PTC Therapeutics

Raising PT to $26 Based on Higher Conviction in DMD Development

Overweight

PTCT, PTCT US

Price: $21.45

▲ **Price Target: $26.00**
Previous: $20.00

We recently had the opportunity to meet with senior management from PTC Therapeutics. The focus was largely on ataluren in Duchene Muscular Dystrophy (DMD) given the competitive news from Prosensa as well as the cystic fibrosis (CF) opportunity. Importantly, enrollment in the phase 3 nmDMD study is on track (complete mid 2014 with data mid 2015) and the company remains quite confident in the enrollment criteria designed to select patients in the declining phase of the disease. This is despite concerns on baseline characteristics raised from the recent failure of the Prosensa's DEMAND III study. Additionally, a response from the CHMP on conditional approval in nmDMD is still expected by YE13, which we continue to view as a low probability event, but could drive significant upside. Overall, we left the meeting with increased conviction on the probability of success in nmDMD. We are raising our Dec 2014 target to $26 from $20 based on an increased expected probability of success for ataluren in nmDMD. We're reiterating our Overweight rating on PTCT shares, given scarcity value in DMD and CF markets as well as the emerging pipeline behind ataluran.

- **Implications of drisapersen phase 3 failure in DMD.** Recall, last week, top-line DEMAND III data for Prosensa's (covered by J.P. Morgan analyst James Gordon) drisapersen resulted in only a 10m benefit in 6MWD compared to placebo (-42m vs. -53m placebo; p=0.415). Some have suggested a negative read through to the phase 3 trial of ataluren in nmDMD, but we believe this is not comparable given the different mechanisms of action (nonsense vs. exon 51 skipping). The failure of drisapersen does highlight the challenges of DMD clinical development but notably there are efficacy differences favoring ataluren in larger DMD trials. Specifically, the 10m net benefit observed in the drisapersen phase 3 is less than the 31m observed in the phase 2b ataluren trial.

- **Phase 3 enrollment criteria looks favorable.** Rigorous analysis of the natural history data from the phase 2b trial of ataluren in nmDMD has indicated that patients older than 7 years with a baseline 6MWD of <350m are most likely to be in the declining phase of the disease. These findings were the basis for the enrollment criteria selected for the ongoing phase 3 ataluren study, which maximizes the chances of success. Of note, patients in the failed DEMAND III study fit this criteria (average age of 8 years and baseline 6MWD of 337-348m) but with limited efficacy on the drug arm based on the DEMAND III results.

US Biotechnology

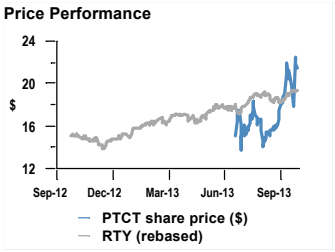
Geoff Meacham AC
(1-212) 622-6531
geoffrey.c.meacham@jpmorgan.com
Bloomberg JPMA MEACHAM <GO>

Michael E Ulz
(1-212) 622-0900
michael.e.ulz@jpmorgan.com

Anupam Rama
(1-212) 622-0105
anupam.rama@jpmorgan.com

Carter L Gould
(1-212) 622-4350
carter.l.gould@jpmorgan.com

J.P. Morgan Securities LLC



	YTD	1m	3m	12m
Abs	43.0%	32.4%	33.7%	43.0%
Rel	19.5%	28.6%	21.8%	13.7%

PTC Therapeutics (PTCT;PTCT US)

FYE Dec	2011A	2012A	2013E	2014E	2015E
EPS Reported ($)					
Q1 (Mar)	-	-	(1.51)A	-	-
Q2 (Jun)	-	-	(0.59)A	-	-
Q3 (Sep)	-	-	(0.64)	-	-
Q4 (Dec)	-	-	(0.68)	-	-
FY	5.39	7.75	(3.41)	(2.68)	(3.09)

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

Company Data	
Price ($)	21.45
Date Of Price	26 Sep 13
52-week Range ($)	24.38-13.04
Market Cap ($ mn)	609.87
Fiscal Year End	Dec
Shares O/S (mn)	28
Price Target ($)	26.00
Price Target End Date	30-Dec-14

See page 5 for analyst certification and important disclosures.

