PTC Therapeutics, Inc (PTCT)

Rating	**OUTPERFORM* [V]**
Price (04 Jun 14, US$)	22.15
Target price (US$)	40.00[1]
52-week price range	33.97 - 13.59
Market cap. (US$ m)	666.15
Enterprise value (US$ m)	482.46

**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 Top Pick PTCT: Near Term Commercial Story With Open-Ended Upside

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.

- **New data in DMD bolsters the Translarna story:** The CHMP decision was in part based on new analyses including improvement in muscle strength in 5-6 year olds, improvements in time function tests, and walking improvement across all subgroups. The new data are reviewed in this note.
- **Potential billion-dollar drug:** We forecast first sales in Q1:15 (could come earlier in H2:14). We have adjusted our model for a smaller DMD target population in EU with a higher peak share and price. Our model now includes unadjusted 2020 global sales of $459M for DMD and $516M for CF. We use a 70% and 65% POS for the confirmatory trials. See table below for EPS revisions.
- **Catalysts:** (1) EU approval in Q3, (2) Q3 update on FDA discussions regarding early filing for DMD in US, (3) Translarna EU launch in late 2014, (4) EU filing for conditional approval for CF, and (5) DMD Phase III read out in mid:2015. News from the Phase I SMA program is also expected.

Financial and valuation metrics

Year	12/13A	12/14E	12/15E	12/16E
EPS (CS adj.) (US$)	-5.18	-3.12	-2.48	-1.70
Prev. EPS (US$)	—	—	-2.59	-1.61
P/E (x)	-4.3	-7.1	-8.9	-13.1
P/E rel. (%)	-24.6	-44.3	-62.0	-100.7
Revenue (US$ m)	34.7	18.2	65.7	94.5
EBITDA (US$ m)	-43.0	-85.3	-73.0	-59.0
OCFPS (US$)	-3.66	-2.53	-1.82	-1.17
P/OCF (x)	-4.6	-8.8	-12.2	-18.9
EV/EBITDA (current)	-9.8	-4.9	-5.7	-7.1
Net debt (US$ 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$)	-12.5	EV/IC (x)		-226.5
Net debt (Next Qtr., US$ 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 CHMP recommendation has several positive implications for other potential regulatory filings.

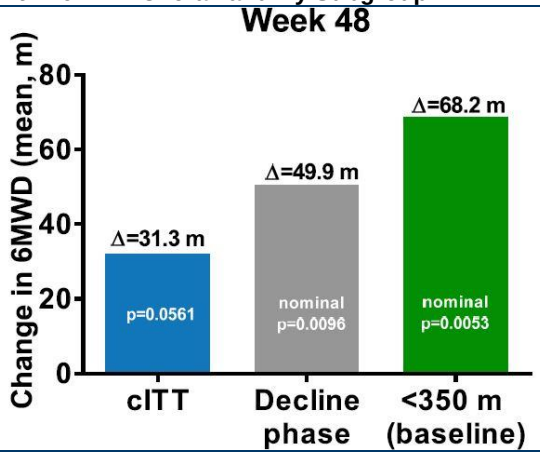
- **EU filing for conditional approval of nmCF:** The situation in CF is very similar to DMD – large randomized trial with positive results in a pre-specified subgroup and significant safety. We now expect PTCT will file for conditional approval for cystic fibrosis in H1:15 based on a subset of its prior 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.

Translarna (ataluren): Compelling Data in DMD

The total data package that was reviewed by CHMP is significantly more robust than the data previously presented and included in the 2013 S-1. In addition to positive results in the primary 6 minute walk (6 MWD), PTCT has now released results including:

