HARMONY BIOSCIENCES

42nd Annual J.P. Morgan Healthcare Conference

January 2024

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Who We Are

HARMONY BIOSCIENCES

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

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

Launched WAKIX

IND for Prader-Willi Syndrome (PWS)

GROWTH & EXPANSION

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

Surpassed $500M in WAKIX Annual 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

Executing Our Growth Strategy: *2023 Accomplishments*

Continued Strong Growth For WAKIX® in Adult Narcolepsy

- FY 2023 WAKIX Net Revenue of ~$582M **+33% Year-over-Year Growth**[1]
- **~6,150** average number of patients on WAKIX in Q4 2023
- **Continued strong growth** in average number of patients & WAKIX prescriber base

Advance and Expand the Pipeline

- **Expanded the pipeline and diversified the portfolio** with acquisition of Zynerba Pharmaceuticals; ZYN-002 in Phase 3 pivotal trial for Fragile X syndrome and Phase 3 ready for 22q deletion syndrome
- Reported topline results from Phase 3 INTUNE study; **remain committed to IH patient community and actively pursuing IH indication**
- **Advanced PWS program** with Phase 3 TEMPO study expected to initiate in Q1 24
- **Reported positive** topline results from DM1 Phase 2 POC study
- **Submitted** pediatric narcolepsy sNDA in Q4 23
- **Advanced new pitolisant based** formulations into the clinic

Disciplined Capital Allocation to Maximize Shareholder Value

- **Profitable**, **cash generating** with **$438.4M** on the balance sheet as of September 30, 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

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1. Preliminary Unaudited

Harmony Today: A Profitable and Rapidly Growing CNS Focused Company

Strong Commercial Success With WAKIX® in Adult Narcolepsy

- ~$582M in Net Revenue for Full Year 2023[1] with ~6,150 Average Patients on WAKIX in Q4 2023
- Potential $1B+ Net Revenue Opportunity in Narcolepsy Alone & Well on Our Way
- More unique prescribers of WAKIX than sodium oxybate

An Expanding Late-Stage Pipeline With Multiple Phase 3 Assets

- Up to Additional $1B, If Approved in Current Pitolisant LCM Programs
- New Pitolisant-based formulations designed to generate new IP out beyond 2040
- ZYN-002 in Phase 3 for Fragile X syndrome (Phase 3 ready for 22q11.2 deletion syndrome)

Profitable and Cash Generating Providing Financial Strength and Flexibility to Further Build Out Our Pipeline and Deploy Capital to Maximize Shareholder Value

- ~$438M in Cash, Cash Equivalents and Investments as of September 30, 2023
- Active in business development to expand our pipeline, diversify our portfolio, and extend our growth trajectory

1. Preliminary Unaudited

Executing Our Growth Strategy: *2024 Priorities*

Continued Strong Growth For WAKIX® in Adult Narcolepsy

- Drive commercial strategy to achieve Net Revenue >$700M
- Grow average number of patients on WAKIX to ~7,000
- Increase educational outreach to drive continued growth in depth and breadth of prescriber base and patient interest in WAKIX

