

Harmony Biosciences

4Q wrap: commercial performance in-line, while Ph3 Zygel data expected in 2025

Reiterate Rating: UNDERPERFORM | PO: 30.00 USD | Price: 30.27 USD

Uneventful quarter, clinical update timelines more clear

HRMY's 4Q update was relatively uneventful after 4Q pre-announcement and '24 guide (provided in January). As such, we make negligible updates to our forecast and our PO remains \$30/shr. We remain Underperform given the lack of visibility on pipeline assets that can replace Wakix post our 2029 LOE assumption. On the call, management did fine-tune its timing assumption for Ph3 Zygel (topical cannabidiol; Fragile X Syndrome) data readout which is expected by mid-'25 whereas asset acquisition CVR indicated data could have come as early as YE24. We currently assign zero value to Zygel given unclear mechanism, prior failed Ph2 study and complicated nature of FXS. There were no new updates offered regarding the Wakix lifecycle management programs which remains on track for initial human (pharmacokinetic) data update on the 1Q EPS call. With tougher Wakix sales comps in 2024 plus an increasingly competitive narcolepsy market, we see limited upside to our/street Wakix numbers and we see a catalyst-light setup in 2024.

Zygel Fragile X Syndrome study tracking mid-'25 readout

Today, management provided its first concrete Ph3 Zygel readout timeline and noted enrollment is set to complete by 1Q25 and readout by mid-'25. The Ph3 study is a 204 patient study with patients randomized to Zygel or placebo (1:1) and pace of enrollment (study started Sep '21) could be slowed by a) rare/orphan population size – 80K US FXS patients; b) screening criteria restricting to those with full methylation of FMR1 gene, which is relevant for 60% of individuals with FXS. Assuming HRMY can complete enrolling by 1Q25, we believe the readout timeline is feasible given 18-week primary endpoint measuring a battery of aberrant patient behaviors.

Wakix life cycle management

Management expects to share pharmacokinetic data related to next-generation pitolisants (Formulation 1 & 2) on next earnings call in May 2024. The company has two formulations, though formulation 1 is an enhanced formulation offering possibility of higher dosage strength and extend IP to 2040+, while formulation 2 is a modified formulation (abbreviated development program) which would launch during the current Wakix lifecycle. The company has not offered any details on target product profile.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	3.00	3.12	3.64	4.53	5.63
GAAP EPS	2.97	2.13	2.96	3.85	4.95
EPS Change (YoY)	44.9%	4.0%	16.7%	24.5%	24.3%
Consensus EPS (Bloomberg)			3.67	4.70	6.54
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	10.1x	9.7x	8.3x	6.7x	5.4x
GAAP P/E	10.2x	14.2x	10.2x	7.9x	6.1x
EV / EBITDA*	11.9x	7.4x	5.7x	4.6x	3.7x
Free Cash Flow Yield*	8.1%	9.2%	11.9%	14.9%	18.6%

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

22 February 2024

Equity

Key Changes

(US\$)	Previous	Current
2024E Rev (m)	701.3	705.0
2025E Rev (m)	816.6	817.6
2026E Rev (m)	915.1	922.4
2024E EPS	3.94	3.64
2025E EPS	4.86	4.53
2026E EPS	5.59	5.63
2024E EBITDA (m)	271.6	257.8
2025E EBITDA (m)	335.5	319.6
2026E EBITDA (m)	382.4	394.3

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Stock Data

Price	30.27 USD
Price Objective	30.00 USD
Date Established	1-Dec-2023
Investment Opinion	C-3-9
52-Week Range	18.61 USD - 46.97 USD
Mkt Val (mn) / Shares Out (mn)	1,773 USD / 58.6
Free Float	54.5%
Average Daily Value (mn)	8.21 USD
BofA Ticker / Exchange	HRMY / NAS
Bloomberg / Reuters	HRMY US / HRMY.OQ
ROE (2024E)	37.7%
Net Dbt to Eqty (Dec-2023A)	-26.0%
ESGMeter TM	Low

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See glossary of acronyms on page 3

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Timestamp: 22 February 2024 02:00PM EST

iQprofileSM Harmony Biosciences

iQmethodSM – Bus Performance*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	27.1%	28.6%	27.8%	25.9%	24.8%
Return on Equity	62.3%	43.1%	37.7%	33.5%	30.3%
Operating Margin	33.6%	38.4%	40.0%	42.1%	45.4%
Free Cash Flow	144	163	211	264	330

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	0.8x	0.9x	1.0x	1.0x	1.0x
Asset Replacement Ratio	0x	0.1x	0.2x	0.2x	0.2x
Tax Rate	NM	19.1%	24.0%	24.0%	24.0%
Net Debt-to-Equity Ratio	-12.9%	-26.0%	-45.7%	-60.0%	-69.4%
Interest Cover	9.4x	24.7x	31.1x	NM	NA

Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	438	582	705	818	922
% Change	43.4%	32.9%	21.1%	16.0%	12.8%
Gross Profit	354	461	557	638	719
% Change	41.8%	30.0%	20.9%	14.5%	12.8%
EBITDA	124	199	258	320	394
% Change	54.2%	60.8%	29.6%	24.0%	23.4%
Net Interest & Other Income	(40)	10	0	7	17
Net Income (Adjusted)	184	188	214	267	331
% Change	49.8%	2.6%	13.7%	24.6%	24.2%

Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	184	188	214	267	331
Depreciation & Amortization	23	23	23	22	22
Change in Working Capital	(4)	(21)	(18)	(15)	(14)
Deferred Taxation Charge	(86)	0	0	0	0
Other Adjustments, Net	28	(25)	(5)	(5)	(5)
Capital Expenditure	0	(3)	(4)	(4)	(5)
Free Cash Flow	144	163	211	264	330
% Change	46.9%	12.7%	29.4%	25.4%	24.9%
Share / Issue Repurchase	0	0	0	0	0
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	(2)	(102)	(20)	(20)	(20)

Balance Sheet Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash & Equivalents	244	314	513	766	1,085
Trade Receivables	55	73	88	102	115
Other Current Assets	102	107	110	113	114
Property, Plant & Equipment	1	3	4	4	5
Other Non-Current Assets	273	246	241	236	237
Total Assets	674	743	957	1,222	1,556
Short-Term Debt	2	2	20	20	20
Other Current Liabilities	77	79	80	81	82
Long-Term Debt	190	190	190	190	190
Other Non-Current Liabilities	3	3	3	3	3
Total Liabilities	271	273	292	293	294
Total Equity	403	470	665	928	1,262
Total Equity & Liabilities	674	743	957	1,222	1,556

* 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 271,112

Quarterly Earnings Estimates

	2023	2024
Q1	0.66A	NAE
Q2	0.76A	NAE
Q3	0.97A	NAE
Q4	0.74A	NAE

Acronyms:

FXS: Fragile X Syndrome

IP: intellectual property

next-gen: next-generation

PK: pharmacokinetic

CT.gov: clinicaltrials.gov

CVR: contingent value right

LOE: loss of exclusivity

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

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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
	Ionis	IONS	IONS US	Jason M. Gerberry
	Jazz Pharmaceuticals	JAZZ	JAZZ US	Jason M. Gerberry
	Lyra Therapeutics	LYRA	LYRA US	Jason M. Gerberry
	Oculis Holding AG	OCS	OCS 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
	ProKidney Corp	PROK	PROK 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
	Viartis 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

$\text{NOPAT} = (\text{EBIT} + \text{Interest Income}) \times (1 - \text{Tax Rate}) + \text{Goodwill Amortization}$

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

$\text{EV} = \text{Current Share Price} \times \text{Current Shares} + \text{Minority Equity} + \text{Net Debt} +$

Other LT Liabilities

Enterprise Value

Denominator

$\text{Total Assets} - \text{Current Liabilities} + \text{ST Debt} + \text{Accumulated Goodwill}$

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

$\text{Market Cap} = \text{Current Share Price} \times \text{Current Basic Shares}$

Sales

Basic EBIT + Depreciation + Amortization

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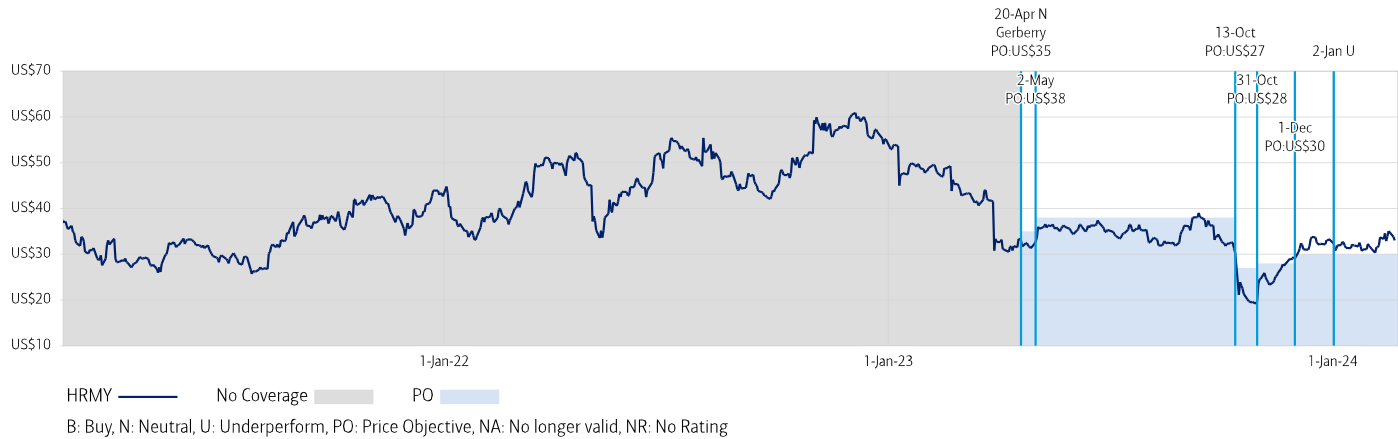
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Harmony Biosciences (HRMY) Price Chart



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Equity Investment Rating Distribution: Health Care Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

^{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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