



Q1 2025

**Financial Results
&
Business Update**

May 6, 2025

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding our full year 2024 net product revenue, expectations for the growth and value of WAKIX, plans to submit an sNDA for pitolisant in idiopathic hypersomnia; our future results of operations and financial position, business strategy, products, prospective products, product approvals, the plans and objectives of management for future operations and future results of anticipated products. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: our commercialization efforts and strategy for WAKIX; the rate and degree of market acceptance and clinical utility of pitolisant in additional indications, if approved, and any other product candidates we may develop or acquire, if approved; our research and development plans, including our plans to explore the therapeutic potential of pitolisant in additional indications; our ongoing and planned clinical trials; our ability to expand the scope of our license agreements with Bioprojet Société Civile de Recherche ("Bioprojet"); the availability of favorable insurance coverage and reimbursement for WAKIX; the timing of, and our ability to obtain, regulatory approvals for pitolisant for other indications as well as any other product candidates; our estimates regarding expenses, future revenue, capital requirements and additional financing needs; our ability to identify, acquire and integrate additional products or product candidates with significant commercial potential that are consistent with our commercial objectives; our commercialization, marketing and manufacturing capabilities and strategy; significant competition in our industry; our intellectual property position; loss or retirement of key members of management; failure to successfully execute our growth strategy, including any delays in our planned future growth; our failure to maintain effective internal controls; the impact of government laws and regulations; volatility and fluctuations in the price of our common stock; the significant costs and required management time as a result of operating as a public company; the fact that the price of Harmony's common stock may be volatile and fluctuate substantially; statements related to our intended share repurchases and repurchase timeframe and the significant costs and required management time as a result of operating as a public company. These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 25, 2025, and our other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

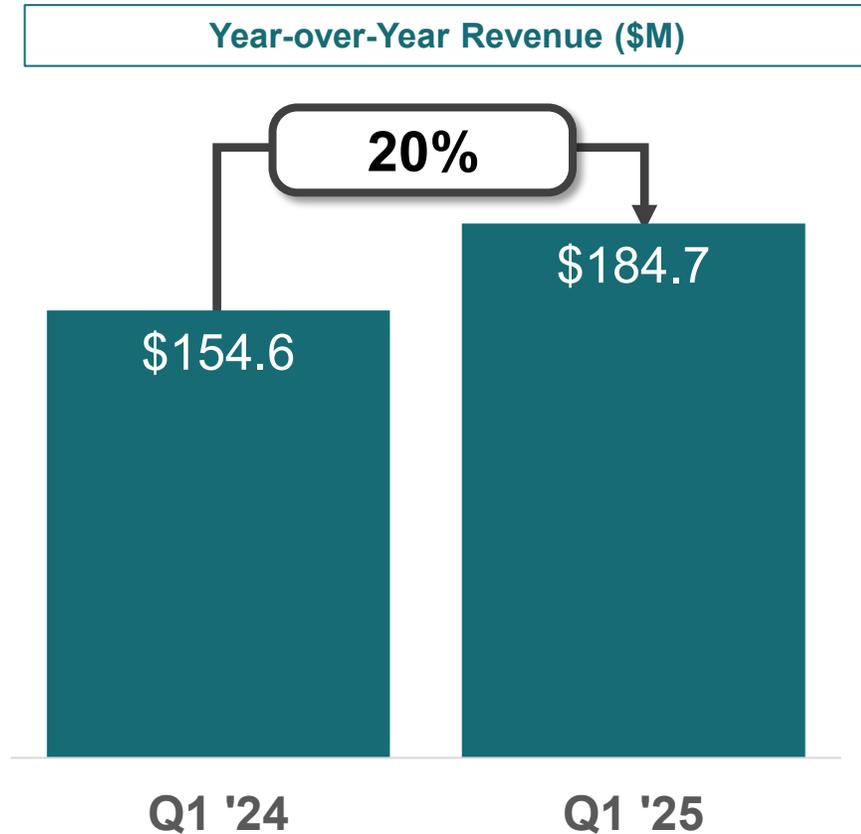


HARMONY
BIOSCIENCES

UNIQUE COMPANY PROFILE

- ✓ 4+ YEARS OF PROFITABILITY;
\$600M+ ON BALANCE SHEET
- ✓ SELF-FUNDING BIOTECH
- ✓ FOUR ONGOING PHASE 3
REGISTRATIONAL TRIALS;
UP TO SIX BY YEAR-END
- ✓ U.S.-CENTRIC OPERATIONS