Advance and Expand the Pipeline

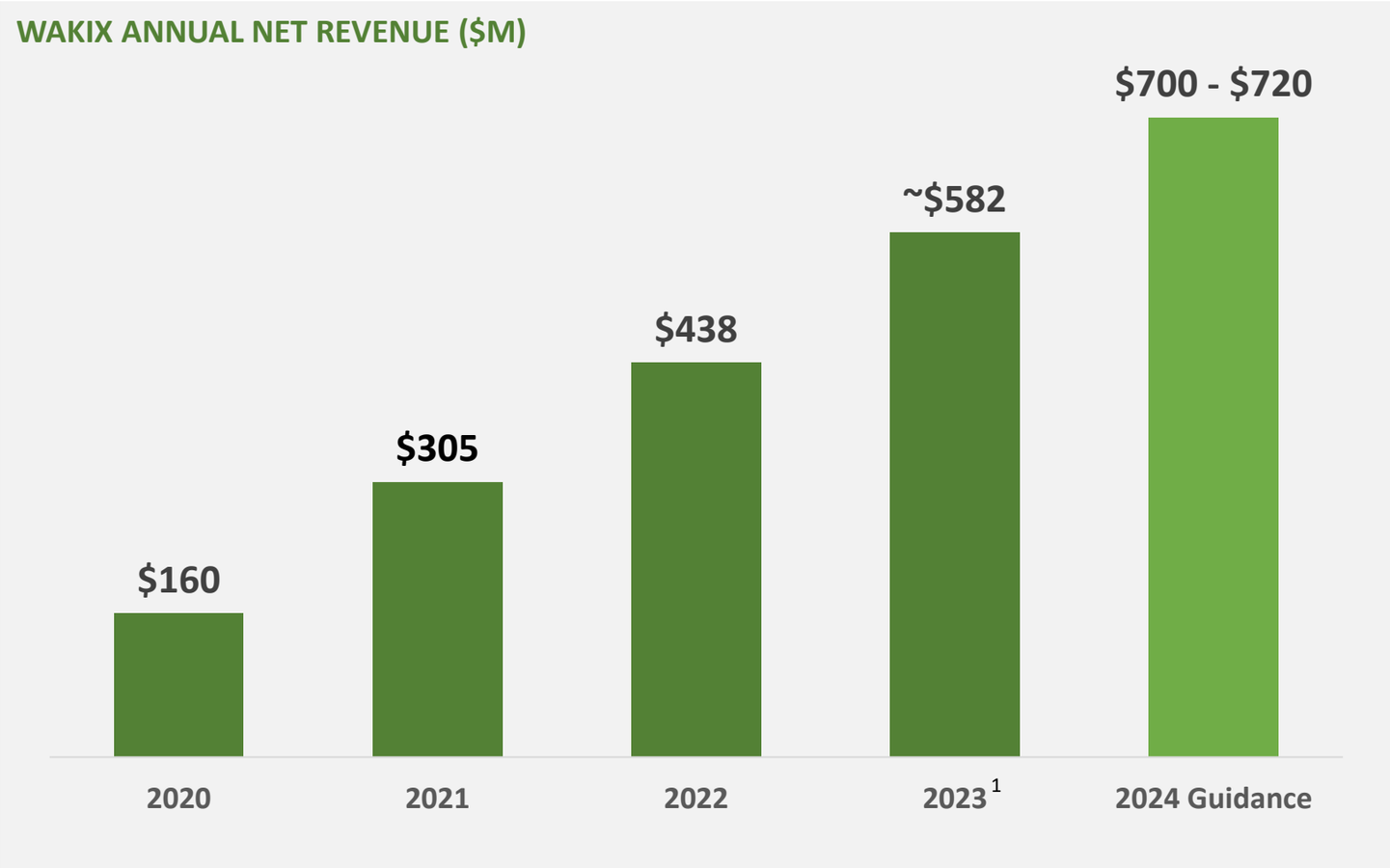
- Report pharmacokinetic (PK) data on new pitolisant-based formulations in 1H 24
- Drive patient enrollment in the Phase 3 pivotal RECONNECT trial for Fragile X syndrome
- Initiate Phase 3 TEMPO study in PWS in Q1 24
- FDA meeting request submitted to discuss IH path forward; anticipate meeting in Q1 24
- Complete review of positive DM1 Phase 2 POC data in EDS and fatigue; assess opportunity

Disciplined Capital Allocation to Maximize Shareholder Value

- Actively pursue business development opportunities to expand our pipeline and diversify our portfolio
- Continued opportunistic execution of share repurchase program

