# Harmony Biosciences Q3 2022 Financial and Business Update

November 1, 2022

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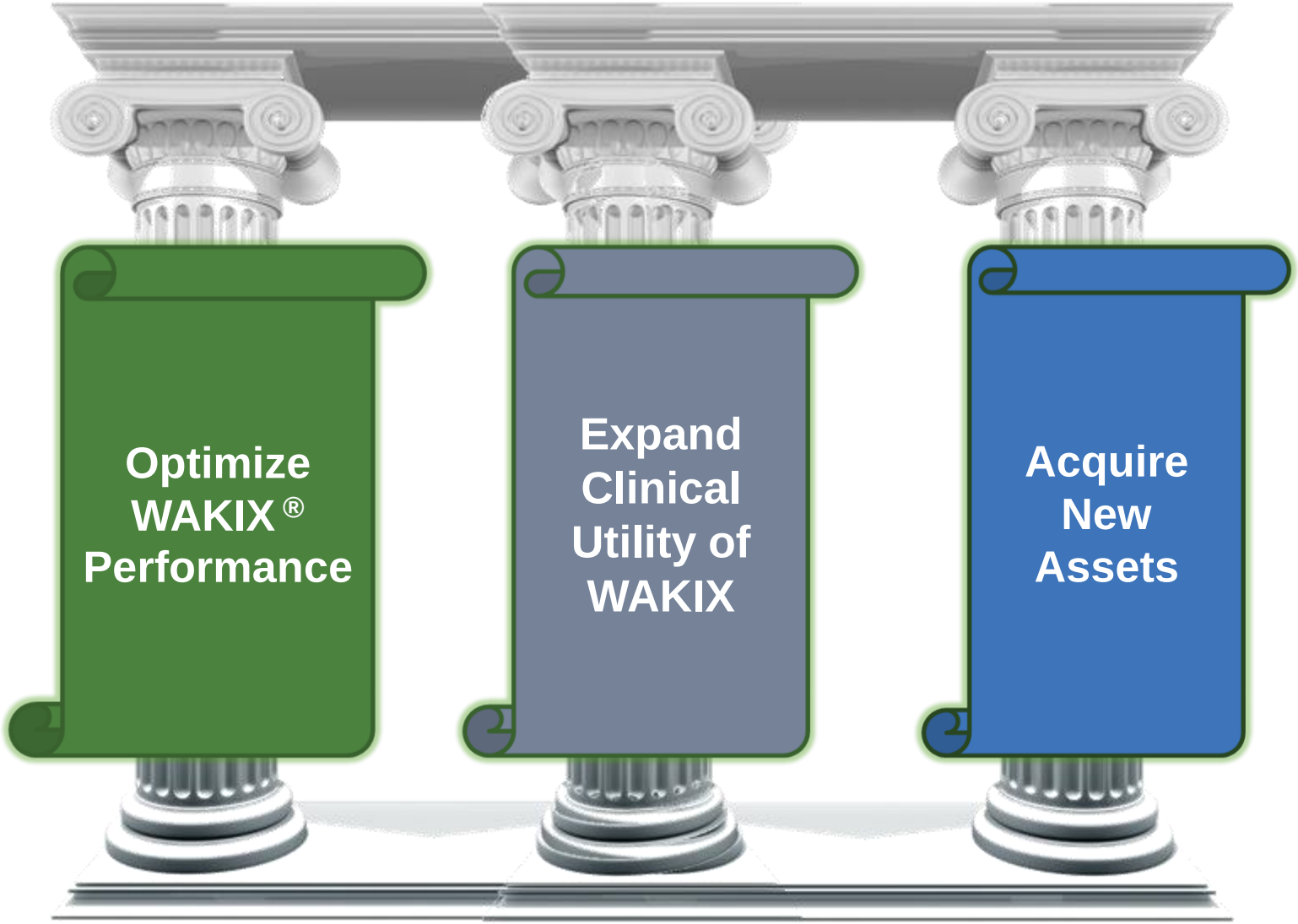
# Harmony's Strategy for Growth



# Q3 2022 WAKIX® Net Revenue Performance

## Q3 2022 Net Revenue of $117.2M


| 3Q21 | 2Q22 | 3Q22 | Δ 3Q22 vs. 2Q22 | Δ 3Q22 vs. 3Q21 |
|---|---|---|---|---|
| $80.7 | $107.0 | $117.2 | 10% | 45% |

