# Harmony Biosciences Q4 2021 Financial and Business Update

February 28, 2022

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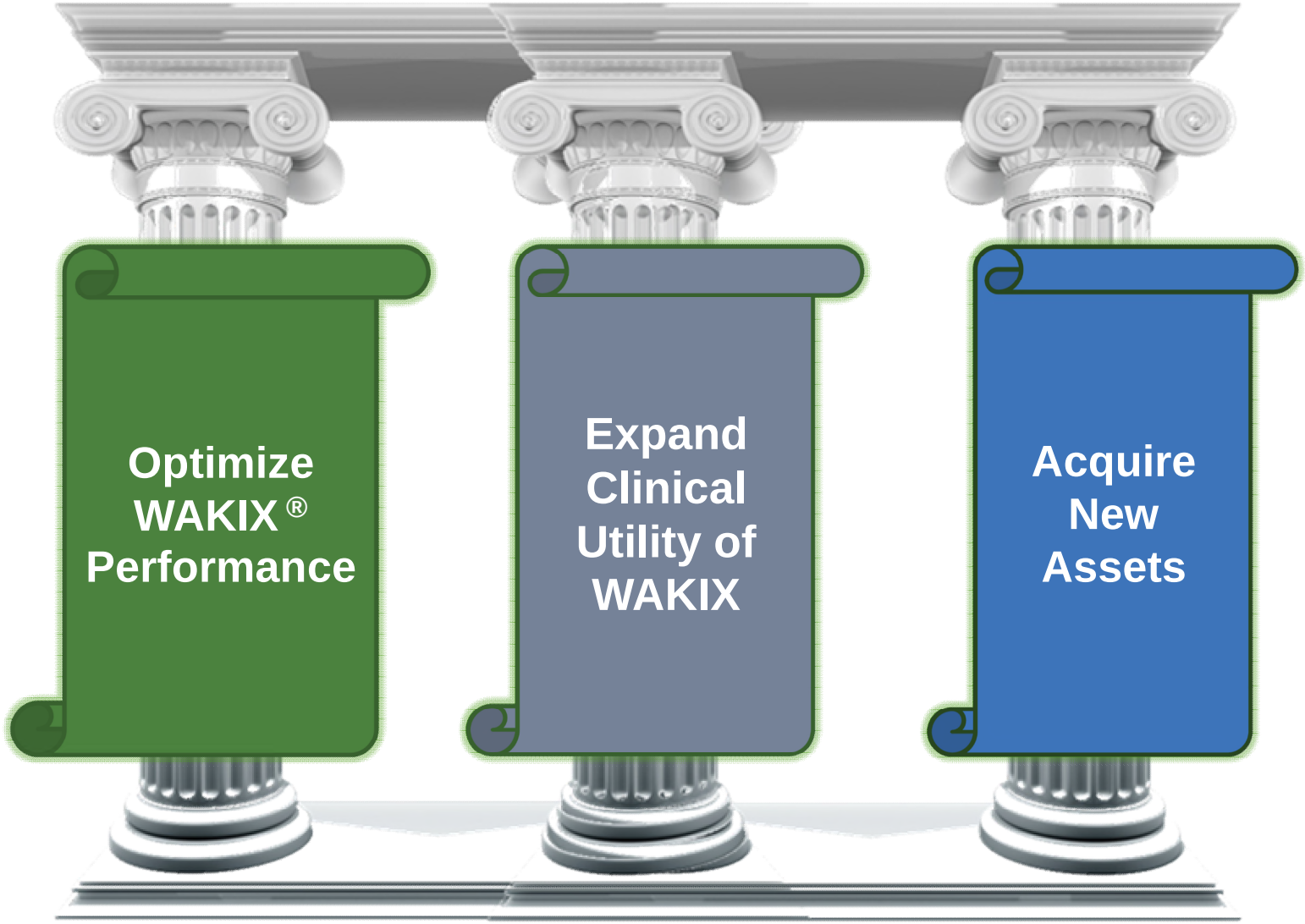
# Harmony's Strategy for Growth