Strong Track Record of Commercial Performance

CONFIDENT IN WAKIX BEING A POTENTIAL $1B+ OPPORTUNITY IN ADULT NARCOLEPSY ALONE



~$582M[1] 2023 Net Revenue

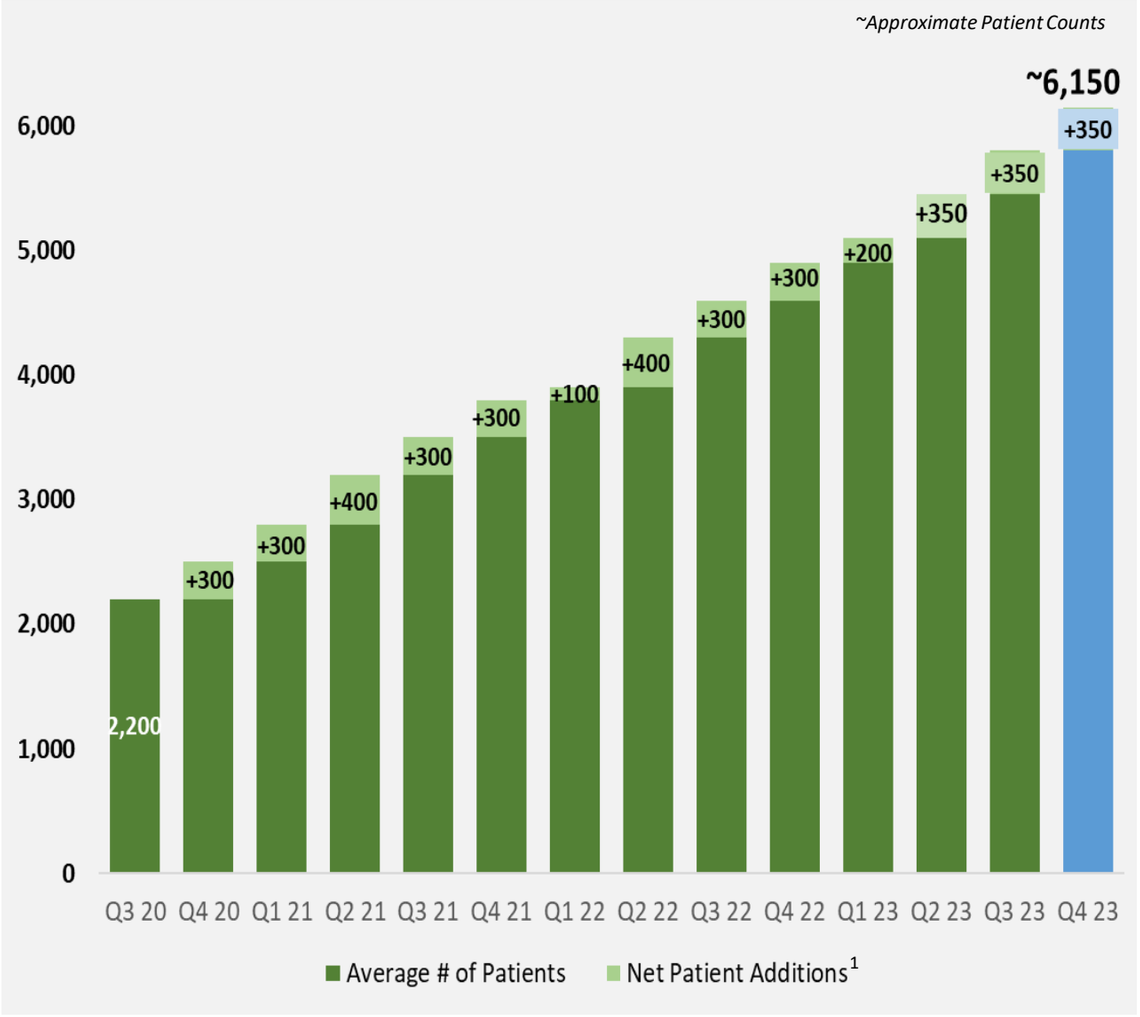
33% Growth[1] vs. 2022

$700-$720M 2024 Guidance

1. Preliminary Unaudited

Solid Business Fundamentals Driving Growth

Continued Strong Performance in 2023 - Year 4 of Commercialization



2023 Highlights

- Highest Number of New Patient Starts in our history (Q2 23)
- ~6,150 Average number patients on WAKIX and growing (Q4 23)
- Highest Quarter of Net Sales in our history- $168M[2] (Q4 23)
- On our way to a $1B+ opportunity in adult narcolepsy

