PTC Therapeutics, Inc (PTCT)

SMALL & MID CAP RESEARCH

Rating	**OUTPERFORM* [V]**
Price (19 Sep 13, US$)	19.52
Target price (US$)	24.00[1]
52-week price range	21.86 - 13.63
Market cap. (US$ m)	486.40
Enterprise value (US$ m)	338.63

**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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Competitor Fails: No Readthrough to Ataluren Phase III

We reiterate our Outperform on PTCT on the news that Prosensa's Phase III trial was unsuccessful.

Prosensa (RNA, Not Rated) announced that its Phase III trial of drisapersen in DMD failed. The source of the shortfall could be (1) the drug or drug class, or (2) the trial design. The first point has more relevance to the other competitor Sarepta (SRPT, Not Rated) as PTCT's Ataluren works through a completely unrelated mechanism and targets a totally different subset of DMD patients. The second point highlights one of the strength of the ongoing PTCT Phase III, which is designed based on the latest understanding of the natural history of the DMD.

- **Ataluren is mechanistically different:** Prosensa's drug is an injectable anti-sense drug designed to promote exon skipping (similar to SRPT). PTCT's Ataluren is an oral small molecule that promotes "read through."
- **Ataluren Phase III is better design:** Based on results from Phase II, PTCT is excluding patients younger than 7. The Prosensa trial enrolled 43% of patients below age 7. Importantly, Prosensa did not appear to stratify based on age.
- **Our $24 TP Is Supported by a Probability-Weighted DCF Analysis of Ataluren in DMD and CF:** We expect PTCT to hit our target ahead of the first Phase III results in mid-2015, with further upside potential from EU conditional approval (not in our numbers), risk-lowering Phase III results, and a potential ex-U.S. partnership. The SMA program is not in our valuation.

Financial and valuation metrics

Year	12/12A	12/13E	12/14E	12/15E
EPS (CS adj.) (US$)	42.50	-3.48	-2.74	-1.76
Prev. EPS (US$)	—	—	—	—
P/E (x)	0.5	-5.6	-7.1	-11.1
P/E rel. (%)	2.8	-36.5	-51.2	-87.8
Revenue (US$ m)	33.9	36.0	11.0	27.0
EBITDA (US$ m)	-24.1	-35.1	-63.4	-55.0
OCFPS (US$)	NM	-2.98	-2.37	-1.31
P/OCF (x)	—	-6.5	-8.2	-14.9
EV/EBITDA (current)	-18.3	-12.5	-6.9	-8.0
Net debt (US$ m)	2	-148	-82	-220
ROIC (%)	160.91	468.89	4,344.44	2,325.51

Number of shares (m)	24.92	IC (current, US$ m)	-16.66
BV/share (Next Qtr., US$)	-115.7	EV/IC (x)	-32.3
Net debt (Next Qtr., US$ m)	-162.9	Dividend (current, US$)	—
Net debt/tot cap (Next Qtr., %)	-106.6	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates

Why There Is No Read Through to PTCT

Bottom line – PTCT and Prosensa were (1) not competing for the same DMD patients, and (2) the drugs and trial designs are very different.

Different class of drugs

Safety – Besides the efficacy shortfall, drisapersen had safety issues including significantly higher injection site reactions (78% vs. 16%) and renal side effects (46% vs. 25%) compared to placebo. It is unclear how these safety signals could have impacted dosing or efficacy, but they are not problems seen with Ataluren, which is an oral small molecule drug with a very clean safety profile.

Efficacy – It is possible that the Prosensa trial failed simply because drisapersen does not work. This could result from lack of adequate tissue penetration, a flawed mechanism, or the production of dystrophin that is not adequately functional. Ataluren is a small molecule that penetrates muscle tissue by diffusion whereas drisapersen is an oligonucleotide, which presents additional stability and tissue penetration challenges. While we believe exon skipping is likely a viable approach, it is possible that protein produced by this method lacks some important function that results in less clinical activity. Again, Ataluren promotes the production of a full length version of dystrophin.

Different trial design

One of the hard lessons that PTCT learned in its large Phase II program was that proper patient selection is critical for a successful DMD study using 6 minute walk as the primary endpoint. The reason for this is that patients below a certain age (specifically 7) may show improvement in walking even as their disease is progressing because of natural growth and increased strength. Also patients with too high of a baseline walking ability are unlikely to deteriorate enough in 12 months regardless of treatment.

Age - Prosensa enrolled patients age 5 and older with approximately 40% below the age of 7. PTCT's Phase III is enrolling only patients that are 7 and older. Importantly, it appears that age was not a stratification factor, so there was an imbalance with more of the older patients randomized to the treated arm.

Baseline walking - The baseline walking ability in the PTCT Phase III is no more than 80% of the predicted distance based on age and height. This would equate to a maximum baseline walking distance slightly more than 350m. It appears from the mean baseline walking distance in the Prosensa study (348m in placebo and 337m in treated arm) that a large portion of patients in the study may have had baseline walking above 350m.

