

Harmony Biosciences

Downgrade to Underperform on lack of catalysts + limited valuation upside

Rating Change: UNDERPERFORM | PO: 30.00 USD | Price: 32.30 USD

Downgrade to Underperform: lack of catalysts & valuation

We downgrade our Harmony rating to Underperform from Neutral but maintain our price objective of \$30/share given a lack of high-impact catalysts and a challenging path to addressing a 2029 Wakix LOE. Harmony is a single-product biotech company selling Wakix for the treatment of narcolepsy. The company is currently profitable and likely to achieve >\$580m in 2023 revenue, but we believe that regulatory exclusivities will only extend another 5 years (to 2029 versus 2030 best case). We believe that out-year cash flows will be discounted as patent litigation approaches.

Limited portfolio diversification + competitive threats

At this juncture, we would have preferred to see Harmony be more active on the BD front, bolstering its mid-/late-stage pipeline versus a loosely defined Wakix life cycle management strategy and share buybacks. With a recently failed Ph3 Wakix IH study, we see modest consensus risk in the near term (2024-25), while we are more meaningfully below the Street for 2026-29E; we see potential for additional Wakix consensus downside from pipeline competitors, notably Axsome's AXS-12 (depending on strength of 1Q24 data).

We model 2029 Wakix LOE; assign no value to polymorph

Wakix is subject to Paragraph 4 patent challenges initiated in August 2023, with 30-month litigation stays (block generic entry) ending mid-February 2026. Our model is highly sensitive to the LOE assumption, assuming that Wakix can exceed \$1bn in 2029+ revenue; thus, extending the LOE to a bull case (1H'2030) could add to valuation. On the flip side, we do not believe that it is prudent for investors to assign credit to the Wakix terminal 2030 patent, which covers a polymorph of API (susceptible to non-infringing alternative polymorphs). We model continued patient growth on Wakix, albeit at a slowing pace through 2029, and adjust our COGS estimates based on tiered royalty.

Fragile X study: low POS study, in our view

The biggest risk to our thesis is if HRMY generates positive Ph3 data for Zygel for Fragile X Syndrome (FXS). In August 2023, Harmony acquired Zynerba's Ph3 Zygel (CBD topical), which is being studied as a treatment for FXS. In 2020, a Ph2 study evaluating Zygel (CBD topical) failed to beat placebo in a 14-week Ph2 trial measuring the impact on developmental disabilities. Nonetheless, Zygel was advanced to Ph3, looking to replicate post-hoc analysis in patients with full gene methylation. A \$30m milestone is payable if the Ph3 Zygel study achieves positive readout by year-end 2024. Given limited data for Zygel, we exclude the drug from our model (estimated 80k addressable US pts).

| Estimates (Dec) (US\$) | 2021A | 2022A | 2023E | 2024E | 2025E |
|---------------------------|--------|-------|-------|-------|-------|
| EPS | 2.07 | 3.00 | 3.09 | 3.94 | 4.86 |
| GAAP EPS | 0.58 | 2.97 | 2.16 | 3.14 | 4.05 |
| EPS Change (YoY) | 885.7% | 44.9% | 3.0% | 27.5% | 23.4% |
| Consensus EPS (Bloomberg) | | | 2.59 | 3.60 | 4.48 |
| DPS | 0 | 0 | 0 | 0 | 0 |
| Valuation (Dec) | | | | | |
| P/E | 16.1x | 11.1x | 10.8x | 8.5x | 6.9x |
| GAAP P/E | 57.5x | 11.2x | 15.4x | 10.6x | 8.2x |
| EV / EBITDA* | 22.9x | 14.8x | 8.2x | 6.8x | 5.5x |
| Free Cash Flow Yield* | 5.0% | 7.4% | 8.2% | 11.2% | 14.0% |

* For full definitions of *IQmethod*SM measures, see page 5.