More unique prescribers of WAKIX than sodium oxybate

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

1. Net Patient Additions based on previously disclosed quarterly average number of patients on WAKIX
2. Preliminary Unaudited

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*

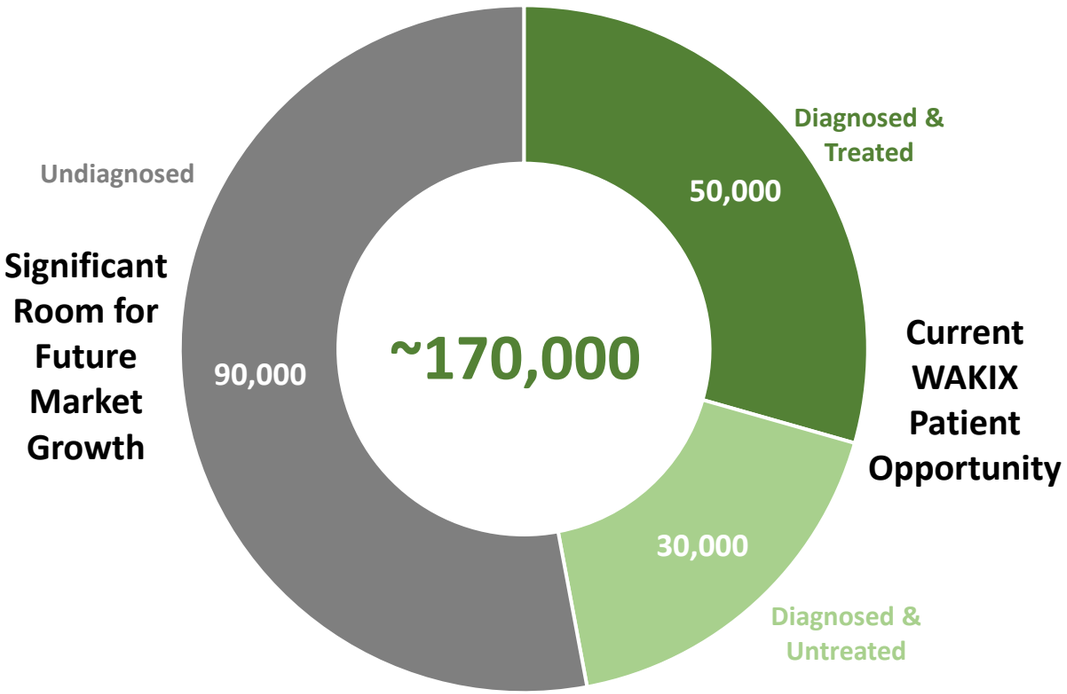
- First and only FDA-approved **non-scheduled** treatment for narcolepsy
- **Established safety & tolerability profile**
- Approved for the **treatment of EDS or cataplexy in narcolepsy**
- First in class molecule with a **novel MOA** - The only selective H3 receptor antagonist/inverse agonist approved by the FDA
- **Once-daily** oral tablet administered in the morning upon wakening
- **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[1]

~$2.5B 2022

Estimated Total Market Opportunity[2]

