PTC Therapeutics, Inc (PTCT)

Rating	**OUTPERFORM* [V]**
Price (27 Jun 14, US$)	27.50
Target price (US$)	40.00[1]
52-week price range	33.97 - 13.59
Market cap. (US$ m)	827.05
Enterprise value (US$ m)	643.36

**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

New Phase III in Cystic Fibrosis

The initiation of a Phase III trial in cystic fibrosis (CF) supports our positive view for PTCT over the next 12 months. (1) It provides a second potential indication for Translarna in addition to DMD, and (2) it starts the process of a potential EU filing for conditional approval based on prior data, which would require an ongoing confirmatory study.

- **Robust news flow:** The next 12 months should be marked by significant clinical, regulatory, and commercial progress. With the recent CHMP recommendation, PTCT may launch Translarna in the EU in H2:14, with meaningful sales starting in 2015. We also now expect PTCT will file for conditional approval for CF in EU and may also approach FDA again regarding an early approval for DMD.
- **CF Phase III:** Translarna targets a subset of CF patients not currently addressed by VRTX's set of compounds. Prior data shows an overall 3.0% improvement in FEV1 over 48 weeks (p=0.124) and a 5.7% improvement in the pre-specified subset of patients not on chronic TOBI. Recall TOBI has been shown to interfere with Translarna's activity, and use of TOBI will be contraindicated in the new Phase III. We believe the study is likely to show a statistically significant 5%+ improvement in FEV1 when patients are prevented from receiving TOBI concurrently.
- **Potential billion-dollar drug:** We forecast first sales in Q1:15 (could come earlier in H2:14). Our model includes unadjusted 2020 global sales of $459M for DMD and $516M for CF. We use a 70% and 65% POS for the confirmatory trials.

Financial and valuation metrics

Year	12/13A	12/14E	12/15E	12/16E
EPS (CS adj.) (US$)	-5.18	-3.12	-2.48	-1.70
Prev. EPS (US$)	—	—	—	—
P/E (x)	-5.3	-8.8	-11.1	-16.2
P/E rel. (%)	-29.5	-53.1	-74.3	-120.8
Revenue (US$ m)	34.7	18.2	65.7	94.5
EBITDA (US$ m)	-43.0	-85.3	-73.0	-59.0
OCFPS (US$)	-3.66	-2.53	-1.82	-1.17
P/OCF (x)	-4.6	-10.9	-15.2	-23.5
EV/EBITDA (current)	-13.5	-6.8	-8.0	-9.8
Net debt (US$ m)	-142	-184	-125	-267
ROIC (%)	760.27	4,162.57	2,539.67	1,613.63

Number of shares (m)	30.07	IC (current, US$ m)	-5.97
BV/share (Next Qtr., US$)	-12.5	EV/IC (x)	-309.9
Net debt (Next Qtr., US$ m)	-228.9	Dividend (current, US$)	—
Net debt/tot cap (Next Qtr., %)	-100.9	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates

Changing View of Regulatory Strategy

The initiation of the confirmatory Phase III trial in CF patient and the recent CHMP recommendation for European conditional approval in DMD have several positive implications for other potential regulatory filings.

- **EU filing for conditional approval of nmCF:** The situation in CF is very similar to DMD – large randomized trial with positive results in a pre-specified subgroup and significant safety. We now expect PTCT will file for conditional approval for cystic fibrosis in H1:15 based on a subset of its prior randomized Phase III trial (excluding patient on chronic aminoglycoside antibiotics). The likely trigger for filing is the enrollment in the Phase III trial. EU regulators will want to see the confirmatory Phase III trial well underway.
- **US filing for nmDMD:** PTCT had received prior guidance from FDA that it would need to run a Phase III trial that met its prospectively defined primary endpoint (its ongoing Phase III). However, FDA appears to be evolving in its approach to DMD, and has apparently given two other companies guidance that an accelerated approval path followed by confirmatory trial was possible, and now both Prosensa and Sarepta plan to file for conditional approval using this path. We expect PTCT to take a similar path, as its data is more compelling (in our view) and a confirmatory trial is well underway.