### Strong Revenue Growth

- 45% growth Q3 2022 vs. Q3 2021
- 10% growth Q3 2022 vs. Q2 2022
- Strong momentum in top line prescription demand

# Driving Growth Through Our Launch For WAKIX®
# Q3 2022 Performance

Wakix® pitolisant tablets

**~85%** In-Person Access to HCPs

Patient Outreach Programs & Support

**~4,600** Average # of WAKIX Patients

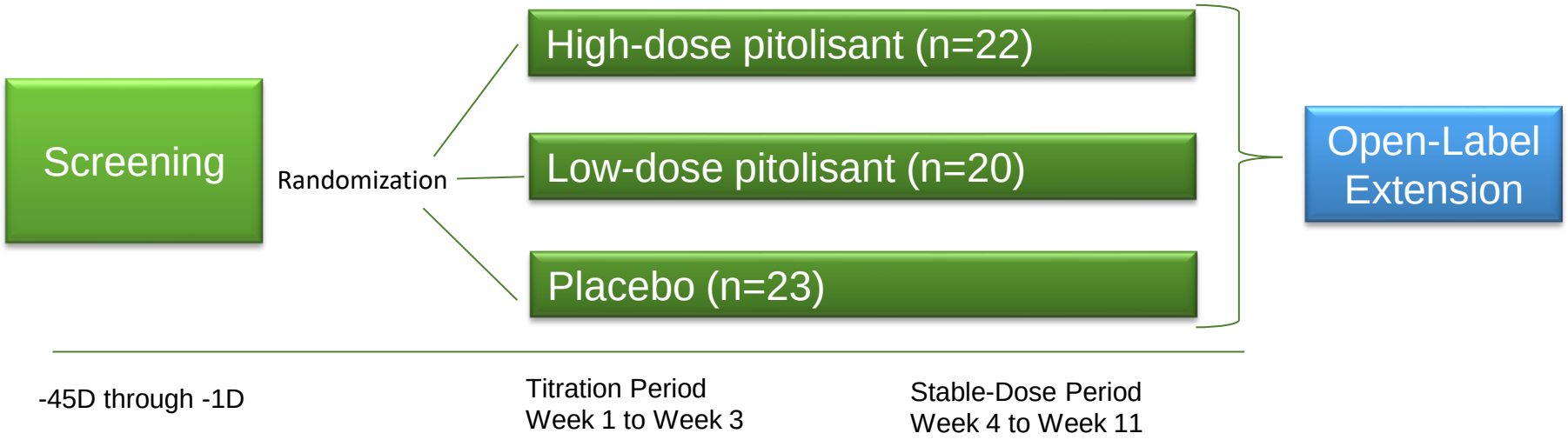
Healthcare Professional Educational Initiatives

**Continued Growth** in Depth & Breadth of Prescriber Base


Managed Care Education & Outreach

**>80%** U.S. Covered Lives With Formulary Access

# Phase 2 Clinical Proof-of-Concept Trial of Pitolisant in PWS




**Trial Design:**

- Randomized, double-blind, placebo-controlled, parallel-group, POC, signal detection study
- 65 patients enrolled at 13 US sites; ages 6 – 65
  - Children ages 6 to < 12 (n=34)
  - Adolescents ages 12 to < 18 (n=19)
  - Adults 18 to 65 (n=12)

