

PTC Therapeutics

CHMP reaffirms negative opinion on Translarna; Reiterate Underperform

Reiterate Rating: UNDERPERFORM | PO: 15.00 USD | Price: 26.66 USD

Official EC ratification expected within 67-days

PTCT announced that the CHMP has decided to maintain their negative opinion regarding the renewal of Translarna's conditional marketing authorization for nmDMD in EU. In accordance with EU regulatory timelines, the EC will have 67-days to adopt the CHMP opinion, resulting in the removal of Translarna from the EU market. We highlight we anticipated this as the most likely outcome for the appeal based on the unconvincing evidence of clinical benefit seen in the pivotal Study 041 trial. In prior conversations, mgmt commented that EU sales contribute roughly 45-48% to total Translarna revenues. Recall, the company has marketing authorization in Israel, South Korea, Chile, Brazil and Russia that are also subject to renewal. Mgmt has previously highlighted that marketing authorization renewal in Israel, South Korea and Chile will rely heavily on continued EMA renewal, which would put those revenues also at risk. We look for clarity on the timing of these renewals in the upcoming 4Q23 earnings call as well as their contribution to total revenue. As a first step, we cut our nominal ex-US Translarna sales by roughly 60% and now model FY24 revenue of \$151.6mn. In our view, there is still additional downside to come given the marketing authorization renewal risk for other territories as well as potential for increased market competition from SRPT's gene therapy, Elevidys. We reiterate our Underperform rating with new \$15 PO (prev. \$20; see model changes) as we look for additional clarity at the upcoming 4Q23 earnings call.

Translarna US approval continues to seem unlikely

On Translarna in the US, PTCT guides to a meeting with the FDA in 1Q to determine a potential NDA submission path for Translarna. Recall, the company received a CRL from the FDA in 2017 and has been working on finding a path for US approval ever since. Mgmt notes this will likely be the company's last attempt for approval. In our view, we think the FDA is unlikely to change their stance without the support of additional clinical data, which PTCT will not be providing. As such, we continue to view US approval as unlikely and think the negative CHMP opinion reaffirms our stance. We currently assign a 15% US LoS as we await FDA feedback from the meeting.

Changes to our DCF-based model

To account for the loss of EU revenues, we increase our ex-US LoS to 100% (prev. 70%) but lower our yearly penetration ramp estimates by ~60%. As such, we now model ~60% lower revenues for Translarna in 2024+ with the program now contributing \$3/sh to our PO (prev. \$8/sh). We also slightly lower our SG&A estimates for the franchise given the company will no longer need an EU Translarna salesforce. We look for updated FY24 revenue and operating expense guidance at the upcoming 4Q23 earnings call.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(7.79)	(3.08)	(8.97)	(8.63)	(5.20)
EPS Change (YoY)	-4.8%	60.5%	-191.2%	3.8%	39.7%
Consensus EPS (Bloomberg)			(5.55)	(4.20)	(1.88)
DPS	0	0	0	0	0
Valuation (Dec)					
EV / EBITDA*	NM	336.2x	NM	NM	NM
Free Cash Flow Yield*	-19.3%	-2.9%	-26.3%	-25.1%	-12.1%

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

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Timestamp: 26 January 2024 08:08AM EST

26 January 2024

Equity

Key Changes

(US\$)	Previous	Current
Price Obj.	20.00	15.00
2024E Rev (m)	574.2	460.5
2025E Rev (m)	592.8	483.7
2026E Rev (m)	NA	720.9
2024E EPS	-5.79	-8.97
2025E EPS	-5.61	-8.63
2026E EPS	NA	-5.20

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Stock Data

Price	26.66 USD
Price Objective	15.00 USD
Date Established	25-Jan-2024
Investment Opinion	C-3-9
52-Week Range	17.53 USD - 59.84 USD
Mkt Val (mn) / Shares Out (mn)	2,012 USD / 75.5
Free Float	98.8%
Average Daily Value (mn)	32.95 USD
BofA Ticker / Exchange	PTCT / NAS
Bloomberg / Reuters	PTCT US / PTCT.OQ
ROE (2024E)	-63.9%
Net Dbt to Eqty (Dec-2023A)	-33.1%
ESGMeter TM	Medium

ESGMeter is not indicative of a company's future stock price performance and is not an investment recommendation or rating. ESGMeter is independent of BofA Global Research's equity investment rating, volatility risk rating, income rating, and price objective for that company. For full details, refer to "BofA ESGMeter Methodology".