WAKIX[®] Net Revenue Performance

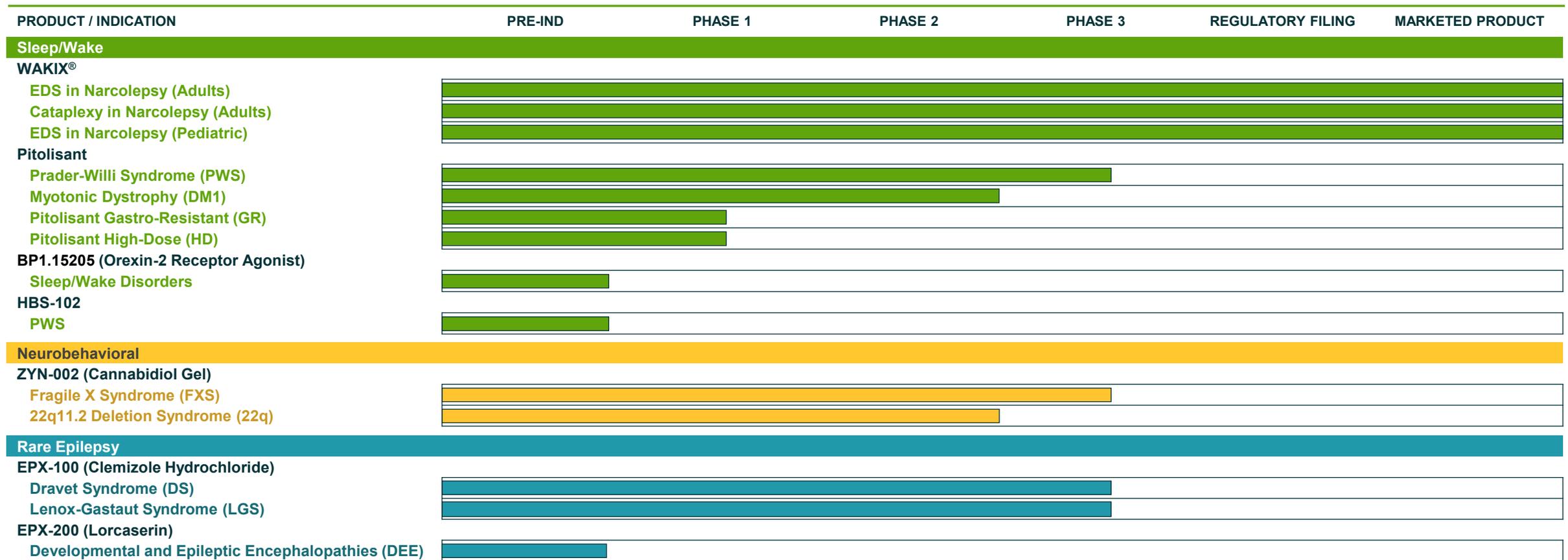


HIGHLIGHTS

- **Q1 2025 Net Revenue of \$184.7M**
- **Durable double-digit sales growth** continued **through year five** on the market
 - Strong patient interest
 - Highly differentiated product profile
 - Continue to add new prescribers and grow prescriber base
 - Continued payer coverage of > 80% of lives
- **Reiterate 2025 Full Year Guidance of \$820-\$860M**

Confident in WAKIX being a potential \$1B+ opportunity in narcolepsy alone

Innovative Late-Stage Pipeline



3 CNS FRANCHISES

8 ASSETS

13 DEVELOPMENT PROGRAMS*

6 PHASE 3 PROGRAMS BY YEAR END

SLEEP/WAKE

Extending Our Leadership Position

- BP1.15205: potential best-in-class orexin-2 agonist data to be presented at SLEEP 2025 in June
- Pitolisant GR: initiated pivotal BE study in Q1 '25; topline data readout Q3 '25
- Pitolisant HD: on track to initiate Phase 3 registrational trials in narcolepsy and IH Q4 '25
- Utility patents filed for both pitolisant GR and pitolisant HD, with potential for patent protection until 2044

NEURO BEHAVIORAL

Next Major Clinical Catalyst

- Recruitment completed in Phase 3 registrational trial with ZYN002 in patients living with Fragile X syndrome (RECONNECT study)
 - On track for topline data in Q3 2025
- Plan to initiate Phase 3 registrational trial in 22q deletion syndrome in Q4 2025

EPILEPSY

Most Advanced 5-HT₂ Development Program

- EPX-100: Phase 3 registrational trials ongoing in Dravet syndrome (ARGUS study) & Lennox-Gastaut syndrome (LIGHTHOUSE study)
 - Topline data anticipated in 2026 from both the ARGUS and LIGHTHOUSE studies