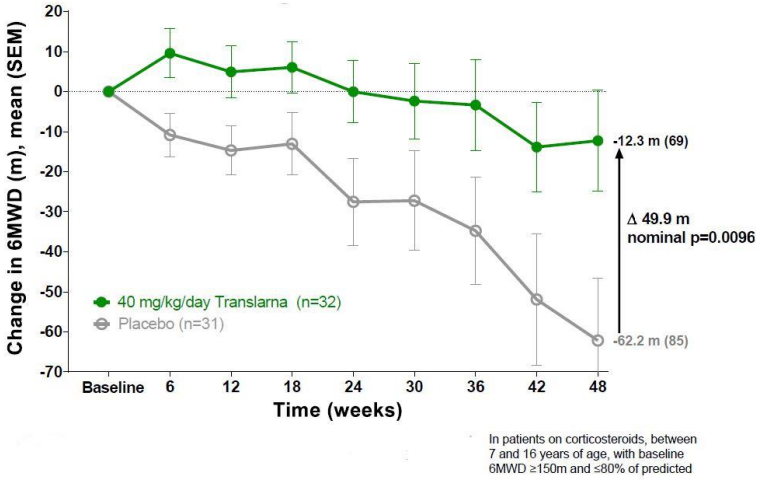
- **Robust efficacy in patients with lower baseline 6MWD**: PTCT previously reported a 49.9m benefit in 6 MWD for patients in the Phase II that met the Phase III enrollment criteria. In a new analysis patients based solely on the pre-specified and stratified cut offs of baseline 6 MWD, patients with less than 350m showed a very robust 68m benefit with Translarna (Exhibit 1). When the data was cut based on percent predicted 6MWD, Translarna had benefit across all ranges of baseline disease (Exhibit 3).
- **Time function tests**: In addition to the primary endpoint of 6 MWD, which measures the distance walked in a fixed time, PTCT also measured the time it takes for patients to complete a fixed task (e.g. stair climb, stair descent, 10m walk-run). These results were presented to CHMP and have now been released. They show that Translarna consistently improves timed function tests, and the benefit is most robust in the population with lower baseline walking ability (Exhibit 4).
- **Myometry (muscle strength) in 5 and 6 year olds**: PTCT previously reported that patients ages 5-6 are not ideally suited for the 6MWD endpoint because they tend to improve over the course of the year, presumably due to growth, and these patients are excluded from the ongoing Phase III trial. However, measures of the natural history of DMD show that these younger patients lose muscle strength much more significantly during these early years, and this can be measured by specific muscle strength tests. PTCT reported improvements in tests of several of the major arm and leg muscles (Exhibit 5). The benefit in these patients helped CHMP separate issues of endpoint selection (i.e. 6 MWD) vs. drug effect, and the proposed indication includes patients 5 years and older.