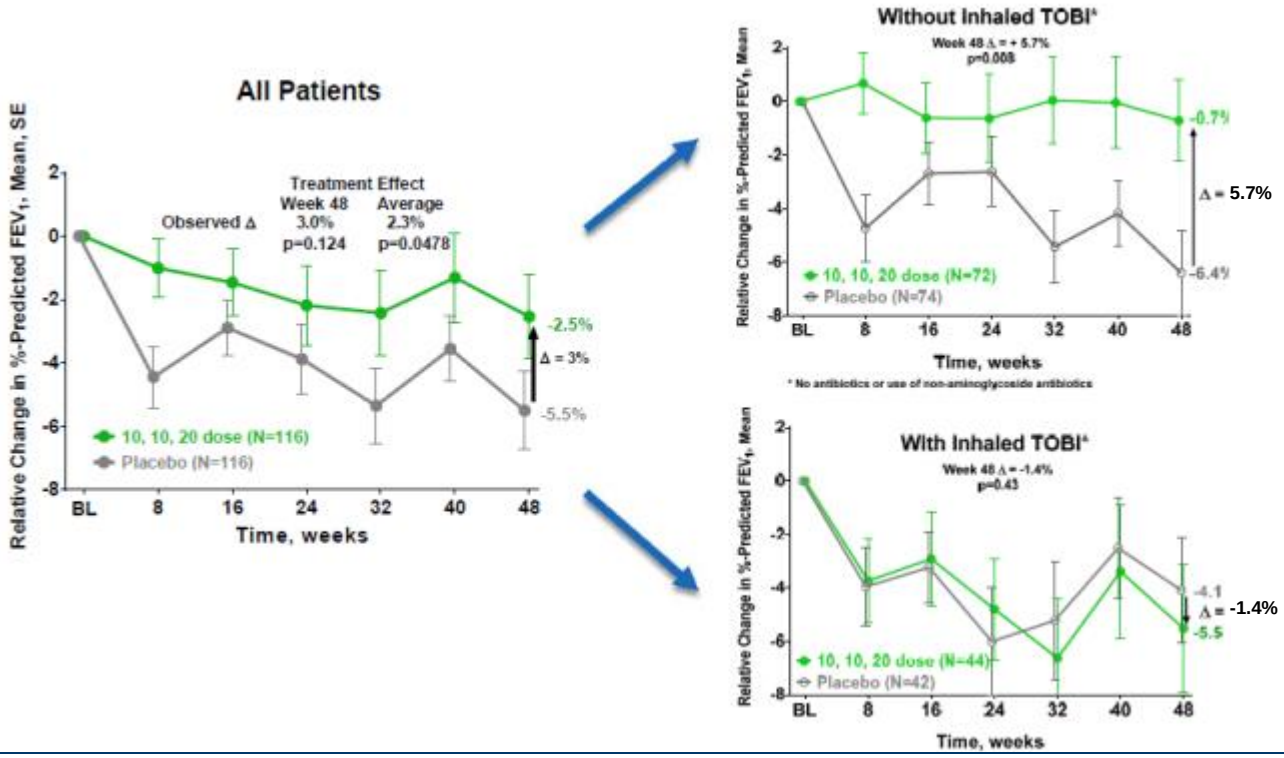
Prior Data in CF Suggests Significant Activity

On an intent-to-treat basis, the original Phase III trial of ataluren in nonsense mutation CF patients missed its primary endpoint. Compared to placebo, ataluren showed a very modest 3% improvement in FEV1 at week 48 with a p value of 0.124. (See Exhibit 1, left panel.) The curves separated early and stayed separated by an average of 2.3% over the course of the study with a p value of 0.0478.

The Phase III trial clearly showed that patients receiving TOBI, an FDA-approved inhaled antibiotic, demonstrated no benefit over placebo either at 48 weeks or throughout the study period. (See Exhibit 1, lower right panel.). Conversely, when patients on TOBI were excluded, the result was much more robust, both in terms of FEV1 improvement (5.7%) and p value (0.008). (See Exhibit 1, top right panel.)

Because the study was very large (232 patients), the subgroups with TOBI (86 patients) and without TOBI (146 patients) were also very large, making the conclusions more statistically believable. With TOBI use excluded, we expect that ataluren can demonstrate at least a 5% improvement in FEV1 versus placebo, and this result should be highly statistically significant.

