PTC Therapeutics (PTCT)

Q2:13 Update - Ataluren Potentially The First DMD Drug to Launch - Conditional Approval and SMA Upside Underappreciated - Reiterate OUTPERFORM

- **PTCT reported their Q2:13 and recently presented on our DMD panel at our Life Sciences Management Access conference.** PTCT ended Q2:13 with $165M in cash, which we anticipate is sufficient to support operations into H2:15.
- **It is likely, in our opinion, that ataluren will be available for the treatment of nmDMD in the EU in 2014.** PTCT has indicated that they have applied for conditional approval of ataluren in the EU based upon Phase IIb data, internally the company has been working to prepare for a potential launch. The company anticipates a response from the EU CHMP, on the MAA submission for conditional approval of ataluren for the treatment of nmDMD by the end of 2013.
- **In Phase IIb trials low-dose ataluren demonstrated a 29.7 m benefit in 6MWD vs. placebo (nominal p=0.0584) (Figure 1, Page 3), this data consists of the ITT population and was not part of a post-hoc analysis.** Additionally, when looking at a pre-defined supportive endpoint time to persistent 10% worsening, 26% in the low-dose ITT population progressed compared to 44% on placebo (nominal p=0.039) (Figure 2, Page 3). Given the severity of the disease, demonstration of clinically relevant benefit the risk/benefit falls in favor of conditional approval in our opinion. Further, we believe that planned YE:13 submission for conditional approval for ataluren in nmCF in the EU suggests conversations regarding ataluren in DMD with the EMA have been positive.
- **Beyond ataluren's potential EU launch in 2014, we see rapid progress of PTC's program in SMA, partnered with Roche representing additional upside to shares in the next 12-months.** During the quarter, PTCT received a $10M milestone payment from Roche for the selection of a lead compound in this program. Management at our life sciences management access conference expressed considerable excitement regarding their program for SMA, despite providing limited updates as dictated by the terms of their partnership.
- **We reiterate our OUTPERFORM rating and 12-month price target of $55/share.** Our $55 price target is derived by applying an 8X multiple to estimated 2017 revenues for ataluren in nmDMD and nmCF, discounted 25% and 35% annually, respectively. Conditional approval of ataluren in the EU and success of the SMA candidate remain upside to our price target.

FYE Dec	2012A	2013E			2014E		
REV	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	--	$7.1A		N/AA	$3.6E		$3.5E
Q2 Jun	--	6.9A		7.6A	7.5E		$3.5E
Q3 Sep	--	17.0E		9.9E	7.5E		$3.5E
Q4 Dec	--	6.1E		7.5E	$7.5E		$3.5E
Year*	**--**	**$37.1E**		**$31.2E**	**$26.1E**		**$3.5E**
Change	--	--			--		
	2012A	**2013E**			**2014E**		
EPS	**ACTUAL**	**CURR.**	**PREV.**	**CONS.**	**CURR.**	**PREV.**	**CONS.**
Q1 Mar	--	($3,245)A		N/AA	($0.62)E		($1.15)E
Q2 Jun	--	(5.51)A		48.29A	($0.48)E		($1.15)E
Q3 Sep	--	(0.02)E		(0.41)E	($0.50)E		($1.15)E
Q4 Dec	--	(0.48)E		(0.52)E	($0.53)E		($1.15)E
Year*	**--**	**($3.18)E**		**($3.36)E**	**($0.53)E**		**($1.15)E**
P/E	--	--			--		
Change	--	--			--		

Consensus estimates are from Thomson First Call.
** Numbers may not add up due to rounding.*

August 21, 2013

Price
$15.80

Rating
OUTPERFORM

12-Month Price Target
$55

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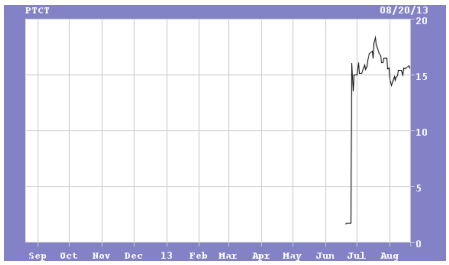
Company Information

Shares Outst (M)	26.1
Market Cap (M)	$411.8
52-Wk Range	$13.04 - $18.50
Book Value/sh	$14.84
Cash/sh	$6.36
Enterprise Value (M)	$246.1
LT Debt/Cap %	0.0
Cash Burn (M) (M)	$56.6
Current Cash (M) (M)	$165.7

Company Description

PTC Therapeutics is a biopharmaceutical company focused on the development of orally administered, proprietary, small molecule drugs that target post-transcriptional control processes for orphan and ultra-orphan disorders including DMD and CF.



Source: Thomson Reuters

Risks to the attainment of our price target include 1) failure of ataluren in the clinic in DMD or CF; 2) regulatory failure of ataluren; and 3) inability to fund the development or execute on the commercializing of ataluren globally

Investment Thesis

PTC is a biotechnology company focused on the development of ataluren, a molecularly targeted, orally delivered treatment for rare and ultra-rare diseases including Duchenne muscular dystrophy and cystic fibrosis caused by nonsense mutations. Ataluren may also be effective in treating 2500 other rare diseases and certain cancers caused by nonsense mutations since its mechanism of action is broadly applicable to these molecular lesions. PTC is also developing a candidate for spinal muscle atrophy a fatal and rare disease that most severely impacts infants. We believe that ataluren will be shown to be safe and efficacious in on going Phase III trials in nmDMD as well as those set to begin (H1:14) in nmCF. In our opinion the street is overly discounting their lead Phase III program for ataluren in nnDMD, which showed mixed results, overall in a Phase II trial, but positive trends and nominal statistically significant benefit in the current subgroups being evaluated in the Phase III trial. We believe that, given lessons learned from prior pioneering trials of ataluren in DMD, PTC has enriched their Phase III trial for success and that it is highly likely to show positive results in mid:2015. Additionally, PTC may also receive conditional approval for ataluren for nmDMD in the EU by YE:13, a scenario which would result in an early 2014 launch and would $20 in upside to our $55, 12-month price target. Final read-outs from a soon to be initiated (H1:14) trial for ataluren CF are anticipated by mid:16. PTC's SMA program, partnered with Roche, remains additional upside to our estimates. We believe that this program likely be accelerated through the clinic due to significant unmet medical need in this devastating disease and that breakthrough results in Phase I/II trials could form the basis for a registration filing as early as 2015.