02 January 2024

Equity

Key Changes

| (US\$) | Previous | Current |
|------------------|----------|--------------|
| Inv. Opinion | C-2-9 | C-3-9 |
| Inv. Rating | NEUTRAL | UNDERPERFORM |
| 2023E Rev (m) | 580.2 | 586.0 |
| 2024E Rev (m) | 745.7 | 701.3 |
| 2025E Rev (m) | 912.1 | 816.6 |
| 2023E EPS | 3.04 | 3.09 |
| 2024E EPS | 4.24 | 3.94 |
| 2025E EPS | 5.43 | 4.86 |
| 2023E EBITDA (m) | 220.4 | 224.8 |
| 2024E EBITDA (m) | 294.8 | 271.6 |
| 2025E EBITDA (m) | 380.5 | 335.5 |

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Timestamp: 02 January 2024 05:00AM EST

Stock Data

| | |
|--------------------|------------|
| Price | 32.30 USD |
| Price Objective | 30.00 USD |
| Date Established | 2-Jan-2024 |
| Investment Opinion | C-3-9 |

iQprofileSM Harmony Biosciences

iQmethodSM – Bus Performance*

| (US\$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|----------------------------|-------|-------|-------|-------|-------|
| Return on Capital Employed | 27.7% | 27.1% | 28.9% | 29.2% | 26.9% |
| Return on Equity | 86.4% | 62.3% | 43.0% | 41.1% | 35.7% |
| Operating Margin | 33.9% | 33.6% | 42.5% | 42.2% | 44.1% |
| Free Cash Flow | 98 | 144 | 160 | 219 | 273 |

iQmethodSM – Quality of Earnings*

| (US\$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|--------------------------|--------|--------|--------|--------|--------|
| Cash Realization Ratio | 0.8x | 0.8x | 0.9x | 1.0x | 1.0x |
| Asset Replacement Ratio | 0x | 0x | 0.1x | 0.2x | 0.2x |
| Tax Rate | NM | NM | 27.0% | 24.0% | 24.0% |
| Net Debt-to-Equity Ratio | -22.7% | -12.9% | -25.6% | -46.2% | -60.6% |
| Interest Cover | NA | 9.4x | 19.2x | 32.7x | NM |

Income Statement Data (Dec)

| (US\$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|------------------------------|------------|--------------|-------------|--------------|--------------|
| Sales | 305 | 438 | 586 | 701 | 817 |
| % Change | 91.2% | 43.4% | 33.8% | 19.7% | 16.4% |
| Gross Profit | 250 | 354 | 470 | 554 | 637 |
| % Change | 89.3% | 41.8% | 32.7% | 17.8% | 15.0% |
| EBITDA | 80 | 124 | 225 | 272 | 335 |
| % Change | NM | 54.2% | 81.8% | 20.8% | 23.5% |
| Net Interest & Other Income | 19 | (40) | 7 | 12 | 19 |
| Net Income (Adjusted) | 122 | 184 | 187 | 234 | 288 |
| % Change | NM | 49.8% | 1.9% | 24.9% | 23.2% |

Free Cash Flow Data (Dec)

| (US\$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|--|-----------|--------------|--------------|--------------|--------------|
| Net Income from Cont Operations (GAAP) | 122 | 184 | 187 | 234 | 288 |
| Depreciation & Amortization | 19 | 23 | 23 | 23 | 22 |
| Change in Working Capital | 1 | (4) | (21) | (17) | (16) |
| Deferred Taxation Charge | 0 | (86) | 0 | 0 | 0 |
| Other Adjustments, Net | (43) | 28 | (27) | (17) | (17) |
| Capital Expenditure | 0 | 0 | (3) | (4) | (4) |
| Free Cash Flow | 98 | 144 | 160 | 219 | 273 |
| % Change | NM | 46.9% | 10.7% | 37.2% | 24.5% |
| Share / Issue Repurchase | 30 | 0 | 0 | 0 | 0 |
| Cost of Dividends Paid | 0 | 0 | 0 | 0 | 0 |
| Change in Debt | (23) | (2) | (102) | (20) | (20) |