Exhibit 1: Use of TOBI Negates the Positive Effect of Ataluren



Source: Company data

Unique Subset of CF Patients Targeted by Translarna

Cystic fibrosis is a genetic disease affecting approximately 70,000 patients worldwide, in which patients lack or have severely impaired function of the CFTR ion channel. Approximately 10% of CF patients have a nonsense mutation. Patients with a nonsense mutation have a severe form of CF because of the lack of CFTR. These mutations are not addressable with either VX-809 or Kalydeco. Ataluren causes read-through of these inappropriate “stop” mutations and allows the production of full-length CFTR.

Unlike DMD, CF is caused by the loss of a gene that is found on both chromosomes; therefore, a patient must have two mutated genes. For this reason, patients with a nonsense mutation on one chromosome most likely harbor a different type of mutation on the second chromosome (typically F508del). For this reason, there may be more overlap between these drug classes than in DMD, in which each patient has only one mutated gene (only boys and only on the X chromosome).

Substantial Near- and Long-term DMD Opportunity

With a positive CHMP decision for Translarna, EMA conditional approval is highly likely in the next 3 months (Q3:14). A full European roll out is likely to take approximately one year with reimbursement and pricing discussions occurring on a country by country basis. We forecast first sales in Q1:15, though it is likely that PTCT will book first sales in Q4:14.

PTCT estimates that there are approximately 2,500 nmDMD patients in the EU. Approximately 1/2 of these patients are ambulatory, and the likely on-label indication of ambulatory and 5 years or older is approximately 1,000 patients. While there may be strong desire by parents and physicians to treat younger patients, reimbursement in EU is likely to be restricted, and PTCT may opt to enroll these patients in a clinical trial or compassionate use program to obtain the necessary data to expand the label.

For this genetically defined population with no other available treatment, we anticipate high awareness and penetration. Price is the biggest variable for the market opportunity. Ultra orphan drugs are typically priced in the $200,000 - $400,000 per year range. We assume $230,000 net EU price for Translarna at launch ($240,000 in US) and peak penetration of 80%.

Exhibit 2: DMD Build

Total sales ($ MM)	2014	2015	2016	2017	2018	2019	2020
US sales	$0	$0	$23	$120	$174	$207	$211
EU sales	$0	$44	$89	$182	$185	$189	$193
ROW sales	$0	$0	$0	$13	$26	$40	$55
Total Sales	$0	$44	$112	$314	$386	$436	$459

Total Revenues ($ MM)	2014	2015	2016	2017	2018	2019	2020
US sales	$0	$0	$23	$120	$174	$207	$211
EU sales	$0	$44	$89	$182	$185	$189	$193
ROW royalties	$0	$0	$0	$4	$8	$12	$16
Total Revenues	$0	$44	$112	$305	$367	$408	$420

Probability adjusted		2014	2015	2016	2017	2018	2019	2020
US	70%	$0	$0	$16	$84	$122	$145	$148
EU	70%	$0	$31	$62	$127	$130	$132	$135
ROW	70%	$0	$0	$0	$3	$6	$8	$11
Total Probability Adjusted Sales		$0	$31	$78	$214	$257	$286	$294

Source: Company data, Credit Suisse estimates

Exhibit 3: PTCT Pipeline

Product/Indication	Phase	Target	Partner
Ataluren - Duchenne Muscular Dystrophy	Phase III; Positive CHMP decision	Nonsense DMD mutations	Proprietary
Ataluren - Cystic Fibrosis	Phase III	Class 1 CFTR Mutations	Proprietary
Spinal muscular atrophy	Phase I	SMN2	Roche
PTC596 - Oncology	Preclinical	BMI1	Proprietary
Antibacterial	Preclinical	MDR Gram (-) bacteria	Proprietary