**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 from open-label extension

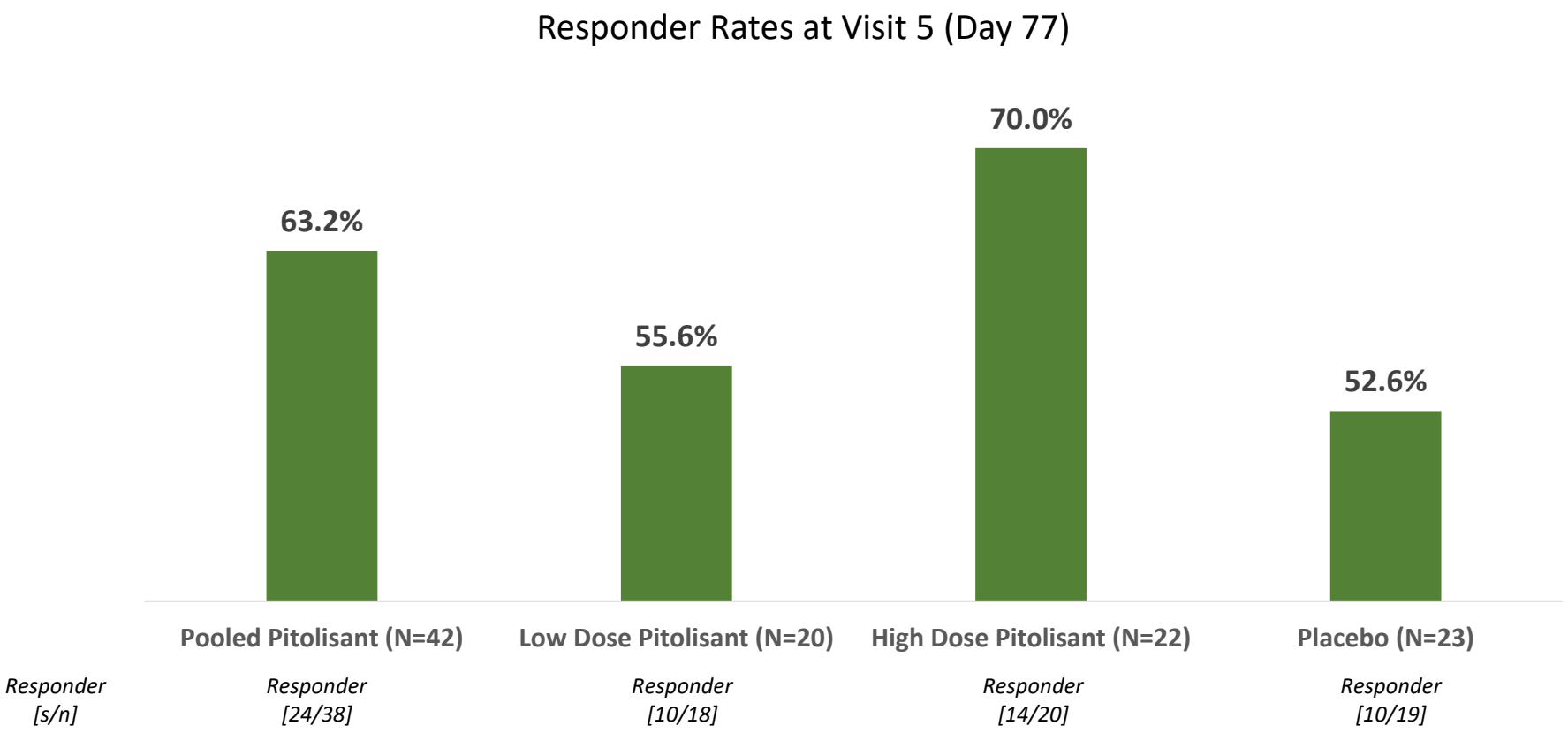
# PWS Phase 2 POC Study Topline Data: Primary Endpoint

ESS-CHAD (Parent/Caregiver Version) Mean Change from Baseline to End of Treatment (Week 11)

| Age | Low Dose Pitolisant (ESS-CHAD Δ from BL) (n; pitolisant dose) | High Dose Pitolisant (ESS-CHAD Δ from BL) (n; pitolisant dose) | Placebo (ESS-CHAD Δ from BL) (n) |
|---|---|---|---|
| Overall population | **-4.1** | **-4.9** | **-3.7** |
| (N=65) | (n=20) | (n=22) | (n=23) |
| Ages 6 to <12 | **-3.7** | **-5.5** | **-2.1** |
| (N=34) | (n=12); 8.9mg | (n=11); 17.8mg | (n=11) |
| Ages 12 to <18 | **-4.5** | **-4.2** | **-6.1** |
| (N=19) | (n=4); 13.35mg | (n=6); 26.7mg | (n=9) |
| Ages 18 to 65 | **-5.0** | **-4.4** | **-2.3** |
| (N=12) | (n=4); 17.8mg | (n=5); 35.6mg | (n=3) |

# PWS Phase 2 POC Study Topline Data: Responder Analysis

**Higher Responder Rate for Pitolisant vs. Placebo; Driven by High Dose Group**




s = Number of responders
n = Number of subjects with baseline assessment and post-baseline assessment at the visit