Geoff Meacham
(1-212) 622-6531
geoffrey.c.meacham@jpmorgan.com

- **Ataluren phase 3 timelines and EU review on track.** Management noted that enrollment in the phase 3 nmDMD study is going well and remains on track to be to be completed in mid 2014 with data in mid 2015. Importantly, there appears to be a higher screen-out rate in the ongoing phase 3 compared to prior phase 2 studies, which shows more careful selection at baseline, in our view. On the EU opportunity, a response from the CHMP on conditional approval in nmDMD is still expected by YE13, though we view this as a "free call option" with low probability. For ataluren in CF, the company is in discussions with the FDA regarding the design of a pivotal trial; we continued to expect the phase 3 to start in 1H14. In our view, the CF opportunity, which isn't assumed in our model, has a lower risk profile but is obviously behind DMD in development. Our recent discussions with leadership from the CF Foundation have highlighted significant enthusiasm for nonsense mutation therapies in CF given the scarcity of current drugs in development.

- **Other pipeline opportunities.** Beyond ataluren, there are several pipeline opportunities that could gain momentum in 2014 and help diversity the portfolio. Specifically, there are next generation nonsense mutation therapies in development beyond ataluren, which have different PK and clinical characteristics and could be used in indications such as oncology. Additionally, the SMN2 program for spinal muscular atrophy, partnered with Roche and the SMA foundation has significant potential. Of note, a development candidate was recently selected for the SMA program and could enter the clinic in the near term. Other areas of focus for the early stage pipeline include oncology and infectious disease. We expect to hear more details on the pipeline at the upcoming PTC analyst day, tentatively scheduled for October 25th.

- **Reiterate Overweight rating.** Based on increased confidence in the probability of success for ataluren in nmDMD, we are raising our December 2014 to $26 from $20.

Geoff Meacham
(1-212) 622-6531
geoffrey.c.meacham@jpmorgan.com

J.P.Morgan

Investment Thesis

PTC is focused on therapies for orphan genetic diseases, with the most advanced compound being ataluren, currently in phase 3 development for Duchene muscular dystrophy (DMD; data 1H15) 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 ataluren, 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 ataluren in DMD, good optionality in CF, plus a "free call option" on EU approval in DMD in 4Q13, we rate PTCT shares Overweight.

Valuation

We are increasing our December 2014 price target to $26 from $20 based on a higher expected probability of success. Our $26 price target for PTCT is based on our sum-of-the-parts analysis including only ataluren in nmDMD. We project ataluren nmDMD sales to 2024, consistent with IP protection, assume no terminal value and an 8% discount rate. We further assume an 80% (previously 70%) 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 $24/share for ataluren. This, taken in combination with net cash of $2/share, supports our December 2014 PT of $26.

Risks to Rating and Price Target

Risks to our Overweight rating include: 1) ataluren'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.

Geoff Meacham
(1-212) 622-6531
geoffrey.c.meacham@jpmorgan.com

J.P.Morgan

PTC Therapeutics: Summary of Financials

Income Statement - Annual	FY12A	FY13E	FY14E	FY15E
Revenues	34	26	10	7
Cost of products sold	0	0	0	0
Gross profit	-	-	-	-
SG&A	(15)	(26)	(27)	(33)
R&D	(46)	(55)	(60)	(67)
Operating income	(27)	(55)	(78)	(92)
EBITDA	(27)	(55)	(78)	(92)
Net interest (income) / expense	(1)	(2)	1	1
Other income / (expense)	2	0	1	1
Income taxes	0	0	0	0
Net income - GAAP	(26)	(56)	(76)	(91)
Net income - recurring	133	(71)	(76)	(91)
Diluted shares outstanding	17	21	28	29
EPS - excluding non-recurring	(1.52)	(2.70)	(2.68)	(3.09)
EPS - recurring	7.75	(3.41)	(2.68)	(3.09)

Balance Sheet and Cash Flow Data	FY12A	FY13E	FY14E	FY15E
Cash and cash equivalents	3	133	137	46
Accounts receivable	-	-	-	-
Inventories	-	-	-	-
Other current assets	2	2	2	2
Current assets	5	135	139	48
PP&E	8	9	9	9
Total assets	13	143	148	58
Total debt	5	5	5	5
Total liabilities	32	32	32	32
Shareholders' equity	(19)	111	117	26
Net income (including charges)	(26)	(71)	(76)	(91)
D&A	3	3	3	3
Change in working capital	(25)	0	0	0
Other	1	0	0	0
Cash flow from operations	(48)	(69)	(74)	(88)
Capex	(0)	(3)	(3)	(3)
Free cash flow	(47)	(70)	(76)	(90)
Cash flow from investing activities	(0)	(3)	(3)	(3)
Cash flow from financing activities	22	114	81	0
Dividends	-	-	-	-
Dividend yield	-	-	-	-