Balance Sheet Data (Dec)

| (US\$ Millions) | 2021A | 2022A | 2023E | 2024E | 2025E |
|---------------------------------------|------------|------------|------------|------------|--------------|
| Cash & Equivalents | 234 | 244 | 311 | 519 | 781 |
| Trade Receivables | 35 | 55 | 73 | 88 | 102 |
| Other Current Assets | 15 | 102 | 106 | 109 | 112 |
| Property, Plant & Equipment | 1 | 1 | 3 | 4 | 4 |
| Other Non-Current Assets | 148 | 273 | 246 | 241 | 236 |
| Total Assets | 433 | 674 | 739 | 961 | 1,235 |
| Short-Term Debt | 2 | 2 | 2 | 20 | 20 |
| Other Current Liabilities | 52 | 77 | 78 | 80 | 81 |
| Long-Term Debt | 190 | 190 | 190 | 190 | 190 |
| Other Non-Current Liabilities | 3 | 3 | 3 | 3 | 3 |
| Total Liabilities | 247 | 271 | 272 | 292 | 293 |
| Total Equity | 187 | 403 | 467 | 669 | 942 |
| Total Equity & Liabilities | 433 | 674 | 739 | 961 | 1,235 |

* For full definitions of iQmethodSM measures, see page 5.

Company Sector

Pharmaceuticals

Company Description

Harmony Biosciences is a mid-cap commercial-stage biotech that sells Wakix for treatment of EDS (excessive daytime sleepiness) and/or cataplexy in adult patients with narcolepsy. The company is conducting Wakix label expansion studies for EDS associated with (1) idiopathic hypersomnia, (2) Prader-Willi Syndrome, and (3) myotonic dystrophy type 1.

Investment Rationale

We rate HRMY Underperform on lack of high-impact catalysts and a challenging path to addressing a '29 Wakix LOE on balanced risk-reward. At this juncture we would have preferred to see the company more active on BD to diversify its product portfolio. Our model is highly sensitive to LOE assumption, assuming Wakix can exceed \$1bn in '29+ revenue, though we do not believe it is prudent for investors to assign value to terminal polymorph patent (susceptible to non-infringing alternative polymorphs)

Stock Data

Average Daily Volume 570,913

Quarterly Earnings Estimates

| | 2022 | 2023 |
|----|-------|-------|
| Q1 | 0.51A | 0.66A |
| Q2 | 0.57A | 0.76A |
| Q3 | 0.95A | 0.97A |
| Q4 | 0.97A | 0.71E |

Acronyms and abbreviations

BD: business development

CBD: cannabinoid

FMR1: gene

FXS: Fragile X Syndrome

k: thousand

LOE: loss of exclusivity

IH: idiopathic hypersomnia

Ph: Phase

PO: price objective

POS: probability of success

pts: patients

Price objective basis & risk

Harmony Biosciences (HRMY)

Our \$30 price objective is based on a sum-of-the-parts (SOTP) analysis. Key assumptions are that we forecast cash flow for each commercial and near-term pipeline asset through 2032E and a discount rate of 9%.

Downside risks are (1) slower-than-expected commercial uptake of Wakix and (2) IP litigation or settlement with generic Wakix manufacturers ahead of LOE.

Upside risks are (1) stronger-than-expected commercial update of Wakix and (2) FDA decision that we expect could maintain status quo on Wakix marketability in response to a recent Citizen's Petition.

Analyst Certification

I, Jason M. Gerberry, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or view expressed in this research report.