Exhibit 1: PTCT News Flow

Timing	Event
Duchenne Muscular Distrophy	
Sep 2013	Receive list of outstanding issues from EMA for filing
H2:13	Seek early access programs for DMD in select territories
YE 2013	Potential conditional EU approval
Mid-2014	Complete enrollment in confirmatory DMD Phase III study
H2:14	Potential data from EU open-label extension study
Mid-2015	Potential data from confirmatory DMD Phase III study
Late-2015	FDA and EMA filing for full approval
Mid-2016	Potential FDA and EMA approval
Cystic Fibrosis	
Q4:13	EMA conditional approval filing
H1:14	Dose first patient in confimatory CF Phase III study
YE 2014	Potential conditional EU approval
Mid-2015	Complete enrollment in confirmatory CF Phase III study
Mid-2016	Potential data from confirmatory CF Phase III study
YE:16/early 201	FDA and MAA filing for full approval
Mid-2017	Potential FDA and EMA approval
SMA program	
2014	IND and Phase I start

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	MDR Gram (-) bacteria	Proprietary

Source: Company data, Credit Suisse estimates

Exhibit 3: PTCT Model

($ in MM; except per share)	2011A	2012A	Q1:13A	Q2:13A	Q3:13E	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	10.0	10.0	31.9	8.0	23.0	16.0	16.0	12.0
Grant revenue	6.5	5.2	1.1	1.0	1.0	1.0	4.1	3.0	4.0			
Total Revenues	105.4	33.9	7.1	6.9	11.0	11.0	36.0	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	11.5	12.0	49.5	50.8	53.8	63.0	70.0	77.0
Sales, General and Administrative Expenses	16.2	14.6	4.5	6.6	6.5	6.5	24.1	26.0	29.0	67.0	101.0	119.2
Total Costs and Expenses	74.8	60.8	15.7	21.3	18.0	18.5	73.5	76.8	82.8	132.3	183.5	219.9
Operating Income (Loss)	30.6	(26.8)	(8.6)	(14.5)	(7.0)	(7.5)	(37.5)	(65.8)	(55.8)	(87.1)	(10.9)	88.2
Interest Expense, net	(2.4)	(1.2)	(6.2)	(0.1)	(0.1)	(0.0)	(6.4)					
Other income, net	0.5	1.8	0.1	(0.0)	(1.0)	(1.0)	(2.0)	(4.0)	(4.0)	(4.0)	(4.0)	(4.0)
Income (Loss) before Tax	28.6	(26.2)	(14.7)	(14.6)	(8.1)	(8.5)	(45.9)	(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)	(8.1)	(8.5)	(45.9)	(69.8)	(59.8)	(91.1)	(14.9)	84.2
Net income attributable to common shareholders	0.0	0.7	(29.5)	(14.6)	(8.1)	(8.5)	(45.9)	(69.8)	(59.8)	(91.1)	(14.9)	84.2
EPS - diluted	4.55	42.50	(6,527)	(5.51)	(0.32)	(0.34)	(3.48)	(2.74)	(1.76)	(2.63)	(0.42)	2.15
Shares Outstanding - basic	0.001	0.003	0.005	2.65	25.00	25.12	13.19	25.44	34.01	34.70	35.39	36.11
Shares Outstanding - diluted	0.006	0.017	0.005	2.65	27.02	27.24	14.23	27.67	36.42	37.31	38.22	39.17

Source: Company data, Credit Suisse estimates

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Companies Mentioned *(Price as of 20-Sep-2013)*

PTC Therapeutics, Inc (PTCT.OQ, $19.52, OUTPERFORM[V], TP $24.0)
Prosensa (RNA.OQ, $24.0)
Roche (ROG.VX, SFr239.6)
Sarepta Theprcs (SRPT.OQ, $36.69)

Disclosure Appendix

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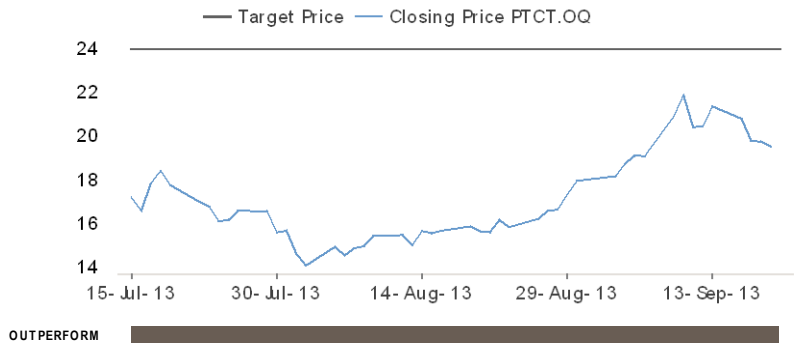
3-Year Price and Rating History for PTC Therapeutics, Inc (PTCT.OQ)

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	3%	

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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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