PTC Therapeutics

Model Update Post Ataluren CHMP Positive Opinion

Overweight

PTCT, PTCT US
Price: $15.32

Price Target: $40.00

The surprise positive opinion for conditional approval of Translarna (ataluren) for patients with nonsense mutation Duchenne Muscular Dystrophy (nmDMD) was a major value creating event for PTC. The approval looks to cover ambulatory patients aged 5+, but we doubt that nmDMD patients who don't meet these criteria will be turned away. After a discussion with management, it is clear that a leadership team was already in place ahead of a potential EU approval, though reimbursement/commercial resources will likely be added. The probability of a formal EMEA approval is high, and we'd argue that the ongoing phase 3 study in nmDMD has to show consistency of clinical effect (and not necessarily be a 'homerun'). We've moved up launch timelines to early 2015 (from late 2016), which importantly has a dramatic P&L impact. For example, 2016 revenues go to $150M from $35M and loss per share goes to $(0.30) from $(3.17); in 2017 and 2018, our EPS estimates are $4.35 and $5.75, reflecting nmDMD sales (excluding nmCF and SMA economics), which shows significant leverage. In terms of the PTCT reaction (+52% vs the NBI: -0.1%), it seems very modest relative to the news. Perhaps because it is a Friday ahead of a holiday weekend or perhaps it's the negative environment in SMid-cap biotech, but we view today's muted reaction as a major buying opportunity for what looks like a transformative de-risking event. Reiterate Overweight rating.

- **Market dynamics:** We are expecting formal EU regulatory approval in the next few months. PTC estimates ~2,500 nmDMD patients in Europe, while we suspect a slightly smaller addressable population given the label (ambulatory aged 5 years+). However, we find it hard to believe use will be restricted in this population given the devastating nature of the disease. Of note, PTC did not make any comments on its pricing strategy, but we would expect "ultra-orphan" pricing of $200K. That said, in line with all EU drug launches, the company stressed that the launch in individual countries could take time (3-18 months, depending on the country).

- **Phase 3 ataluren trial in nmDMD on track for data in mid-2015:** On the call, the company reiterated that completion of enrollment in the Phase 3 nmDMD study remains on track for mid-2014. Recall, in the phase 2b trial, ataluren resulted in a 31-meter improvement in6MWD compared with placebo (p=0.0561) in nmDMD. That said, the benefit was 50m in subgroup matching the phase 3 enrollment criteria (p=0.0096), which we believe de-risks the ongoing study.

Biotechnology

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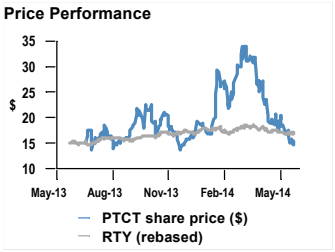

	YTD	1m	3m	12m
Abs	-8.5%	-26.1%	-48.9%	2.1%
Rel	-5.3%	-22.5%	-43.7%	-11.3%

PTC Therapeutics (PTCT;PTCT US)

FYE Dec	2013A	2014E	2015E (Prev)	2015E (Curr)	2016E (Prev)	2016E (Curr)
EPS Reported ($)						
Q1 (Mar)	(1.51)	(0.58)A	-	-	-	-
Q2 (Jun)	(0.59)	(0.69)	-	-	-	-
Q3 (Sep)	(0.19)	(0.75)	-	-	-	-
Q4 (Dec)	(0.75)	(0.79)	-	-	-	-
FY	(2.75)	(2.83)	(3.02)	(2.59)	(3.17)	(0.30)

Source: Company data, Bloomberg, J.P. Morgan estimates.

Company Data	
Price ($)	15.32
Date Of Price	22 May 14
52-week Range ($)	34.65-13.04
Market Cap ($ mn)	438.42
Fiscal Year End	Dec
Shares O/S (mn)	29
Price Target ($)	40.00
Price Target End Date	30-Dec-14

See page 6 for analyst certification and important disclosures.

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- **Adjusting estimates:** Given the positive CHMP opinion, we have brought forward the European launch of Translarna in nm DMD from late 2016 to early 2015, while our US launch remains unchanged. Our 2015-2016 WW Translarna sales increase to $20M and $140M from $0M and $25M, respectively. We have also increased associated SG&A expenses. The net impact is our 2015-2016 GAAP EPS increases to $(2.59) and $(0.30) from $(3.02) and $(3.17), respectively.