US - Specialty Pharma & Biotechnology Coverage Cluster

| Investment rating | Company | BofA Ticker | Bloomberg symbol | Analyst |
|---------------------|---------------------------|-------------|------------------|-------------------|
| BUY | | | | |
| | Arcellx, Inc. | ACLX | ACLX US | Jason M. Gerberry |
| | Arrowhead Pharmaceuticals | ARWR | ARWR US | Jason M. Gerberry |
| | bluebird bio | BLUE | BLUE US | Jason M. Gerberry |
| | Exelixis | EXEL | EXEL US | Jason M. Gerberry |
| | Immunovant, Inc. | IMVT | IMVT US | Jason M. Gerberry |
| | Intra-Cellular Therapies | ITCI | ITCI US | Jason M. Gerberry |
| | Jazz Pharmaceuticals | JAZZ | JAZZ US | Jason M. Gerberry |
| | Lyra Therapeutics | LYRA | LYRA US | Jason M. Gerberry |
| | Oculus Holding AG | OCS | OCS US | Jason M. Gerberry |
| | ProKidney Corp | PROK | PROK US | Jason M. Gerberry |
| | Relay Therapeutics | RLAY | RLAY US | Jason M. Gerberry |
| | Tarsus Pharmaceuticals | TARS | TARS US | Jason M. Gerberry |
| | Teva Pharmaceuticals | TEVA | TEVA US | Jason M. Gerberry |
| | Vaxcyte Inc | PCVX | PCVX US | Jason M. Gerberry |
| | Xenon Pharmaceuticals | XENE | XENE US | Jason M. Gerberry |
| NEUTRAL | | | | |
| | Alkermes | ALKS | ALKS US | Jason M. Gerberry |
| | Amphastar Pharmaceuticals | AMPH | AMPH US | Jason M. Gerberry |
| | Axsome Therapeutics | AXSM | AXSM US | Jason M. Gerberry |
| | Galapagos | GLPG | GLPG US | Jason M. Gerberry |
| | Ionis | IONS | IONS US | Jason M. Gerberry |
| | Roivant | ROIV | ROIV US | Chi M. Fong |
| UNDERPERFORM | | | | |
| | Bausch Health Cos Inc | BHC | BHC US | Jason M. Gerberry |
| | FibroGen Inc. | FGEN | FGEN US | Jason M. Gerberry |
| | Harmony Biosciences | HRMY | HRMY US | Jason M. Gerberry |
| | Organon | OGN | OGN US | Jason M. Gerberry |
| | Viatis Inc. | VTRS | VTRS US | Jason M. Gerberry |

IQmethodSM Measures Definitions

Business Performance

Return On Capital Employed

Return On Equity
Operating Margin
Earnings Growth
Free Cash Flow

Quality of Earnings

Cash Realization Ratio
Asset Replacement Ratio
Tax Rate
Net Debt-To-Equity Ratio
Interest Cover

Valuation Toolkit

Price / Earnings Ratio
Price / Book Value
Dividend Yield
Free Cash Flow Yield
Enterprise Value / Sales

EV / EBITDA

Numerator

NOPAT = (EBIT + Interest Income) × (1 – Tax Rate) + Goodwill Amortization

Net Income
Operating Profit
Expected 5 Year CAGR From Latest Actual
Cash Flow From Operations – Total Capex

Numerator

Cash Flow From Operations
Capex
Tax Charge
Net Debt = Total Debt – Cash & Equivalents
EBIT

Numerator

Current Share Price
Current Share Price
Annualised Declared Cash Dividend
Cash Flow From Operations – Total Capex
EV = Current Share Price × Current Shares + Minority Equity + Net Debt +
Other LT Liabilities
Enterprise Value

Denominator

Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill
Amortization
Shareholders' Equity
Sales
N/A
N/A

Denominator

Net Income
Depreciation
Pre-Tax Income
Total Equity
Interest Expense

Denominator

Diluted Earnings Per Share (Basis As Specified)
Shareholders' Equity / Current Basic Shares
Current Share Price
Market Cap = Current Share Price × Current Basic Shares
Sales