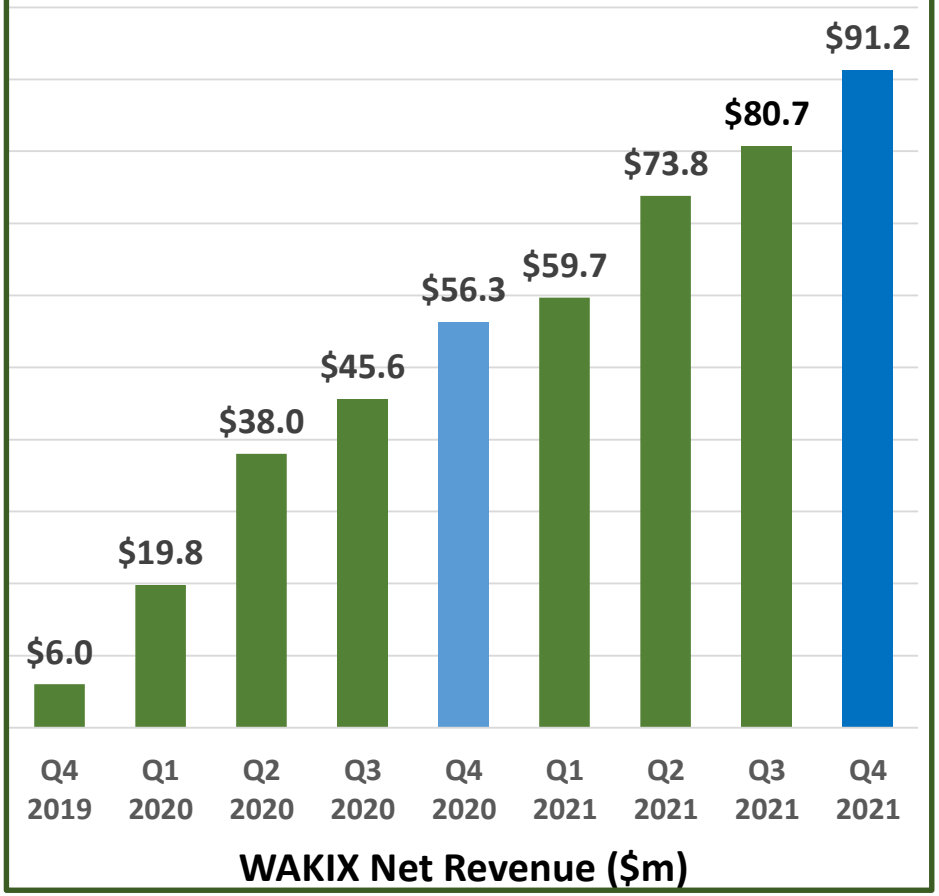


# Q4/FY 2021 WAKIX® Revenue Performance

## Strong Sequential Growth QoQ, YoY

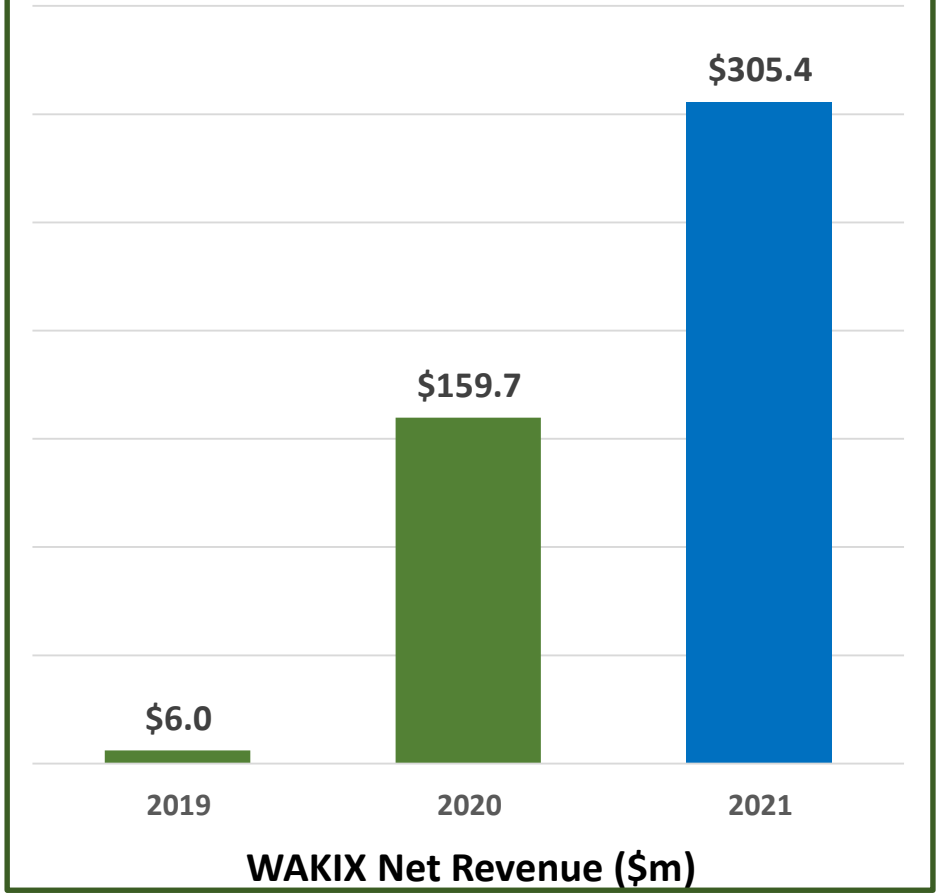
### Q4 2021 Revenue of $91.2M

| 4Q20 | 3Q21 | 4Q21 | 4Q21 vs. 3Q21 | 4Q21 vs. 4Q20 |
|---|---|---|---|---|
| $56.3 | $80.7 | $91.2 | 13% | 62% |




### FY 2021 Revenue of $305.4M

| 2021 vs. 2020 |
|---|
| 91% |



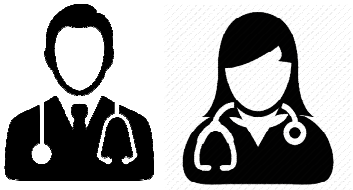
# Driving Growth Through Our Launch For WAKIX
# Q4 2021 Performance

Wakix pitolisant tablets

**~2/3** In-Person Access to HCPs

Patient Outreach Programs & Support