**A responder was defined as a subject with an improvement of ≥ 3 points from Baseline or a score ≤ 10 at EOT**

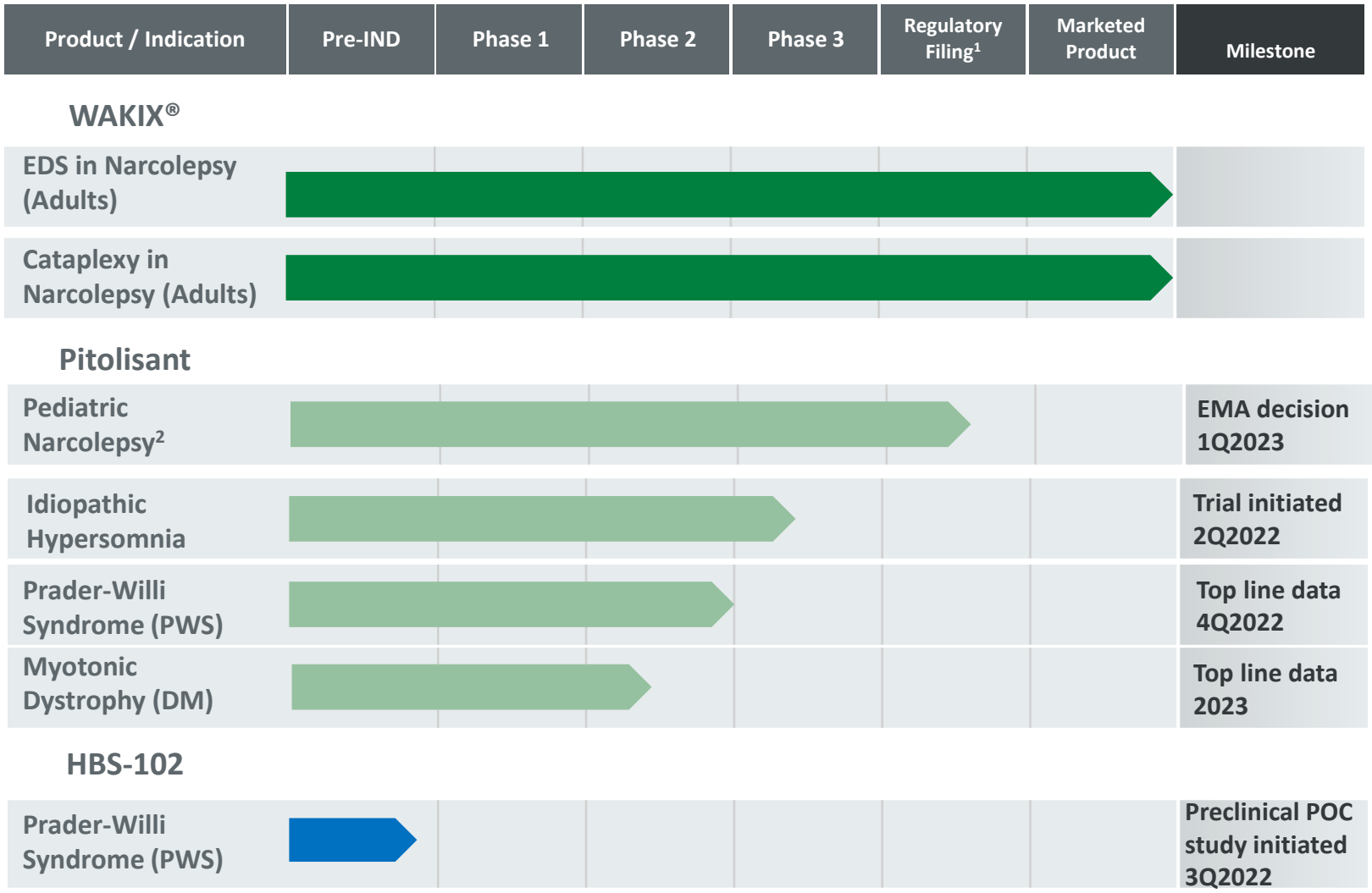
# PWS Phase 2 POC Study Topline Data: Summary of Safety

| Category | Pooled Pitolisant (N=42) [n; %] | Low Dose Pitolisant (N=20) [n; %] | High Dose Pitolisant (N=22) [n; %] | Placebo (N=23) [n; %] |
|---|---|---|---|---|
| Any TEAE | 24<br>57.1% | 13<br>65.0% | 11<br>50.0% | 15<br>65.2% |
| Any Treatment-Related TEAE | 11<br>26.2% | 7<br>35.0% | 4<br>18.2% | 7<br>30.4% |
| Any Severe TEAE | 0 | 0 | 0 | 0 |
| Any Severe Treatment-Related TEAE | 0 | 0 | 0 | 0 |
| Any Serious TEAE | 0 | 0 | 0 | 1<br>4.3% |
| Any Serious Treatment-Related TEAE | 0 | 0 | 0 | 0 |