~$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

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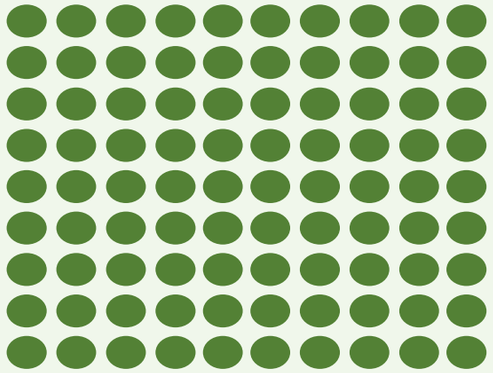
Source: 1. 2022 Net Sales based on US Market: Generics-based on IMS Data Nov 2022 MAT and internal factoring of narcolepsy use; Sodium oxybate, Sunosi based on Q4 2022 Jazz/Axsome Earnings calls
2. 2030 Projections based on US Market: Generics-based on IMS Data Nov 2022 MAT and internal factoring of narcolepsy use; Sodium oxybate based on Q4 2022 Jazz Earning call, Cowen analyst report projections – 4May 2022; Sunosi based on Axsome Earnings call projections; Other branded entrants modeled based on Internal Harmony market research

Prescriber Dynamics Support Continued WAKIX® Growth in Adult Narcolepsy

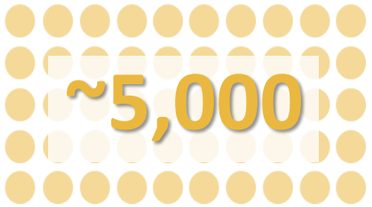


~9,000
Narcolepsy Treating HCPs

Harmony Field Sales Team covers narcolepsy treating HCP universe

Access to ~100% of diagnosed adult patient opportunity

~4,000 HCPs enrolled in oxybate REMS



~5,000 HCPs not enrolled in oxybates REMS

WAKIX **growth**

Depth of prescribing in oxybate REMS enrolled HCPs

Breadth of prescribing in HCPs not enrolled in oxybate REMS

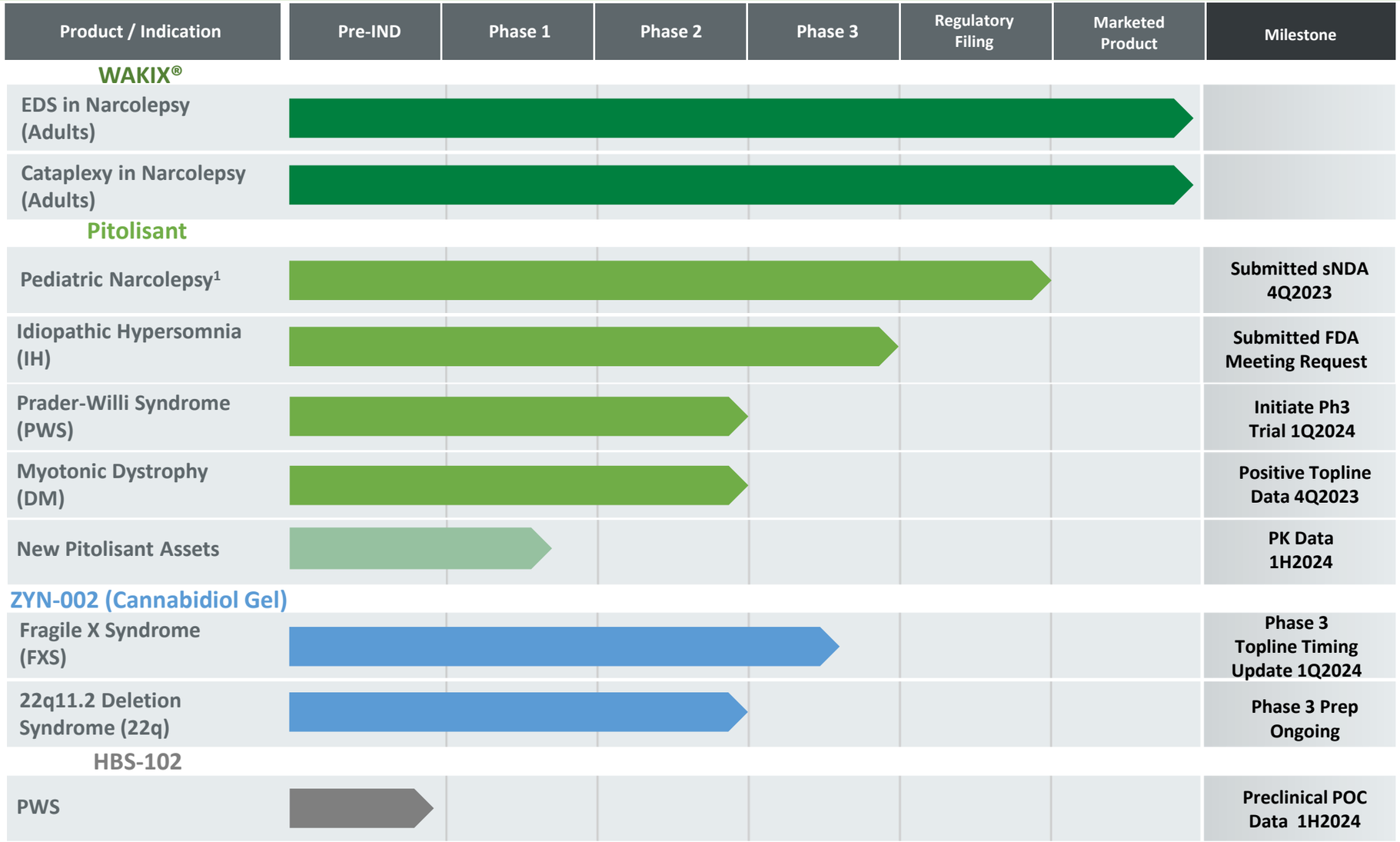
100% of HCPs surveyed with WAKIX experience stated they would write the **same/increase Rx in next 6 months.**[1]