**~3,800** 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

# Publications for WAKIX®: Clinically Relevant Data

CNS Drugs (2021) 35:1303–1315
https://doi.org/10.1007/s40263-021-00866-1

ORIGINAL RESEARCH ARTICLE

## Time to Onset of Response to Pitolisant for the Treatment of Excessive Daytime Sleepiness and Cataplexy in Patients With Narcolepsy: An Analysis of Randomized, Placebo-Controlled Trials

Nathaniel F. Watson[1] · Craig W. Davis[2] · Donna Zarycranski[2] · Ben Vaughn[3] · Jeffrey M. Dayno[2] · Yves Dauvilliers[4,5,6] · Jean-Charles Schwartz[7]

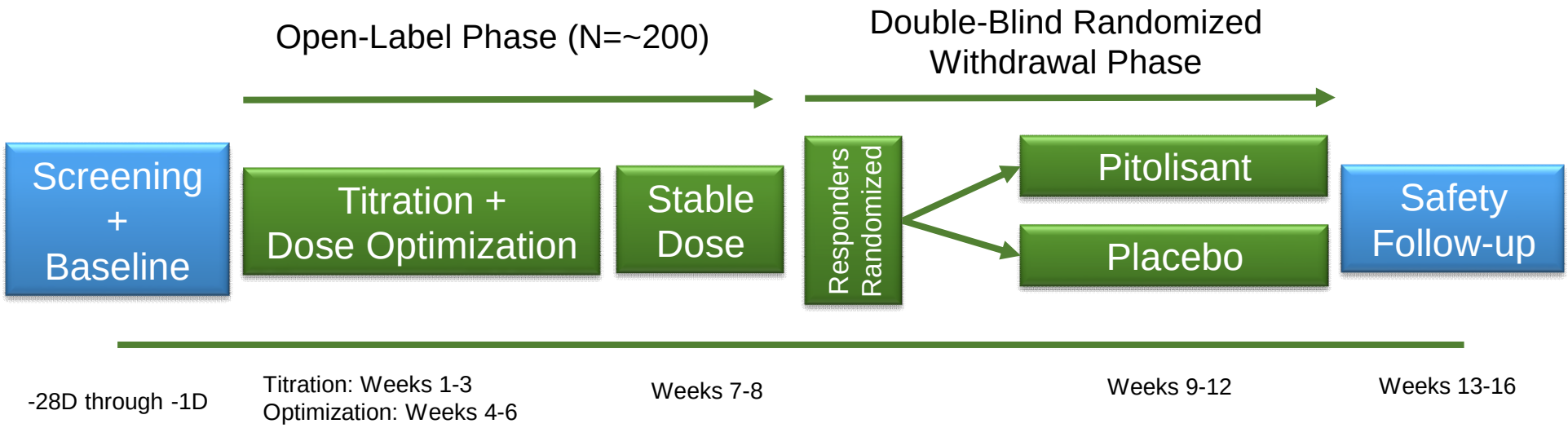
CNS Drugs (2022) 36:61–69
https://doi.org/10.1007/s40263-021-00886-x