TEAE: treatment-emergent adverse event

- The safety and tolerability profile of pitolisant in patients with Prader-Willi syndrome in this trial was consistent with the known safety/tolerability profile of pitolisant
- Most common adverse events:
  - Anxiety (11.9% pitolisant; 4.3% placebo)
  - Irritability (9.5% pitolisant; 4.3% placebo)
  - Headache (7.1% pitolisant; 4.3% placebo)

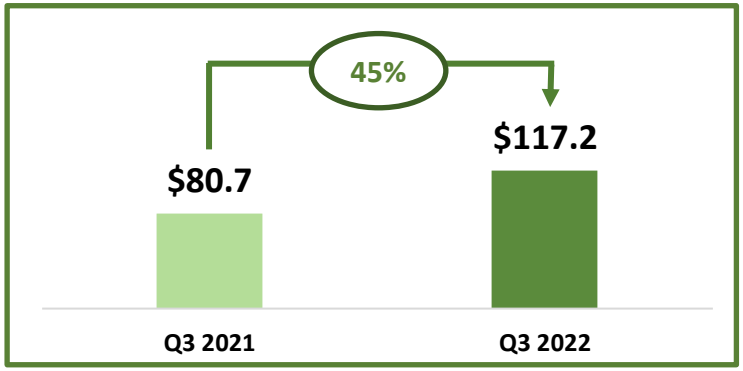
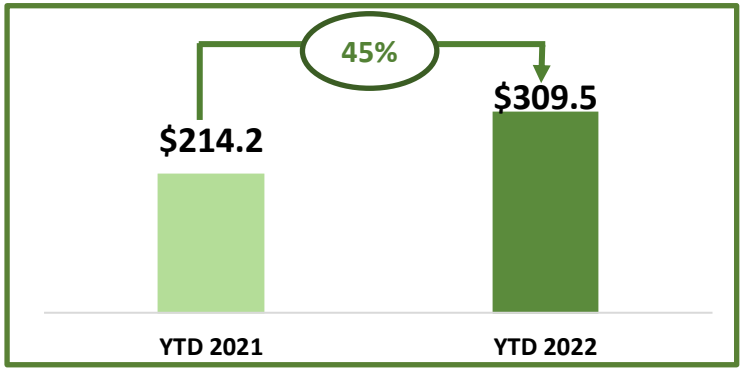
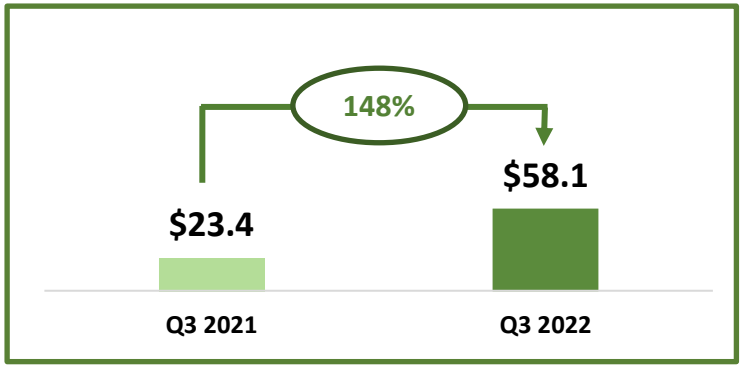
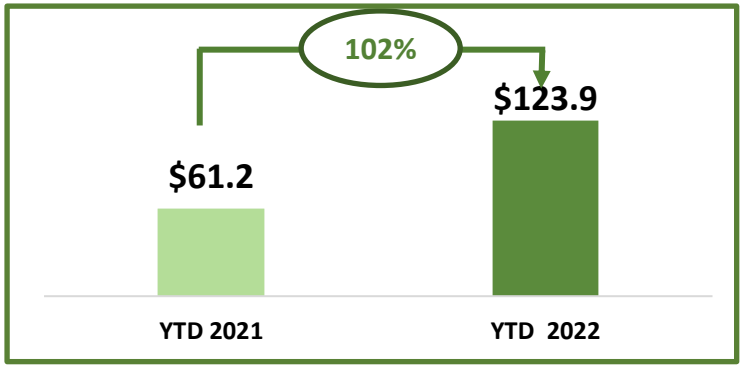
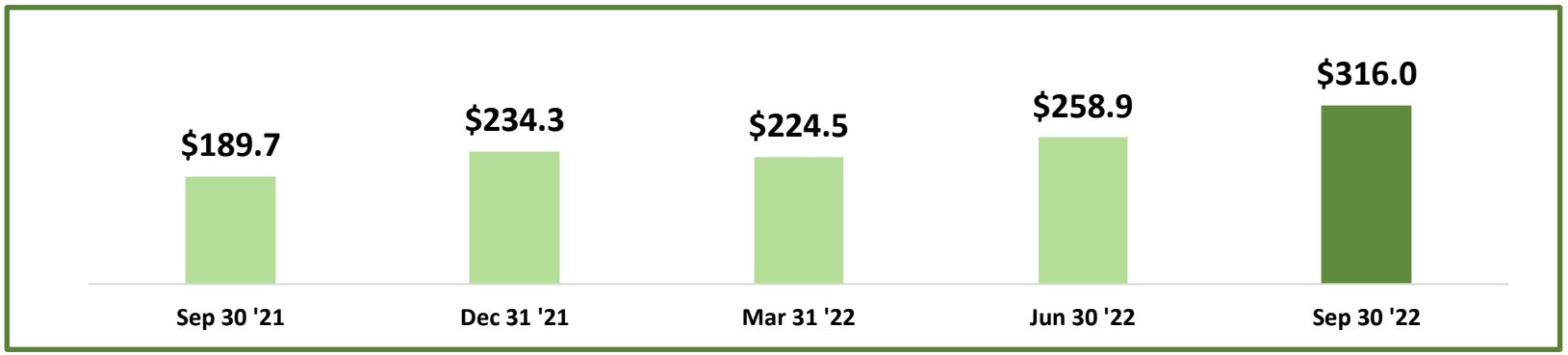
# Harmony Development Pipeline