Source: Company data, Credit Suisse estimates

Exhibit 4: PTCT Newsflow

Product	Indication	Catalyst	Expected Date	Price Sensitivity
Ataluren	Duchenne Muscular Dystrophy	Complete Phase III enrollment	Mid-2014	Low
Ataluren	Duchenne Muscular Dystrophy	Data from EU open-label extension study	H2:14	High
Ataluren	3rd indication	Initiate Phase I testing	2014	Low
SMA program	Spinal muscular atrophy	Complete Phase I	YE:2014	Medium
Ataluren	Duchenne Muscular Dystrophy	Phase III data	Mid-2015	High
Ataluren	Cystic Fibrosis	Complete Phase III enrollment	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	Phase III data	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 5: PTCT Model

($ in MM; except per share)	2011A	2012A	2013A	Q1:14A	Q2:14E	Q3:14E	Q4:14E	2014E	2015E	2016E	2017E	2018E
US Sales										16.1	109.1	201.4
EU Sales									43.7	62.4	140.7	170.9
ROW Royalties											2.7	7.8
Ataluren revenue (total)									43.7	78.5	252.5	380.0
Collaboration revenue	99.0	28.8	31.3	9.1	2.0	2.0	2.0	15.1	18.0	16.0	16.0	12.0
Grant revenue	6.5	5.2	3.4	0.1	1.0	1.0	1.0	3.1	4.0			
Total Revenues	105.4	33.9	34.7	9.2	3.0	3.0	3.0	18.2	65.7	94.5	268.5	392.0
COGS										6.3	20.2	30.4
Research and Development Expenses	58.7	46.1	54.9	15.9	16.3	18.3	19.3	69.8	73.5	66.0	70.0	77.0
Sales, General and Administrative Expenses	16.2	14.6	25.2	7.5	7.6	9.0	12.0	36.1	66.0	82.0	101.0	119.2
Total Costs and Expenses	74.8	60.8	80.1	23.4	23.9	27.3	31.3	105.9	139.5	154.3	191.2	226.6
Operating Income (Loss)	30.6	(26.8)	(45.4)	(14.2)	(20.9)	(24.3)	(28.3)	(87.7)	(73.8)	(59.8)	77.3	165.4
Interest Expense, net	(2.4)	(1.2)	(6.1)	0.2				0.2				
Other income, net	0.5	1.8	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.4)	(0.4)	(0.4)	(1.0)	(1.0)
Income (Loss) before Tax	28.6	(26.2)	(51.6)	(14.1)	(21.0)	(24.4)	(28.4)	(87.9)	(74.2)	(60.2)	76.3	164.4
Provision for Income Tax (benefit)	2.3											
Net income (loss)	30.9	(26.2)	(51.6)	(14.1)	(21.0)	(24.4)	(28.4)	(87.9)	(74.2)	(60.2)	76.3	164.4
Net income attributable to common shareholders	0.0	0.7	(66.4)	(14.1)	(21.0)	(24.4)	(28.4)	(87.9)	(74.2)	(60.2)	76.3	164.4
EPS - diluted	4.55	42.50	(5.18)	(0.6)	(0.7)	(0.8)	(1.0)	(3.12)	(2.48)	(1.70)	1.95	4.11
Shares Outstanding - basic	0.001	0.003	12.83	24.49	29.20	29.35	29.50	28.14	29.87	35.51	36.22	36.95
Shares Outstanding - diluted	0.006	0.017	12.83	26.66	31.41	31.60	31.79	30.37	32.28	38.12	39.05	40.01

Source: Company data, Credit Suisse estimates

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Companies Mentioned *(Price as of 27-Jun-2014)*

PTC Therapeutics, Inc (PTCT.OQ, $27.5, OUTPERFORM[V], TP $40.0)

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 *
31-Jan-14	26.07		R
18-Feb-14	28.43	35.00	O
23-May-14	20.03	40.00	

** Asterisk signifies initiation or assumption of coverage.*

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Underperform/Sell*	13%	(47% banking clients)
Restricted	3%	

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

Method: Our $40 target price for PTCT is calculated by DCF (discounted cash flow), using probability-weighted sales estimates for ataluren in Duchenne muscular dystrophy (70% probability) and in cystic fibrosis (65% probability) modeled through 2030, and the SMA program (20% probability). We use a 38% tax rate and a 12% discount rate, and arrive at a $40 valuation based on a projected share count.

Risk: Risks to our $40 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 CF, (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 2016).

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See the Companies Mentioned section for full company names

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