ORIGINAL RESEARCH ARTICLE

## Clinical Impact of Pitolisant on Excessive Daytime Sleepiness and Cataplexy in Adults With Narcolepsy: An Analysis of Randomized Placebo-Controlled Trials

Gerard J. Meskill[1] · Craig W. Davis[2] · Donna Zarycranski[2] · Markiyan Doliba[2] · Jean-Charles Schwartz[3] · Jeffrey M. Dayno[2]

# Phase 3 Clinical Trial of Pitolisant in Idiopathic Hypersomnia: *On Track to Initiate 1H2022*




## 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
- ~80 clinical trial sites in the US

## Objectives:

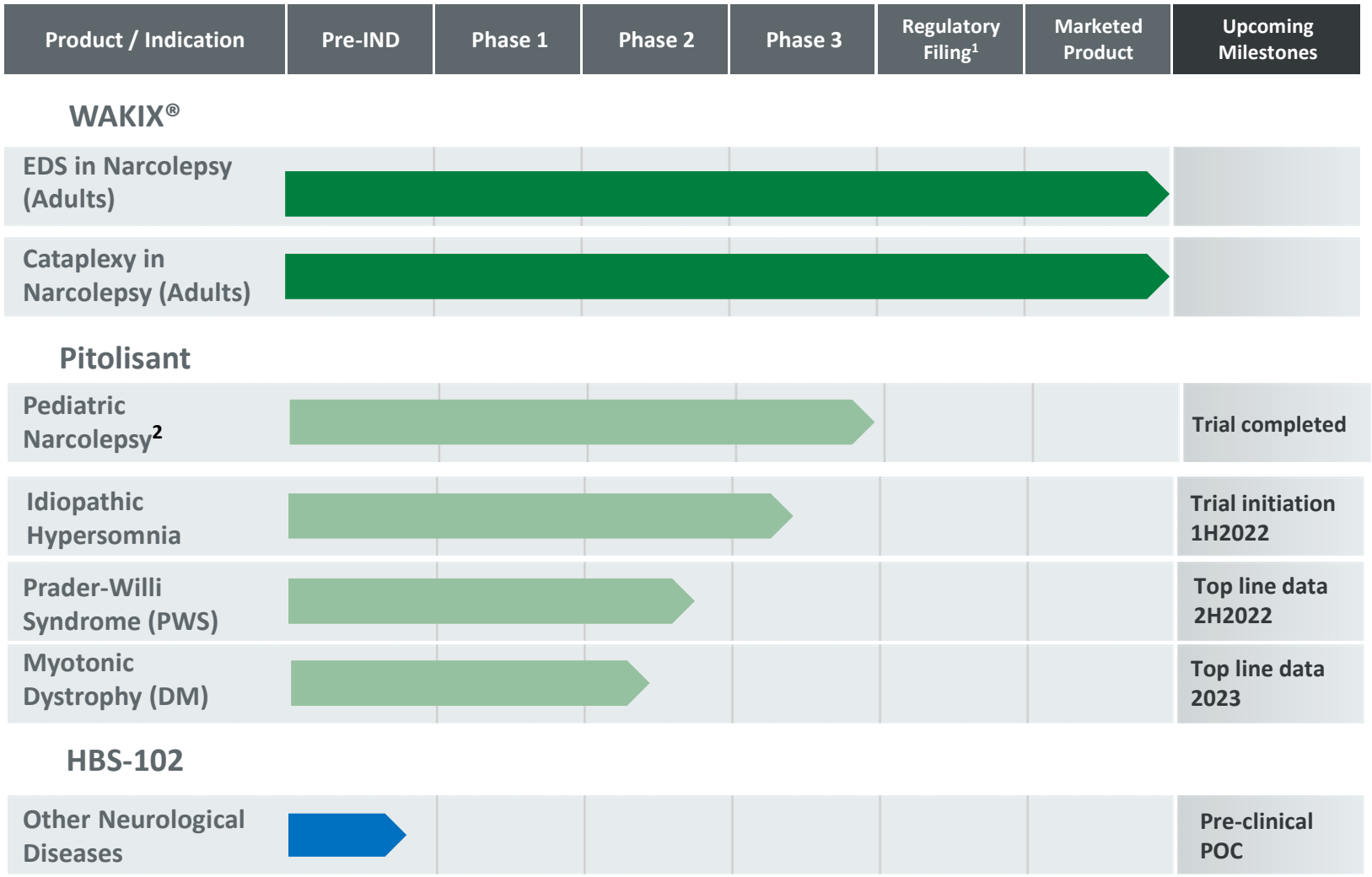
- Primary objective: to evaluate the safety and efficacy of pitolisant compared with placebo in treating EDS in patients with IH ≥18 years old
- Secondary objectives: to assess the impact of pitolisant on overall symptoms of IH, patient impression of overall change in their IH, investigator assessment of overall IH severity, functional status and activities of daily living, sleep-related impairment, sleep inertia, and cognitive function

