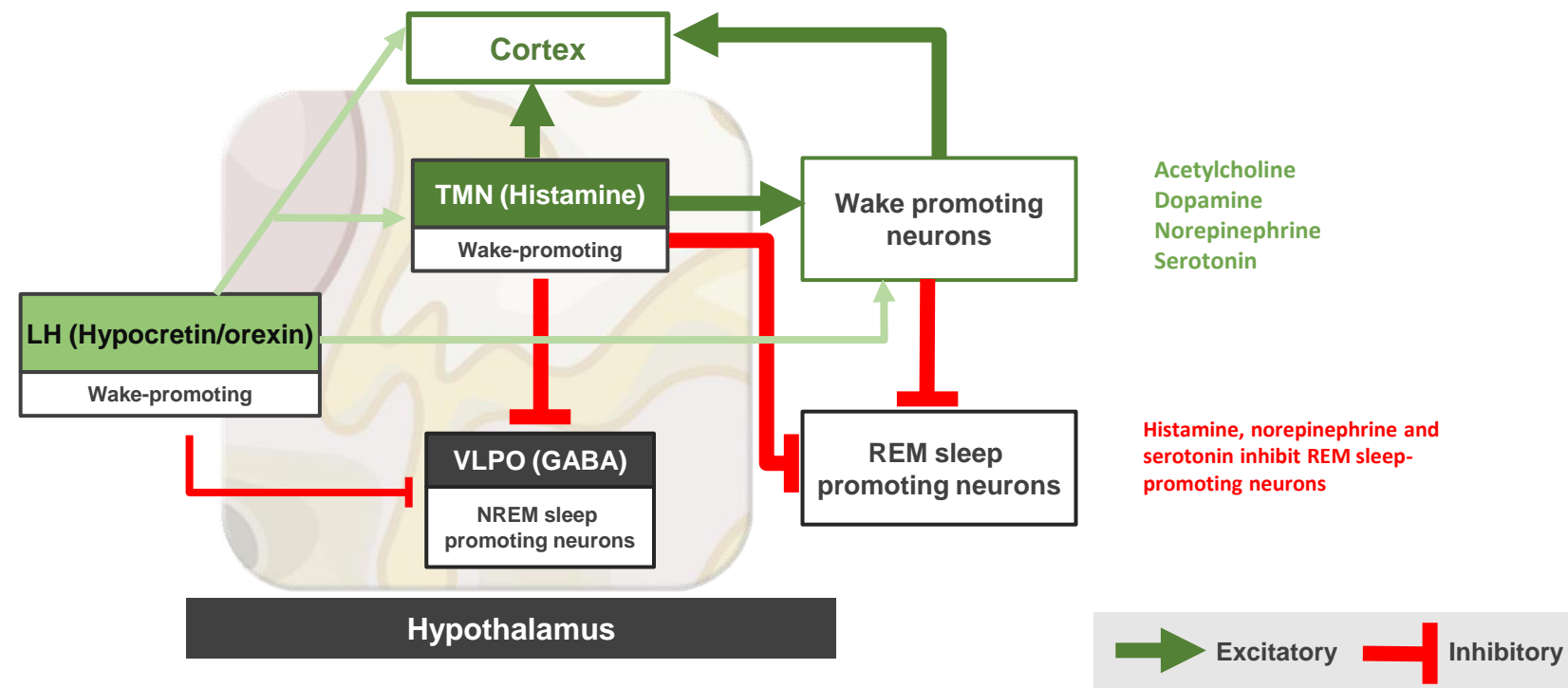


# Appendix



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

- **Pitolisant** - Potent, highly selective histamine 3 (H<sub>3</sub>) 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<sup>®</sup> Phase 3 Clinical Development Program

Name of Study Study Design	Number of Patients	Maximum Dose; % at that Dose	Primary Objective	Results
<b>HARMONY 1</b> 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)
<b>HARMONY 1bis</b> 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)
<b>HARMONY CTP</b> 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)
<b>HARMONY 3</b> 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
<b>Human Abuse Potential Study</b> 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)

# WAKIX<sup>®</sup> : 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

# AASM Treatment Guideline on Central Disorders of Hypersomnolence

**Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline**  
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**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.

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Thank You