Innovation driving growth of the portfolio



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2025 Anticipated Catalysts

2Q25

BP1.15205

(OX2R agonist)

- Preclinical data presentation at SLEEP 2025
- IMPD submission (IND submission 2H)

3Q25

ZYN002

FXS Phase 3
Registrational Trial
(RECONNECT Study)
topline data readout

4Q25

Pitolisant HD

Initiation of Phase 3
registrational trials in
narcolepsy and **idiopathic
hypersomnia (IH)**

KEY
TAKEAWAY

Late-stage pipeline driving a catalyst-rich 2025

BP1.15205: Potential Best-in-Class Orexin 2 Receptor (OX2R) Agonist

2Q 25

**Preclinical Safety
and Efficacy Data
Presentation at
SLEEP 2025**

OREXIN CLASS

Next wave of Sleep/Wake therapeutic innovation

TEIJIN

Tokyo-based Pharma; innovator of TPM-1116 (now BP1.15205)

PRECLINICAL DATA PRESENTATION AT SLEEP IN JUNE

Preclinical safety and efficacy data presentation at SLEEP 2025 meeting in June
Demonstrates pre-clinical efficacy in sleepiness consistent with high potency

UNIQUE STRUCTURE/CHEMICAL SCAFFOLD

Differentiated from other known OX2R agonist chemical structures

CLINICAL POTENTIAL

- Potency and selectivity
- Potent on-target effects
- Potentially better AE profile
- Once-daily dosing

ZYN002: Potential for First Approved Treatment in Fragile X Syndrome

3Q 25

Topline Data

**Readout from Phase
3 Registrational
Trial, RECONNECT
Study**

ZYN002: INNOVATIVE PRODUCT PROFILE

Purely synthetic cannabidiol (CBD); devoid of THC; Permeation enhanced gel

LEAD PROGRAM IN FRAGILE X SYNDROME (FXS)

Phase 3 RECONNECT Study designed to replicate the positive findings from the prespecified analysis of primary endpoint in Phase 2/3 CONNECT Study in fully methylated patients

- Additional opportunity in related disorder, 22q deletion syndrome (22q)

MARKET OPPORTUNITY

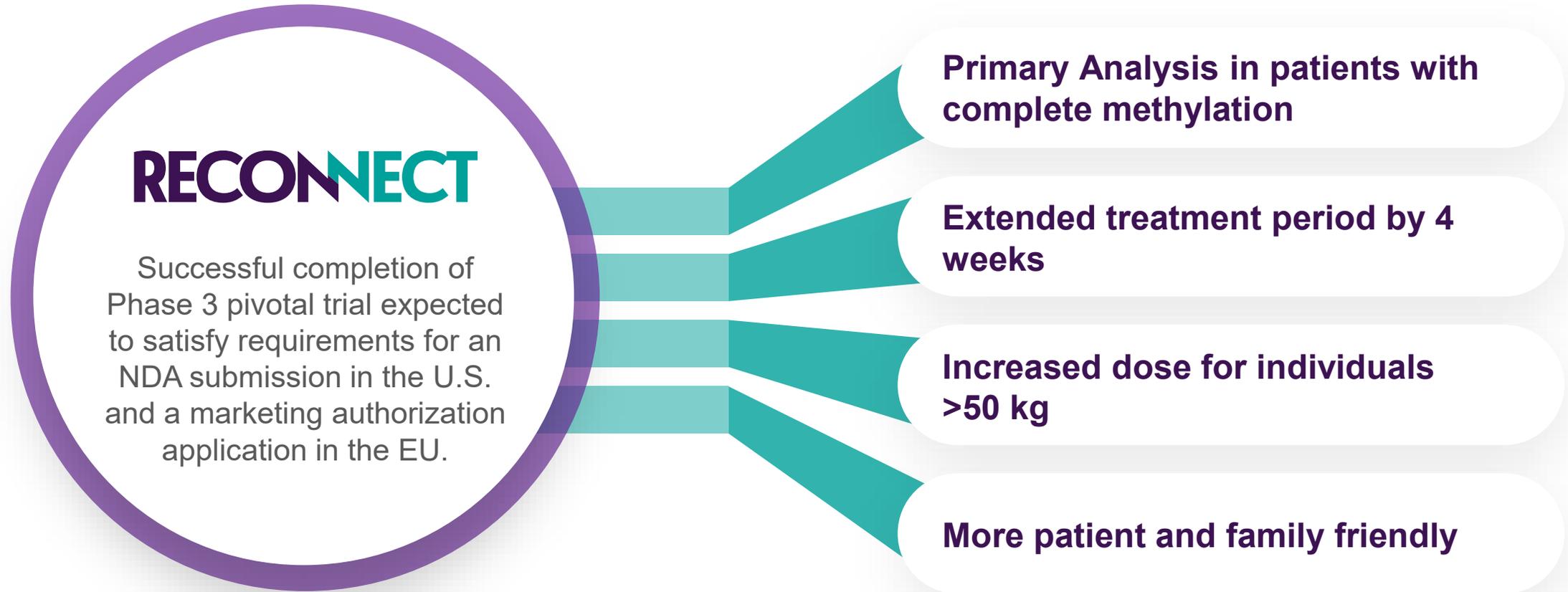
~80,000 patients in the US with FXS; similar for 22q; Worldwide rights