IH=Idiopathic Hypersomnia; ESS=Epworth Sleepiness Scale; EDS=Excessive Daytime Sleepiness

# Clinical Development: COVID-19 Contingency Efforts

- Mechanism put in place for electronic signatures for ‘e-consent’ on Informed Consent Forms (ICFs); allows for remote screening
- Protocol amendments to allow for remote visits during the trial in both the PWS and DM1 Phase 2 trials; include telemedicine visits for clinical assessments and home nursing visits to perform ECGs and draw labs (for safety assessments)
- Connecting trial sites with additional sleep labs to perform objective sleep testing when their institution’s sleep lab is not available due to resources or personnel being diverted to care for COVID patients
- Adding additional trial sites in regions of the country that are not as affected by COVID and/or directing patients from sites that are not able to enroll patients to those sites that are actively enrolling patients
- Other strategies to reduce overall burden of the trials for both patients/families and the clinical trial sites

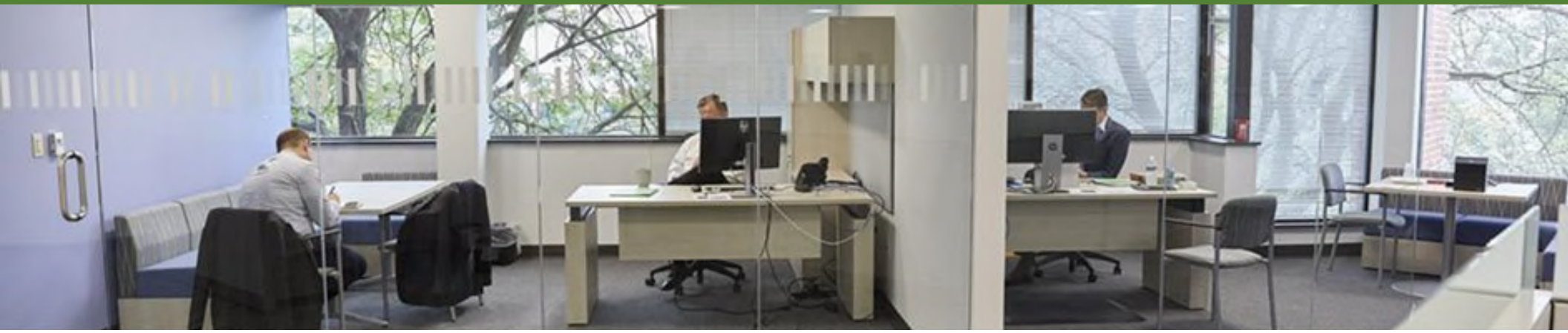
# Harmony Development Pipeline




**1.** Includes New Drug Applications and supplemental New Drug Applications.

**2.** Bioprojet conducted pediatric narcolepsy trial

# Historical Financials



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# Q4 2021 Financial Highlights

(In millions, USD)