- **Reiterate Overweight rating.**

Changes to Our Model

Given the positive CHMP opinion, we have brought forward the European launch of Translarna in nm DMD from late 2016 to early 2015, while our US launch remains unchanged. Our 2015-2016 WW Translarna sales increase to $20M and $140M from $0M and $25M, respectively. We have also increased associated SG&A expenses. The net impact is our 2015-2016 GAAP EPS increases to $(2.59) and $(0.30) from $(3.02) and $(3.17), respectively.

Table 1: Changes to our Model

	2014		2015		2016	
	Old	New	Old	New	Old	New
Total Revenues	21.2	21.2	22.0	42.6	34.8	149.6
Cost of sales	0.0	0.0	0.0	2.1	2.5	14.0
Research and development	69.6	69.6	76.6	76.6	84.3	84.3
Sales, general and administrative	33.8	33.8	40.6	45.7	56.8	63.9
Operating Income	-82.2	-82.2	-95.2	-81.8	-108.8	-12.6
Net Income	-81.0	-81.0	-93.7	-80.3	-106.3	-10.1
Diluted GAAP EPS	-2.83	-2.83	-3.02	-2.59	-3.17	-0.30

Source: J.P. Morgan estimates.

Investment Thesis, Valuation and Risks

PTC Therapeutics *(Overweight; Price Target: $40.00)*

Investment Thesis

PTC is focused on therapies for orphan genetic diseases, with the most advanced compound being Translarna (ataluren), currently in phase 3 development for Duchene muscular dystrophy (DMD; data mid-2015) and cystic fibrosis (CF; beginning second study 1H14). We believe insights gained in prior ataluren clinical studies maximize the probability for success in phase 3. While Translarna, which is unpartnered, has potential in both indications, we conservatively include revenues only for DMD with peak WW sales of $700M, which could easily double should CF also be successful. Given a high probability of success for Translarna in DMD, good optionality in CF, and the conditional approval in the EU expected in 3Q14, we rate PTCT shares Overweight.

Valuation

Our $40 December 2014 price target for PTCT is based on our sum-of-the-parts analysis including Translarna only in nmDMD as well as the pipeline/platform technology. We project Translarna nmDMD sales to 2024, consistent with IP protection, assume no terminal value and an 8% discount rate. We further assume a high probability of success for ataluren in phase 3. We believe this appropriately reflects the risks of the phase 3 DMD program. We derive a value of $25/share for

ataluren. This, taken in combination with $7/share for the pipeline/platform technology and net cash of $7/share, supports our December 2014 PT of $40.

Risks to Rating and Price Target

Risks to our Overweight rating include: 1) Translarna's inability to demonstrate a meaningful benefit in DMD and CF in late-stage clinical trials, 2) regulatory risk in both the US and EU, 3) failure for ataluren to gain meaningful market shares if approved, and 4) potential future share dilution.

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PTC Therapeutics: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E
Revenues	35	21	43	150
Cost of products sold	0	0	(2)	(14)
Gross profit	-	-	-	-
SG&A	(25)	(34)	(46)	(64)
R&D	(55)	(70)	(77)	(84)
Operating income	(45)	(82)	(82)	(13)
EBITDA	(45)	(82)	(82)	(13)
Net interest (income) / expense	(1)	1	1	2
Other income / (expense)	0	0	1	1
Income taxes	0	0	0	0
Net income - GAAP	(46)	(81)	(80)	(10)
Net income - recurring	(61)	(81)	(80)	(10)
Diluted shares outstanding	22	29	31	33
EPS - excluding non-recurring	(2.08)	(2.83)	(2.59)	(0.30)
EPS - recurring	(2.75)	(2.83)	(2.59)	(0.30)

Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	143	172	92	186
Accounts receivable	-	-	-	-
Inventories	-	-	-	-
Other current assets	2	2	2	2
Current assets	145	174	93	188
PP&E	9	9	9	9
Total assets	154	183	103	197
Total debt	5	5	5	5
Total liabilities	32	32	32	32
Shareholders' equity	122	151	71	166
Net income (including charges)	(61)	(81)	(80)	(10)
D&A	3	3	3	3
Change in working capital	0	0	0	0
Other	0	0	0	0
Cash flow from operations	(58)	(78)	(78)	(7)
Capex	(3)	(3)	(3)	(3)
Free cash flow	(61)	(80)	(80)	(8)
Cash flow from investing activities	(3)	(3)	(3)	(3)
Cash flow from financing activities	114	110	0	105
Dividends	-	-	-	-
Dividend yield	-	-	-	-

Income Statement - Quarterly	1Q14A	2Q14E	3Q14E	4Q14E
Revenues	9A	4	4	4
Cost of products sold	0A	0	0	(2)
Gross profit	-	-	-	-
SG&A	(8)A	(8)	(9)	(9)
R&D	(16)A	(17)	(18)	(19)
Operating income	(14)A	(21)	(23)	(26)
EBITDA	(14)A	(21)	(23)	(26)
Net interest (income) / expense	0A	0	0	0
Other income / (expense)	(0)A	0	0	0
Income taxes	0A	0	0	0
Net income - GAAP	(14)A	(21)	(22)	(26)
Net income - recurring	(14)A	(21)	(22)	(24)
Diluted shares outstanding	24A	30	30	30
EPS - excluding non-recurring	(0.58)A	(0.69)	(0.75)	(0.86)
EPS - recurring	(0.58)A	(0.69)	(0.75)	(0.79)

Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Sales growth	2.2%	(38.8%)	100.6%	251.4%
EBIT growth	69.3%	81.2%	(0.6%)	(84.6%)
EPS growth - recurring	(135.5%)	2.9%	(8.5%)	(88.4%)
Gross margin	-	-	-	-
EBIT margin	(130.8%)	(387.6%)	(192.1%)	(8.4%)
EBITDA margin	(130.8%)	(387.6%)	(192.1%)	(8.4%)
Tax rate	0.0%	0.0%	0.0%	0.0%
Net margin	(175.1%)	(381.8%)	(188.6%)	(6.7%)
Net Debt / EBITDA	304.7%	203.4%	106.1%	1438.8%
Net Debt / Capital (book)	845.6%	1041.6%	550.3%	1170.6%
Return on assets (ROA)	(72.8%)	(48.1%)	(56.1%)	(6.7%)
Return on equity (ROE)	(117.8%)	(59.3%)	(72.2%)	(8.5%)
Enterprise value / sales	-	-	-	-
Enterprise value / EBITDA	-	-	-	-
Free cash flow yield	(17.9%)	(18.3%)	(16.8%)	(1.6%)

Source: Company reports and J.P. Morgan estimates.
Note: $ in millions (except per-share data).Fiscal year ends Dec

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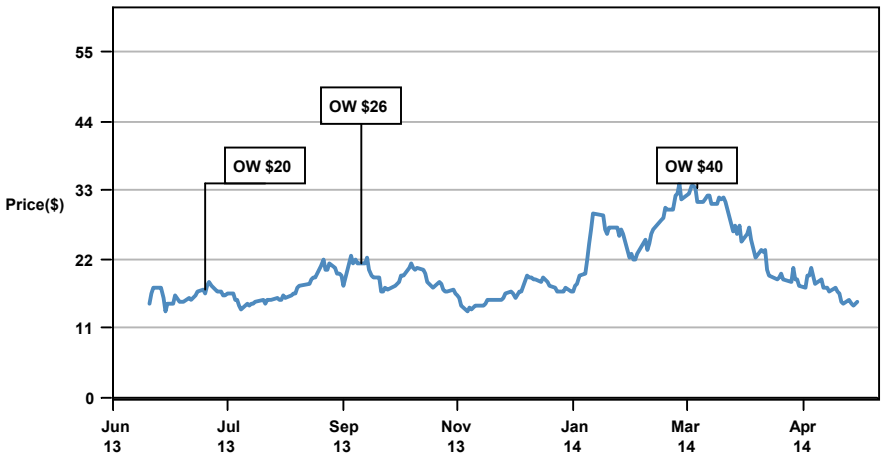
PTC Therapeutics (PTCT, PTCT US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
15-Jul-13	OW	17.17	20.00
27-Sep-13	OW	21.37	26.00
06-Mar-14	OW	33.38	40.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Jul 15, 2013.

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