>40% of HCPs surveyed who had not prescribed WAKIX to date indicated intent to **Rx in next 6 months.**[1]

Unique feature as **non-scheduled treatment** is the **highest performing driver and differentiator for WAKIX.**[1]

1. Harmony Market Research, October 2023

Development Pipeline: Continues to Grow



1. Trial conducted by Bioprojet; received EMA approval on March 15, 2023.

Advancing our Pitolisant Lifecycle Management Programs

Patient Opportunity Represents >100K Diagnosed Patients

	Data / Proof Point	Patient Opportunity	Catalyst / Timing
Idiopathic Hypersomnia (IH)	▪ **83%** Responder Rate* ▪ **9.4 pt.** Reduction in EDS as measured by ESS in OLTP	**~40,000** Diagnosed Patients [1]	FDA Meeting Request submitted in Q4 23 Update Q1 24 Earnings Call
Prader-Willi Syndrome (PWS)	▪ Clinically meaningful improvements seen in EDS and behavioral symptoms	**~20,000** Diagnosed Patients[2]	Phase 3 study initiation Q1 24 Update Q4 23 Earnings Call
Myotonic Dystrophy (DM)	▪ Clinically meaningful improvements seen in EDS and fatigue symptoms	**~40,000** Diagnosed Patients[3]	Review of data ongoing Update in Q2 24
Pediatric Narcolepsy	▪ Positive Phase 3 study ▪ Approval in EU for EDS and cataplexy in age 6 and older	**~4,000** Diagnosed Patients	sNDA filed with FDA in Q4 23 Update Q4 23 Earnings Call

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

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Sources: 1. Acquavella et al., *J Clin Sleep Med*, 2020; 2. Camfferman, Sleep Medicine Reviews, 2008; 3. https://www.myotonic.org/; accessed June 2020.

Extending the Pitolisant Franchise With New Formulations

Anticipate Data in First Half of 2024

Formulation 1

- **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

Formulation 2

- **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

ZYN-002: 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 ZYN-002 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

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**

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Thank You