VERY HIGH UNMET NEED

No approved products for FXS or 22q

Would be first approved treatment for patients with FXS

Pivotal Phase 3 RECONNECT Trial: Design Optimized from Phase 2/3 CONNECT-FX Trial



Learnings from Connect-FX trial informed RECONNECT study design

Pitolisant HD: Phase 3 Registrational Trials in Narcolepsy and IH in Q4 2025

4Q 25

**Initiation of Phase 3
Registrational Trials
of Pitolisant HD in
Narcolepsy and IH**

OPTIMIZED PK PROFILE AND HIGHER DOSE

Designed to address the need for greater efficacy in excessive daytime sleeping (EDS) and other symptoms in patients with central disorders of hypersomnolence

PROGRAMS TO PURSUE A DIFFERENTIATED LABEL

Fatigue in narcolepsy; sleep inertia in idiopathic hypersomnia

NARCOLEPSY AND IH PHASE 3 REGISTRATIONAL TRIALS TO BE INITIATED Q4 2025

Topline data readout anticipated 2027; PDUFA dates targeted for 2028

UTILITY PATENTS FILED TO EXTEND PITOLISANT FRANCHISE INTO 2040'S

Financial Highlights Q1 2025

(In millions, USD)

Three Months Ended March 31, 2025

UNIQUE COMPANY PROFILE

- ✓ **20% Revenue Growth:** Year 6 on the market
- ✓ **2025 Full Year Revenue Guidance:** \$820-\$860M
- ✓ **Strong Profitability:** 4+ Years
- ✓ **Significant Cash Generation:** \$600M+ Cash, Cash Equivalents and Investments

Net Product Revenue



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

Financial Summary Q1 2025

(In millions, USD)

Totals may not foot due to rounding	Three Months Ended March 31,		% Change
	2025	2024	
Net Product Revenue	\$184.7	\$154.6	20%
Cost of Product Sold	32.0	27.5	16%
Total Operating Expenses	\$96.5	\$75.1	29%
R&D Expense	34.5	22.2	56%
S&M Expense	30.7	27.2	13%
G&A Expense	31.2	25.7	22%
Net Income	\$45.6	\$38.3	19%
Cash, cash equivalents & investments	\$610.2		

NM denotes not meaningful % change

GAAP vs NON-GAAP Reconciliation Q1 2025

(In millions, USD)

Totals may not foot due to rounding	Three Months Ended March 31,	
	2025	2024
GAAP net income	\$45.6	\$38.3
Non-cash interest expense ⁽¹⁾	0.2	0.2
Depreciation	0.0	0.2
Amortization ⁽²⁾	6.0	6.0
Stock-based compensation expense	12.5	10.4
Income tax effect related to Non-GAAP adjustments ⁽³⁾	(3.8)	(4.4)
Non-GAAP adjusted net income	\$60.4	\$50.7
GAAP net income per diluted share	\$0.78	\$0.67
Non-GAAP adjusted net income per diluted share	\$1.03	\$0.88
Weighted average number of shares of common stock used in non-GAAP diluted per share	58,524,566	57,597,627

(1) Includes amortization of deferred finance charges.

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

(3) Calculated using the reported effective tax rate for the periods presented less impact of discrete items.

DELIVER ON PROMISE TO PATIENTS

Commitment to patients

Addressing unmet medical needs

Delivering meaningful treatment options

Helping patients thrive

DELIVER STRONG VALUE TO SHAREHOLDERS

Innovative

Catalyst-rich pipeline

Profitable biotech company

Meaningful investment opportunity

THANK YOU



HARMONY
BIOSCIENCES



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HRMY