1. Includes New Drug Applications and supplemental New Drug Applications.
2. Trial conducted by Bioprojet and Bioprojet submitted regulatory package to EMA.

# Financial Highlights

*(In millions, USD)*

| | Three Months Ended September 30, 2022 | Nine Months Ended September 30, 2022 |
|---|---|---|
| Net Product Revenues |  |  |
| 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

# Q3 2022 Financial Summary

| *(In millions, USD)* Totals may not foot due to rounding | Three Months Ended September 30, | | % Change |
|---|---|---|---|
| | 2022 | 2021 | |
| **Net Product Revenues** | **$117.2** | **$80.7** | **45%** |
| Cost of Product Sold | 23.0 | 14.6 | 57% |
| **Total Operating Expenses** | **$82.3** | **$45.1** | **83%** |
| R&D Expense | 40.5 | 11.7 | NM |
| S&M Expense | 20.5 | 16.5 | 24% |
| G&A Expense | 21.3 | 16.9 | 27% |
| **Net Income** | **$87.9** | **($9.6)** | **NM** |
| **Cash, cash equivalents & investment securities** | **$316.0** | | |

NM denotes not meaningful % change

# Q3 2022 GAAP vs Non-GAAP Reconciliation

| *(In millions, USD)*<br>Totals may not foot due to rounding | Three Months Ended September 30, | |
|---|---|---|
| | 2022 | 2021 |
| **GAAP net income** | **$87.9** | **($9.6)** |
| Non-cash interest expense(1) | 0.4 | 0.5 |
| Depreciation | 0.1 | 0.1 |
| Amortization(2) | 6.0 | 4.6 |
| Stock-based compensation expense | 7.0 | 4.7 |
| Licensing fee(3) | 30.0 | - |
| Loss on debt extinguishment | - | 26.1 |
| Valuation allowance release | (74.5) | - |
| Income tax effect related to Non-GAAP adjustments(4) | 1.2 | (2.9) |
| **Non-GAAP adjusted net income** | **$58.1** | **$23.4** |
| | | |
| **GAAP net income per diluted share** | **$1.44** | **($0.17)** |
| **Non-GAAP adjusted net income per diluted share** | **$0.95** | **$0.41** |
| Weighted average number of shares of common stock used in non-GAAP diluted per share | 61,207,625 | 57,722,163 |

(1) Includes amortization of deferred finance charges
(2) Includes amortization of intangible assets related to WAKIX
(3) Amount represents initial licensing fee incurred upon closing the 2022 Licensing and Commercialization Agreement with Bioprojet
(4) Calculated using the reported effective tax rate for the periods presented

HARMONY BIOSCIENCES

# Thank You