Exhibit 1: Improvement in 6MWD Overall and By Subgroup



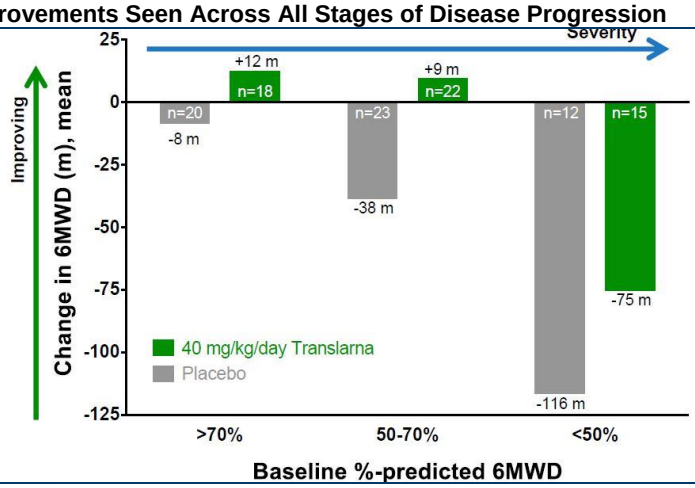
Source: PTCT company presentation

Exhibit 2: Primary Endpoint in Phase II for Subgroup Matching Phase III Criteria



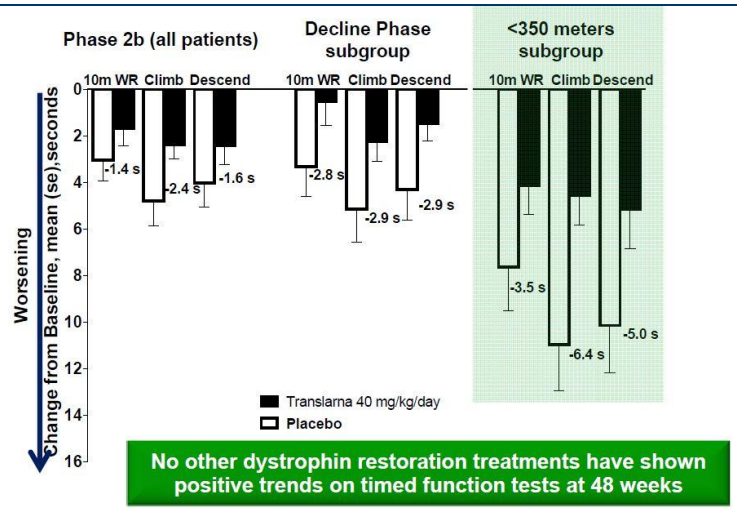
Source: PTCT company presentation

Exhibit 3: Improvements Seen Across All Stages of Disease Progression



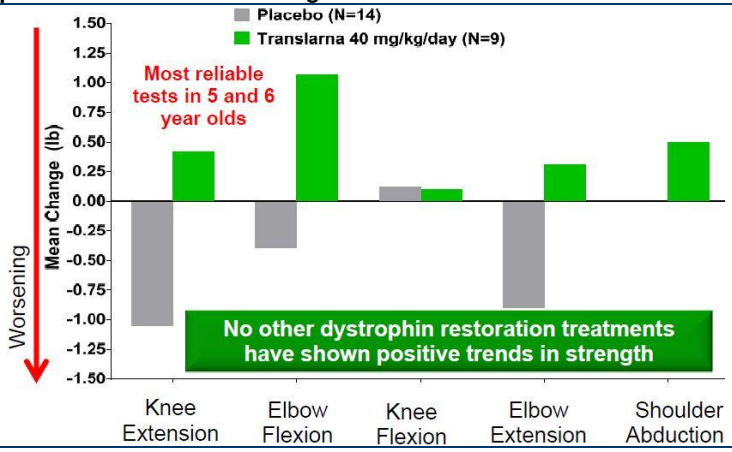
Source: PTCT company presentation

Exhibit 4: Improvements Seen in Timed Function Tests



Source: PTCT company presentation

Exhibit 5: Improvement in Muscle Strength in 5-6 Year Olds



Source: PTCT company presentation

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 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 6: 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 7: 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 8: 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 9: 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 04-Jun-2014)*

PTC Therapeutics, Inc (PTCT.OQ, $22.15, OUTPERFORM[V], TP $40.0)
Prosensa (RNA.OQ, $10.83)
Sarepta (SRPT.OQ, $32.68)

Disclosure Appendix

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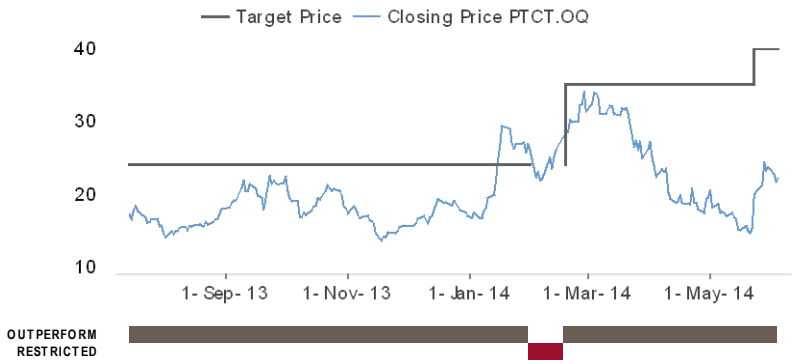
3-Year Price and Rating History for PTC Therapeutics, Inc (PTCT.OQ)

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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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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