PTC Therapeutics, Inc (PTCT)

Rating	**OUTPERFORM* [V]**
Price (23 Jan 14, US$)	26.22
Target price (US$)	24.00[1]
52-week price range	29.32 - 13.59
Market cap. (US$ m)	653.33
Enterprise value (US$ m)	506.89

**Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.*
[1]Target price is for 12 months.
[V] = Stock considered volatile (see Disclosure Appendix).

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SMALL & MID CAP RESEARCH

Negative CHMP Decision; No Change to Thesis

The CHMP has adopted a negative opinion regarding conditional approval for ataluren, and PTCT plans to request a re-examination and expects a final ruling in Q2:14. Prior to the very recent run-up in the stock, we did not believe that there were any expectations for approval baked into the stock price. However, we now expect PTCT to give up most of the recent gain.

- **Negative opinion:** This was the expected, high-probability outcome from what we considered a long-shot filing (LINK to preview). The main reason cited by CHMP was inadequate proof of efficacy, stating that "the main study failed to show" a benefit in 6-minute walking distance, and the additional analyses "were insufficient to provide enough evidence of effectiveness." This is consistent with the language in the S-1 regarding the 120 day questions.
- **Re-examination:** In its release, PTCT implies that CHMP was concerned about the completion of the confirmatory Phase III. Guidance is to complete enrollment in mid-2014, so the trial should be mostly complete when CHMP re-examines the application in Q2:14. We still see this as a long-shot.
- **Catalysts:** (1) Re-examination in Q2:14; (2) complete enrollment in DMD Phase III in mid-2014, (3) SMA Phase I readout in 2014/15, (4) DMD Phase III read out in mid:2015, and (5) CF Phase III read out in 2016.
- **Our $24 TP is supported by a probability-weighted DCF of ataluren in DMD and CF:** Our valuation does not include any value for an early approval of ataluren or the SMA program, which recently entered Phase I.

Financial and valuation metrics

Year	12/12A	12/13E	12/14E	12/15E
EPS (CS adj.) (US$)	42.50	-3.68	-2.47	-1.92
Prev. EPS (US$)	—	—	—	—
P/E (x)	0.6	-7.1	-10.6	-13.7
P/E rel. (%)	3.5	-43.0	-70.3	-100.4
Revenue (US$ m)	33.9	36.3	18.5	22.0
EBITDA (US$ m)	-24.1	-37.4	-55.9	-60.0
OCFPS (US$)	NM	-3.27	-2.12	-1.46
P/OCF (x)	—	-8.0	-12.4	-18.0
EV/EBITDA (current)	-20.6	-13.3	-8.9	-8.3
Net debt (US$ m)	2	-146	-88	-222
ROIC (%)	160.91	497.33	3,849.25	2,533.89

Number of shares (m)	24.92	IC (current, US$ m)	-16.66
BV/share (Next Qtr., US$)	-13.0	EV/IC (x)	-63.3
Net debt (Next Qtr., US$ m)	-146.4	Dividend (current, US$)	—
Net debt/tot cap (Next Qtr., %)	-105.8	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates

CHMP Decision

Comments posted by CHMP

> " The CHMP noted that the main study failed to show that patients taking Translarna could walk in six minutes a greater distance than patients taking placebo. Although the company performed additional analyses of the data, the CHMP considered that these were insufficient to provide enough evidence of effectiveness. When other measures of effectiveness were considered, including those directly linked to patients' daily activities, these provided only limited supportive evidence of the beneficial effects of Translarna. Finally, insufficient data had been provided to determine how the medicine works in the body and how its effects change with the dose."

We think PTCT not likely to file for conditional approval for CF until resolution of DMD filing

PTCT filed an MAA in Oct. 2012 seeking conditional approval of ataluren in DMD and received a decision roughly 15 months later. We do not expect PTCT to file an MAA for the CF indication (based on the prior Phase III results) until the DMD re-examination is completed. We also believe that PTCT may wait even longer to file for CF, until the confirmatory Phase III trial is well underway.

Exhibit 1: PTCT News Flow

Product/ Event	Indication	Catalyst	Expected Date	Price Sensitivity
Ataluren	Duchenne Muscular Dystrophy	Final ruling on ataluren re-examination	Q2:14	Medium
Ataluren	Cystic Fibrosis	Dose first patient in confirmatory CF Phase III study	H1:14	Low
Ataluren	Duchenne Muscular Dystrophy	Complete enrollment in confirmatory DMD Phase III study	Mid-2014	Low
Ataluren	Duchenne Muscular Dystrophy	Potential data from EU open-label extension study	H2:14	High
Ataluren	Cystic Fibrosis	Potential conditional EU approval	YE 2014	High
SMA program	Spinal muscular atrophy	Additional SMA data	YE 2014	Medium
SMA program	Spinal muscular atrophy	Complete Phase I	YE:2014	Low
Ataluren	Duchenne Muscular Dystrophy	Potential data from confirmatory DMD Phase III study	Mid-2015	High
Ataluren	Cystic Fibrosis	Complete enrollment in confirmatory CF Phase III study	Mid-2015	Low
Ataluren	Duchenne Muscular Dystrophy	FDA and EMA filing for full approval	Late-2015	Low
Ataluren	Duchenne Muscular Dystrophy	Potential FDA and EMA approval	Mid-2016	High
Ataluren	Cystic Fibrosis	Potential data from confirmatory CF Phase III study	Mid-2016	High
Ataluren	Cystic Fibrosis	FDA and MAA filing for full approval	YE:16/early 2017	Low
Ataluren	Cystic Fibrosis	Potential FDA and EMA approval	Mid-2017	High