**Q4 '21 Net Product Revenues**

**$91.2M**

62.0% vs prior year

**Q4 '21 Non-GAAP Adjusted Net Income[1]**

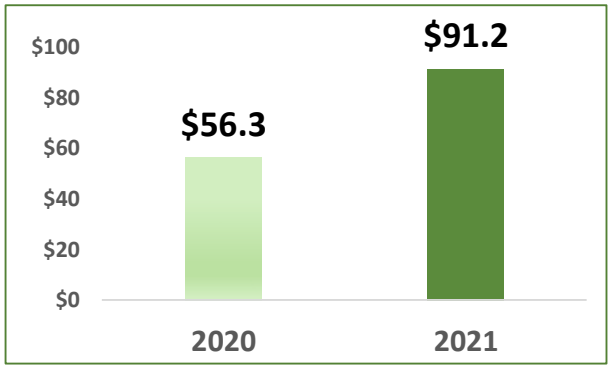
**$37.8M**

150.3% vs prior year

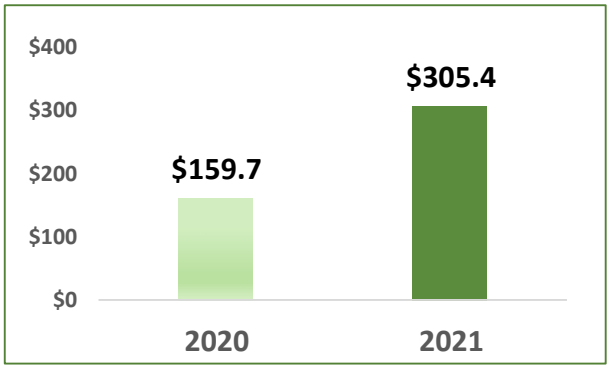
**Cash, Cash Equivalents at 12/31/21**

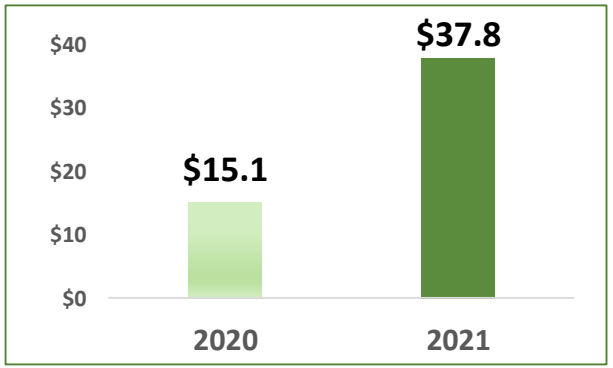
**$234.3M**

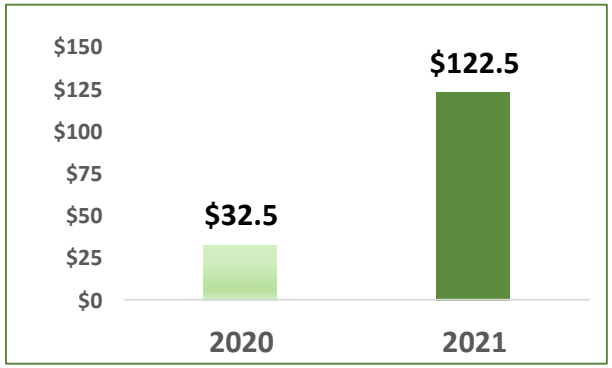
**Three Months Ended December 31,2021**

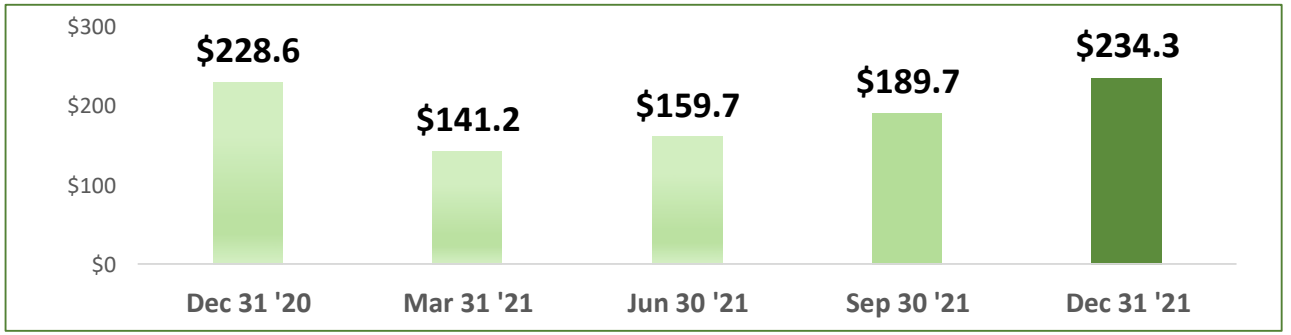



**Year Ended December 31,2021**




*1. Non-GAAP Adjusted Net Income = EBITDA plus add backs for Stock-based compensation expense, Loss on debt extinguishment and Warrant Expense*

# Q4 2021 Financial Summary

| (In millions, USD) | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| **Net Product Revenues** | **$91.2** | **$56.3** | **$305.4** | **$159.7** |
| Cost of Product Sold | 17.8 | 9.9 | 55.5 | 27.7 |
| | | | | |
| **Total Operating Expenses** | **$44.8** | **$38.6** | **$162.4** | **$115.0** |
| R&D Expense | 7.5 | 7.6 | 30.4 | 19.5 |
| S&M Expense | 19.1 | 17.5 | 68.1 | 55.8 |
| G&A Expense | 18.2 | 13.5 | 63.9 | 39.7 |
| | | | | |
| **Net Income (Loss)** | **$22.7** | **$(0.2)** | **$34.6** | **$(36.9)** |
| | | | | |
| **Cash & cash equivalents** | | | **$234.3** | **$228.6** |