Basic EBIT + Depreciation + Amortization

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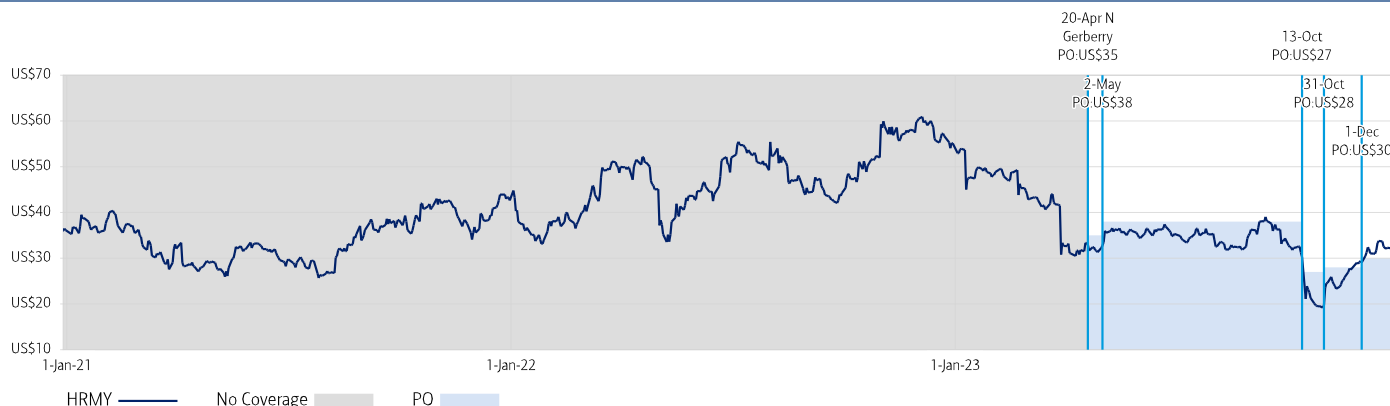
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Disclosures

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Harmony Biosciences (HRMY) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

The Investment Opinion System is contained at the end of the report under the heading "Fundamental Equity Opinion Key". Dark grey shading indicates the security is restricted with the opinion suspended. Medium grey shading indicates the security is under review with the opinion withdrawn. Light grey shading indicates the security is not covered. Chart is current as of a date no more than one trading day prior to the date of the report.

Equity Investment Rating Distribution: Health Care Group (as of 30 Sep 2023)

| Coverage Universe | Count | Percent | Inv. Banking Relationships ^{R1} | Count | Percent |
|-------------------|-------|---------|--|-------|---------|
| Buy | 233 | 60.21% | Buy | 113 | 48.50% |
| Hold | 83 | 21.45% | Hold | 33 | 39.76% |
| Sell | 71 | 18.35% | Sell | 25 | 35.21% |

Equity Investment Rating Distribution: Global Group (as of 30 Sep 2023)

| Coverage Universe | Count | Percent | Inv. Banking Relationships ^{R1} | Count | Percent |
|-------------------|-------|---------|--|-------|---------|
| Buy | 1869 | 53.48% | Buy | 1046 | 55.97% |
| Hold | 828 | 23.69% | Hold | 461 | 55.68% |
| Sell | 798 | 22.83% | Sell | 370 | 46.37% |

^{R1} Issuers that were investment banking clients of BofA Securities or one of its affiliates within the past 12 months. For purposes of this Investment Rating Distribution, the coverage universe includes only stocks. A stock rated Neutral is included as a Hold, and a stock rated Underperform is included as a Sell.

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| Investment rating | Total return expectation (within 12-month period of date of initial rating) | Ratings dispersion guidelines for coverage cluster ^{R2} |
|-------------------|---|--|
| Buy | ≥ 10% | ≤ 70% |
| Neutral | ≥ 0% | ≤ 30% |
| Underperform | N/A | ≥ 20% |

^{R2} Ratings dispersions may vary from time to time where BofA Global Research believes it better reflects the investment prospects of stocks in a Coverage Cluster.

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