Source: Company data, Credit Suisse estimates

Exhibit 2: PTCT Pipeline

Product/Indication	Phase	Target	Partner
Ataluren - Duchenne Muscular Dystrophy	Phase III; MAA submitted	Nonsense DMD mutations	Proprietary
Ataluren - Cystic Fibrosis	Phase III ready	Class 1 CFTR Mutations	Proprietary
Spinal muscular atrophy	Preclinical	SMN2	Roche
PTC596 - Oncology	Preclinical	BMI1	Proprietary
Antibacterial	Preclinical	DR gonorrhea, Gram (-) bacteria, MRSA	Proprietary

Source: Company data, Credit Suisse estimates

Exhibit 3: PTCT Model

($ in MM; except per share)	2011A	2012A	Q1:13A	Q2:13A	Q3:13A	Q4:13E	2013E	2014E	2015E	2016E	2017E	2018E
US Sales										15.6	102.2	174.7
EU Sales										13.7	51.8	114.4
ROW Royalties											2.7	7.0
Ataluren revenue (total)										29.3	156.6	296.1
Collaboration revenue	99.0	28.8	6.1	5.9	15.5	5.0	32.4	8.0	23.0	16.0	16.0	12.0
Grant revenue	6.5	5.2	1.1	1.0	0.8	1.0	3.9	3.0	4.0			
Total Revenues	105.4	33.9	7.1	6.9	16.3	6.0	36.3	11.0	27.0	45.3	172.6	308.1
COGS										2.3	12.5	23.7
Research and Development Expenses	58.7	46.1	11.3	14.7	13.9	12.0	51.9	50.8	53.8	63.0	70.0	77.0
Sales, General and Administrative Expenses	16.2	14.6	4.5	6.6	6.7	6.5	24.2	26.0	29.0	67.0	101.0	119.2
Total Costs and Expenses	74.8	60.8	15.7	21.3	20.6	18.5	76.1	76.8	82.8	132.3	183.5	219.9
Operating Income (Loss)	30.6	(26.8)	(8.6)	(14.5)	(4.3)	(12.5)	(39.8)	(65.8)	(55.8)	(87.1)	(10.9)	88.2
Interest Expense, net	(2.4)	(1.2)	(6.2)	(0.1)	0.0	(0.0)	(6.3)					
Other income, net	0.5	1.8	0.1	(0.0)	(0.2)	(1.0)	(1.1)	(4.0)	(4.0)	(4.0)	(4.0)	(4.0)
Income (Loss) before Tax	28.6	(26.2)	(14.7)	(14.6)	(4.4)	(13.5)	(47.2)	(69.8)	(59.8)	(91.1)	(14.9)	84.2
Provision for Income Tax (benefit)	2.3											
Net income (loss)	30.9	(26.2)	(14.7)	(14.6)	(4.4)	(13.5)	(47.2)	(69.8)	(59.8)	(91.1)	(14.9)	84.2
Net income attributable to common shareholders	0.0	0.7	(29.5)	(14.6)	(4.4)	(13.5)	(47.2)	(69.8)	(59.8)	(91.1)	(14.9)	84.2
EPS - diluted	4.55	42.50	(6,527)	(5.51)	(0.19)	(0.54)	(3.68)	(2.77)	(1.77)	(2.64)	(0.42)	2.16
Shares Outstanding - basic	0.001	0.003	0.005	2.65	23.80	24.92	12.84	25.23	33.80	34.48	35.17	35.88
Shares Outstanding - diluted	0.006	0.017	0.005	2.65	23.80	27.04	13.37	27.46	36.21	37.09	38.00	38.94

Source: Company data, Credit Suisse estimates

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Companies Mentioned *(Price as of 23-Jan-2014)*

PTC Therapeutics, Inc (PTCT.OQ, $26.22, OUTPERFORM[V], TP $24.0)
Roche (ROG.VX, SFr248.2)

Disclosure Appendix

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3-Year Price and Rating History for PTC Therapeutics, Inc (PTCT.OQ)

PTCT.OQ	Closing Price	Target Price	
Date	(US$)	(US$)	Rating
15-Jul-13	17.17	24.00	O *

** Asterisk signifies initiation or assumption of coverage.*

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Restricted	2%	

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Price Target: (12 months) for PTC Therapeutics, Inc (PTCT.OQ)

Method: Our $24 target price for PTCT is calculated by DCF (discounted cash flow), using probability-weighted sales estimates for ataluren in Duchenne muscular dystrophy (60% probability) and in cystic fibrosis (60% probability) modeled through 2030. We use a 38% tax rate and a 12% discount rate, and arrive at a $30 valuation based on current share count. We conservatively assume that PTCT will raise additional capital in 2015 and therefore adjust our valuation by adding 5 to 8M additional shares, which gives us a $24 target price.

Risk: Risks to our $24 target price for PTCT are (1) unexpected negative result in the Duchenne muscular dystrophy (DMD) or cystic fibrosis (CF) Phase III studies, (2) headline risk should the EMA (European Medicines Agency) reject conditional approval of ataluren in DMD, (3) limited newsflow in 2014, (4) potential emergence a competitive molecule in the DMD or CF space, and (5) potential need for additional capital (we model an equity raise in 2015).

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Investment principal on bonds can be eroded depending on sale price or market price. In addition, there are bonds on which investment principal can be eroded due to changes in redemption amounts. Care is required when investing in such instruments.

When you purchase non-listed Japanese fixed income securities (Japanese government bonds, Japanese municipal bonds, Japanese government guaranteed bonds, Japanese corporate bonds) from CS as a seller, you will be requested to pay the purchase price only.