# Q4 2021 GAAP vs Non-GAAP Reconciliation

| (In millions, USD) | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| **GAAP reported net income (loss)** | **$22.7** | **$(0.2)** | **$34.6** | **$(36.9)** |
| Interest expense / income | 4.2 | 8.0 | 24.0 | 28.2 |
| Taxes | 1.8 | - | 2.8 | - |
| Depreciation | 0.1 | 0.1 | 0.4 | 0.4 |
| Amortization | 4.6 | 4.3 | 18.4 | 9.8 |
| **EBITDA** | **33.4** | **12.1** | **80.2** | **1.5** |
| Stock-based compensation expense | 4.4 | 2.9 | 16.1 | 5.2 |
| Loss on debt extinguishment | - | - | 26.1 | 22.6 |
| Warrant expense | - | - | - | 3.1 |
| **Non-GAAP adjusted net income** | **$37.8** | **$15.1** | **$122.5** | **$32.5** |
| Accumulation of yield on preferred stock | - | - | - | (26.9) |
| **Non-GAAP adjusted net income available to common stockholders** | **$37.8** | **$15.1** | **$122.5** | **$5.5** |
| GAAP reported net income (loss) per diluted share | $0.38 | $(0.00) | $0.58 | $(24.07) |
| Non-GAAP adjusted net income per diluted share | $0.63 | $0.25 | $2.07 | $0.21 |
| **Weighted average number of shares of common stock used in non-GAAP diluted per share** | **60,314,396** | **59,128,981** | **59,205,213** | **26,282,978** |

Totals may not foot due to rounding

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# Thank You

February 2022