See page 3 for abbreviations

iQprofileSM PTC Therapeutics

iQmethodSM – Bus Performance*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-28.0%	-8.1%	-44.8%	-52.3%	-26.2%
Return on Equity	NM	-51.6%	-63.9%	-76.4%	-44.0%
Operating Margin	-64.0%	-12.6%	-122.6%	-112.2%	-39.6%
Free Cash Flow	(389)	(58)	(529)	(505)	(244)

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	NM	NM	NM	NM	NM
Asset Replacement Ratio	0.2x	0.2x	0.2x	0.2x	0.2x
Tax Rate	4.8%	11.0%	4.0%	4.2%	6.7%
Net Debt-to-Equity Ratio	NM	-33.1%	-6.0%	-1.7%	-13.6%
Interest Cover	-5.6x	-1.5x	-7.1x	-6.9x	-3.6x

Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	699	946	460	484	721
% Change	29.7%	35.4%	-51.3%	5.0%	49.0%
Gross Profit	654	891	423	425	666
% Change	29.2%	36.2%	-52.5%	0.6%	56.5%
EBITDA	(319)	10	(436)	(414)	(156)
% Change	-2.7%	NM	NM	5.0%	62.2%
Net Interest & Other Income	(140)	(140)	(140)	(140)	(140)
Net Income (Adjusted)	(559)	(230)	(676)	(654)	(397)
% Change	-6.7%	58.7%	-193.2%	3.2%	39.3%

Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(559)	(231)	(676)	(655)	(397)
Depreciation & Amortization	129	129	129	129	129
Change in Working Capital	(82)	(3)	(4)	(5)	(6)
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	155	79	54	58	62
Capital Expenditure	(32)	(32)	(32)	(32)	(32)
Free Cash Flow	-389	-58	-529	-505	-244
% Change	-39.0%	85.0%	-809.4%	4.7%	51.7%
Share / Issue Repurchase	71	200	100	250	200
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	97	(497)	0	0	0

Balance Sheet Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash & Equivalents	280	485	128	89	206
Trade Receivables	156	171	188	207	228
Other Current Assets	258	241	233	234	241
Property, Plant & Equipment	73	8	8	8	8
Other Non-Current Assets	939	784	784	784	784
Total Assets	1,706	1,689	1,340	1,321	1,467
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	406	372	388	406	425
Long-Term Debt	572	75	75	75	75
Other Non-Current Liabilities	1,075	2	2	2	2
Total Liabilities	2,053	449	465	483	502
Total Equity	(347)	1,240	875	838	965
Total Equity & Liabilities	1,706	1,689	1,340	1,321	1,467

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

Company Sector

Biotechnology

Company Description

PTC is a biopharmaceutical company in South Plainfield, New Jersey focused on the discovery and development of orally administered, proprietary small molecule drugs that target post-transcriptional control processes. The company has several approved assets in Duchenne muscular dystrophy (DMD), Translarna in ex-US market and Emflaza. PTC also has partnered with Roche to develop Evrysdi in spinal muscular atrophy (SMA) that received approval in US.

Investment Rationale

We rate PTCT shares Underperform. PTCT's Evrysdi is approved for SMA patients. While we believe Evrysdi can become the standard of care in a competitive landscape, we already assume high penetration, many questions remain on the rest of the portfolio and we await visibility on other opportunities including gene therapy candidates for AADC deficiency and Friedrich ataxia (FA). Updates on its Bio-e and splicing platforms, Evrysdi performance, and Translarna patent expiration are also of focus.

Stock Data

Average Daily Volume 1,235,858

Quarterly Earnings Estimates

	2023	2024
Q1	-1.88A	-1.56E
Q2	-2.66A	-2.37E
Q3	-1.76A	-2.55E
Q4	-0.01A	-2.47E

Abbreviations

CHMP: Committee for Medicinal Products for Human Use

CRL: complete response letter

EC: European Commission

EMA: European medicines Agency

FDA: Food and Drug Administration

LoS: likelihood-of-success

NDA: New Drug Application

nmDMD: nonsense mutation Duchenne muscular dystrophy

Ph: phase

SRPT: Sarepta Therapeutics

Price objective basis & risk

PTC Therapeutics (PTCT)

Our \$15 price objective for PTC reflects \$3 for Translarna in DMD, \$7 for Evrysdi in SMA, \$3 for Emflaza, \$8 for GT-AADC, \$5 for PKU, and the remainder of our valuation is cash and pipeline spend. We use an 10% WACC for Translarna, a 9% WACC for Emflaza and Evrysdi, and an 10% WACC for Upstaza (PCT-AADC) and sepiapterin, consistent with how we model drugs in similar stage of development. We attach a 14% WACC to the early-stage pipeline pending presentation of data. We assume zero terminal value for all products, also consistent with our valuation of other covered companies.

Downside risks to our price objective are removal of the approval for Translarna in other ex-US territories, failure to receive approval for Translarna in the US, and slower than expected uptake for Evrysdi in SMA and Upstaza in AADC deficiency.

