

PTC Therapeutics

Clarity needed on 2024 commercial and pipeline outlook; Reiterate Underperform

Reiterate Rating: UNDERPERFORM | PO: 15.00 USD | Price: 31.95 USD

Shaky 2024 commercial outlook facing multiple pressures

PTCT reported FY23 total revenue of \$938mn including \$356mn in Translarna sales and \$255mn in Emflaza sales in-line with preannounced numbers. Mgmt narrowed FY24 total revenue guidance to \$600-680mn (prev. \$600-850mn). Recall, the CHMP decided to maintain their [negative opinion for renewal of Translarna EU conditional approval in January](#). Official EC ratification is expected either in late-March or early-April resulting in Translarna removal from EU markets. On impacts to other markets where Translarna has conditional approval, mgmt noted they expect other territories to act independently of the EMA. However, we highlight language in the company's recent 2023 10-K filing notes several territories outside of the EEA reference and depend on the determinations of the EMA when deciding on marketing renewal. As such, we note high focus on the upcoming Brazil renewal decision in April as it will likely set precedence for how other territories will respond. Additionally, we highlight the recent Emflaza US LOE in February is also expected to negatively impact FY24 revenues. Given the shaky 2024 commercial franchise outlook, we model FY24 revenue of \$600mn on the low end of guidance. In our view, there is considerable risk for additional downside to our estimates if Translarna approval is withdrawn in additional territories and Emflaza US LOE impacts are greater than expected. We reiterate our Underperform rating with \$15 PO.

Multiple upcoming 2024 pipeline regulatory catalysts

We highlight our continued view that PTCT's pipeline still needs de-risking and note near-term focus on several upcoming regulatory catalysts. On vatiquinone in FA, mgmt noted a recent positive Type C meeting with FDA in 1Q, which focused on the importance of the upright stability mFARS subscale. PTCT now guides to a potential NDA submission path in late-24 using the results from ph 3 MOVE-FA study and OLE data. While encouraged by the positive FDA discussion, we look for clarity on the NDA submission path and think it is likely the FDA may still require an additional confirmatory study prior to submission. On sepiapterin in PKU, mgmt guides to submitting an MAA to the EMA in March as well as an NDA submission to the FDA no later than 3Q. Additionally, in March, the company expects to submit a BLA for Upstaza and meet with the FDA to discuss a Translarna approval path. Data-wise, PTCT expects to report interim 12-mos ph 2 HD data in 2Q and ph 2 ALS topline data in 4Q.

Changes to our DCF-based model

We update for final FY23 results, cash and share count and tweak op ex in-line with guidance. We also raise our FY24 Translarna and Emflaza estimates to \$264mn and \$186m, respectively, to be in-line with FY24 total revenue mgmt guidance.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(7.79)	(8.37)	(6.43)	(7.24)	(4.02)
EPS Change (YoY)	-4.8%	-7.4%	23.2%	-12.6%	44.5%
Consensus EPS (Bloomberg)			(6.23)	(5.00)	(2.61)
DPS	0	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	-15.9%	-18.7%	-13.8%	-16.3%	-6.3%

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

04 March 2024

Equity

Key Changes

(US\$)	Previous	Current
2024E Rev (m)	460.5	600.5
2025E Rev (m)	483.7	529.4
2026E Rev (m)	720.9	749.9
2024E EPS	-8.97	-6.43
2025E EPS	-8.63	-7.24
2026E EPS	-5.20	-4.02

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Stock Data

Price	31.95 USD
Price Objective	15.00 USD
Date Established	26-Jan-2024
Investment Opinion	C-3-9
52-Week Range	17.53 USD - 59.84 USD
Mkt Val (mn) / Shares Out (mn)	2,448 USD / 76.6
Free Float	98.5%
Average Daily Value (mn)	34.88 USD
BofA Ticker / Exchange	PTCT / NAS
Bloomberg / Reuters	PTCT US / PTCT.OQ
ROE (2024E)	-42.0%
Net Dbt to Eqty (Dec-2023A)	-33.1%
ESGMeter TM	Medium

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See abbreviations page 3

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Timestamp: 04 March 2024 06:11AM EST

iQprofileSM PTC Therapeutics

iQmethodSM – Bus Performance*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-28.0%	-30.2%	-30.9%	-37.6%	-15.9%
Return on Equity	NM	-140.2%	-42.0%	-49.8%	-24.7%
Operating Margin	-64.0%	-46.9%	-72.4%	-94.4%	-34.3%
Free Cash Flow	(389)	(457)	(337)	(399)	(154)

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%	10.0%	12.6%	11.2%	18.5%
Net Debt-to-Equity Ratio	NM	-33.1%	-23.0%	-27.5%	-38.4%
Interest Cover	-5.6x	-3.4x	-3.4x	-3.9x	-2.0x

Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	699	938	600	529	750
% Change	29.7%	34.2%	-36.0%	-11.8%	41.6%
Gross Profit	654	872	553	468	693
% Change	29.2%	33.4%	-36.6%	-15.3%	48.0%
EBITDA	(319)	(311)	(306)	(371)	(129)
% Change	-2.7%	2.5%	1.6%	-21.3%	65.3%
Net Interest & Other Income	(140)	(257)	(119)	(119)	(119)
Net Income (Adjusted)	(559)	(626)	(484)	(549)	(307)
% Change	-6.7%	-12.1%	22.7%	-13.3%	44.1%

Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(559)	(627)	(484)	(549)	(307)
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	76	54	58	62
Capital Expenditure	(32)	(32)	(32)	(32)	(32)
Free Cash Flow	-389	-457	-337	-399	-154
% Change	-39.0%	-17.7%	26.2%	-18.4%	61.4%
Share / Issue Repurchase	71	400	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	486	321	387	594
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	1,533	1,619	1,855
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)	1,241	1,068	1,136	1,353
Total Equity & Liabilities	1,706	1,689	1,533	1,619	1,855

* 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 1,091,661

Quarterly Earnings Estimates

	2023	2024
Q1	-1.88A	-1.14E
Q2	-2.66A	-1.73E
Q3	-1.76A	-1.90E
Q4	-2.06A	-1.65E

Abbreviations

ALS: amyotrophic lateral sclerosis

BLA: Biologics License Application

CHMP: Committee for Medicinal Products for Human Use

EC: European Commission

EEA: European Economic Area

EMA: European Medicines Agency

FA: Friedrich's ataxia

HD: Huntington's disease

LOE: loss of exclusivity

MAA: marketing authorization application

mFARS: modified Friedreich's Ataxia Rating Scale

Mgmt: management

Mos: months

NDA: New Drug Application

OLE: open label extension

Op ex: operating expenses

Ph: phase

PKU: phenylketonuria

Price objective basis & risk

PTC Therapeutics (PTCT)

Our \$15 price objective for PTC reflects \$4 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

I, Tazeen Ahmad, 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 - 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
	Ocular Therapeutix	OCUL	OCUL US	Tazeen Ahmad
	PepGen Inc	PEPG	PEPG 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
	Prothena Corporation	PRTA	PRTA 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

US - Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
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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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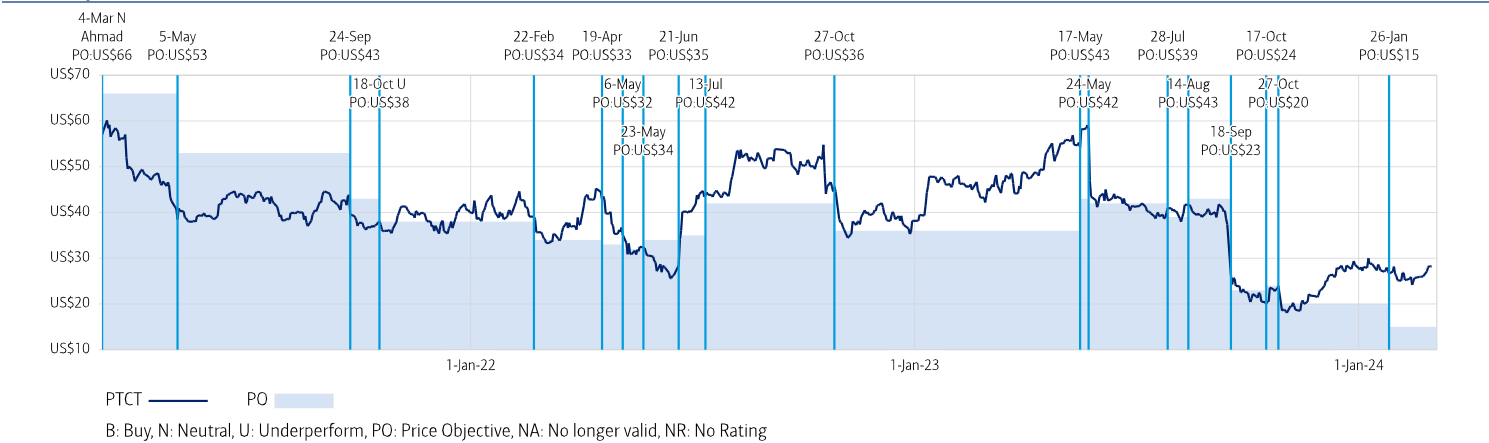
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PTC Therapeutics (PTCT) Price Chart



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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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