Income Statement - Quarterly	1Q13A	2Q13A	3Q13E	4Q13E
Revenues	7A	7A	6	6
Cost of products sold	0A	0A	0	0
Gross profit	-	-	-	-
SG&A	(4)A	(7)A	(7)	(8)
R&D	(11)A	(15)A	(15)	(15)
Operating income	(9)A	(14)A	(16)	(17)
EBITDA	(9)A	(14)A	(16)	(17)
Net interest (income) / expense	(1)A	(0)A	(1)	(1)
Other income / (expense)	0A	(0)A	0	0
Income taxes	0A	0A	0	0
Net income - GAAP	(9)A	(15)A	(16)	(17)
Net income - recurring	(24)A	(15)A	(16)	(17)
Diluted shares outstanding	16A	25A	25	25
EPS - excluding non-recurring	(0.57)A	(0.59)A	(0.64)	(0.68)
EPS - recurring	(1.51)A	(0.59)A	(0.64)	(0.68)

Ratio Analysis	FY12A	FY13E	FY14E	FY15E
Sales growth	(67.8%)	(23.4%)	(61.5%)	(30.0%)
EBIT growth	(187.7%)	105.3%	41.4%	18.7%
EPS growth - recurring	43.7%	(144.0%)	(21.3%)	15.0%
Gross margin	-	-	-	-
EBIT margin	(79.0%)	(211.7%)	(778.2%)	(1319.2%)
EBITDA margin	(79.0%)	(211.7%)	(778.2%)	(1319.2%)
Tax rate	0.0%	0.0%	0.0%	0.0%
Net margin	392.8%	(274.1%)	(763.2%)	(1297.8%)
Net Debt / EBITDA	(8.0%)	232.3%	170.4%	44.9%
Net Debt / Capital (book)	(12.9%)	781.4%	825.6%	262.9%
Return on assets (ROA)	466.1%	(91.1%)	(52.3%)	(88.2%)
Return on equity (ROE)	(619.6%)	(153.8%)	(67.0%)	(127.8%)
Enterprise value / sales	-	-	-	-
Enterprise value / EBITDA	-	-	-	-
Free cash flow yield	(12.7%)	(15.6%)	(12.4%)	(14.3%)

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

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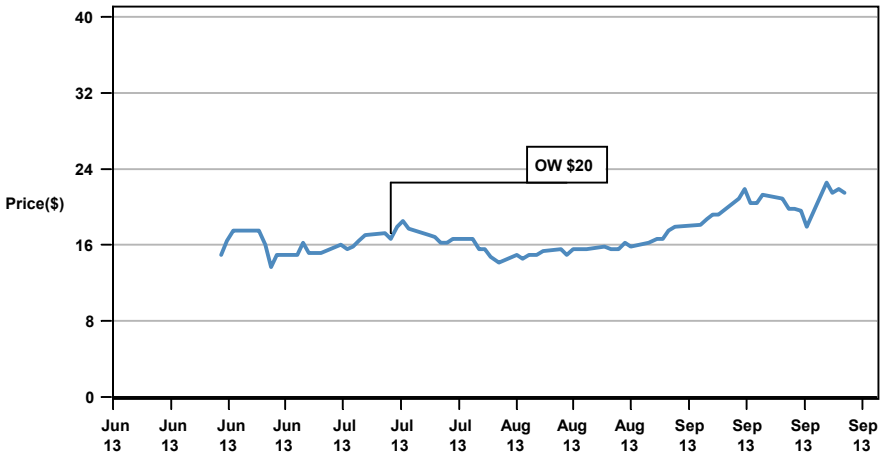
PTC Therapeutics (PTCT, PTCT US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
15-Jul-13	OW	17.17	20.00

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

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IB clients*	76%	66%	55%

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"Other Disclosures" last revised May 4, 2013.

Geoff Meacham
(1-212) 622-6531
geoffrey.c.meacham@jpmorgan.com

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