Upside risks to our price objective are faster-than-expected uptake of Evrysdi in SMA, higher Emflaza or Translarna sales than expected, US approval for DMD, and a successful AADC launch.

Analyst Certification

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US - Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	4D Molecular Therapeutics, Inc.	FDMT	FDMT US	Tazeen Ahmad
	Alnylam Pharmaceuticals	ALNY	ALNY US	Tazeen Ahmad
	Amicus Therapeutics	FOLD	FOLD US	Tazeen Ahmad
	Annexon Biosciences	ANNX	ANNX US	Tazeen Ahmad
	Apellis Pharmaceuticals	APLS	APLS US	Tazeen Ahmad
	Argenx SE	ARGX	ARGX US	Tazeen Ahmad
	Arvinas	ARVN	ARVN US	Tazeen Ahmad
	Ascendis Pharma	ASND	ASND US	Tazeen Ahmad
	Biocryst Pharmaceuticals Inc	BCRX	BCRX US	Tazeen Ahmad
	BioNTech	BNTX	BNTX US	Tazeen Ahmad
	Denali Therapeutics	DNLI	DNLI US	Tazeen Ahmad
	Inozyme Pharma, Inc.	INZY	INZY US	Tazeen Ahmad
	Merus	MRUS	MRUS US	Tazeen Ahmad
	Neurocrine Biosciences	NBIX	NBIX US	Tazeen Ahmad
	PepGen Inc	PEPG	PEPG US	Tazeen Ahmad
	Prothena Corporation	PRTA	PRTA US	Tazeen Ahmad
	Rhythm Pharmaceuticals	RYTM	RYTM US	Tazeen Ahmad
	Sarepta Therapeutics	SRPT	SRPT US	Tazeen Ahmad
	Ultragenyx Pharmaceuticals	RARE	RARE US	Tazeen Ahmad
NEUTRAL				
	Acadia Pharmaceuticals	ACAD	ACAD US	Tazeen Ahmad
	Incyte Corporation	INCY	INCY US	Tazeen Ahmad
	SAGE Therapeutics	SAGE	SAGE US	Tazeen Ahmad
UNDERPERFORM				
	Achilles Therapeutics	ACHL	ACHL US	Tazeen Ahmad
	Fate Therapeutics	FATE	FATE US	Tazeen Ahmad
	Fulcrum Therapeutics	FULC	FULC US	Tazeen Ahmad
	Pharvaris	PHVS	PHVS US	Tazeen Ahmad
	PTC Therapeutics	PTCT	PTCT US	Tazeen Ahmad

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

iQmethodSM is the set of BofA Global Research standard measures that serve to maintain global consistency under three broad headings: Business Performance, Quality of Earnings, and validations. The key features of iQmethod are: A consistently structured, detailed, and transparent methodology. Guidelines to maximize the effectiveness of the comparative valuation process, and to identify some common pitfalls.

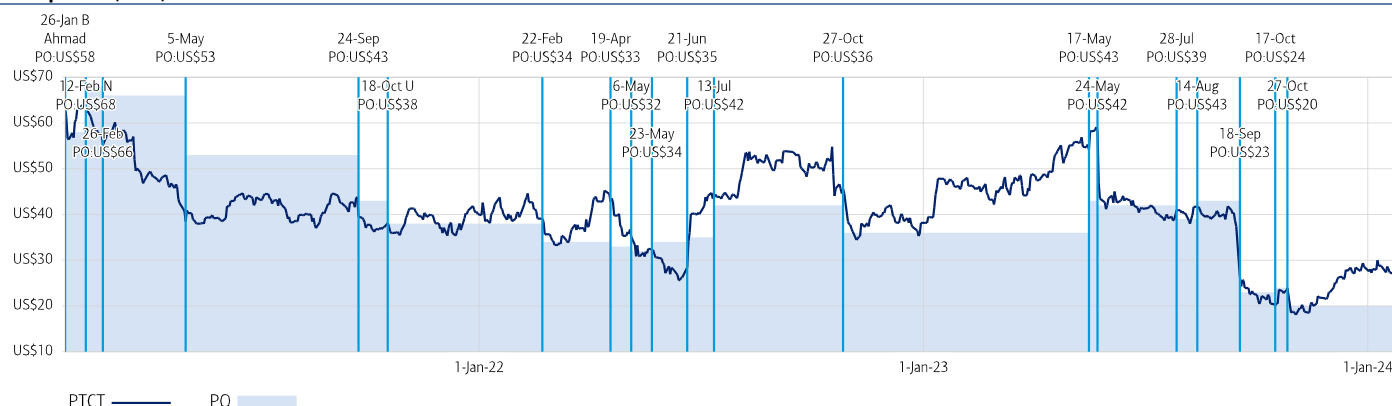
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PTC Therapeutics (PTCT) Price Chart



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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%

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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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