Valuation Methodology

Our $55 price target is derived by applying an 8X multiple to estimated 2017 revenues for ataluren in nmDMD and nmCF, discounted 25% and 35% annually, respectively. Conditional approval of ataluren in the EU by YE:13 remains upside to our price target and would yield a 12-month price target of $75/share. We project that approval and commercialization of ataluren could generate ~$550 million in annual worldwide revenues in 2017 (our valuation year) in nmDMD and nmCF and potential peak global sales of >$1.5 billion. Success of the PTC's pre-clinical SMA candidate remains upside to our estimates. Similarly we arrive at our $55 price target by applying a 15x multiple to PTC's fully taxed EPS in 2017 discounted back 20% annually.

Upcoming Milestones

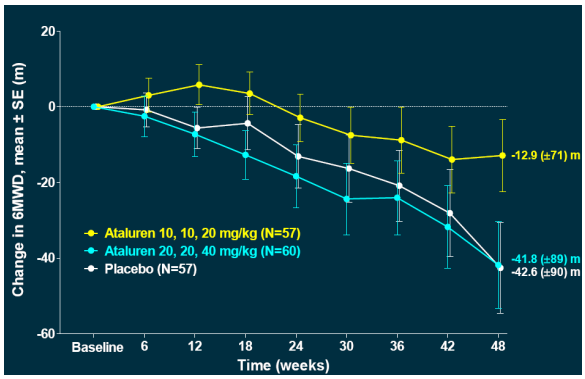
H2:13	Seek early access programs (in select territories) for ataluren in nmDMD
Q4:13	MAA filing for conditional approval of ataluren for nmCF in the EU
YE:13	Potential conditional approval of ataluren for nmDMD in the EU
Mid:14	Full enrollment in the confirmatory Phase III trial of ataluren in nmDMD
Q1:14	Initiation of a Phase III trial of ataluren in nmCF
H2:14	Potential data from the Phase IIb open-label extension study in the EU
YE:14	Potential conditional approval of ataluren for nmCF in the EU
2014	Initiation of Phase I/II trials of SMN2 candidate for SMA
H1:15	Completion of the confirmatory Phase III trial of ataluren in nmDMD
H2:15	FDA and MAA filing for full approval of ataluren for nmDMD
H2:15	Completion of the confirmatory Phase III trial of ataluren in nmCF
2015	Potential accelerated approval of candidate for SMA
H1:16	FDA and MAA filing for full approval of ataluren for nmCF

Conditional Approval in the EU Could Lead to the First Launch in DMD in 2014

We believe that with an enterprise value of <$200M the street is largely overlooking evidence of ataluren's efficacy and the near term market opportunity for the drug in the EU. We believe that the Street has largely overlooked Phase IIb data that showed low-dose ataluren resulted in a 29.7-meter benefit vs. placebo in 6MWD at 48-weeks (nominal p=0.0584). We note that this low-dose cohort was predefined as part of the primary endpoint of the Phase IIb study design and that ataluren's demonstrated benefit is *independent of any post-hoc data analysis*. We believe that this result, a near 30-meter benefit, will be looked upon favorably by EU regulators, particularly given what is now known about the heterogeneity of the disease, the cohort enrolled in the trial and ataluren's dose response. Recall that investigators broadly believe that a 30-meter benefit is considered a clinically relevant benefit in DMD.

Data from Ataluren's Phase IIb Study – Near Clinically Relevant Efficacy in Pre-Specified ITT Populations (Not Post-Hoc Analysis)

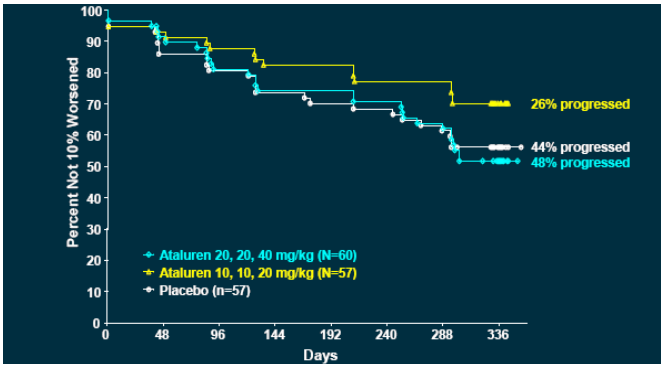
Figure 1: Low-Dose Ataluren Results in a 29.7 m Meter Benefit in the Pre-Specified ITT Population (nominal p=0.0584)



Source: Company data, Wedbush Securities, Inc.

Pre-specified supportive analyses of ambulation, supports benefit in 6MWD vs. placebo. The protocol for PTC's Phase 2b clinical trial also included time to persistent 6-minute walk distance 10% worsening from baseline. The 10% persistent worsening threshold was defined in advance and reflects the clinical meaningfulness of a 10% change in walking ability in Duchenne muscular dystrophy.

Figure 2: Low-Dose Ataluren Resulted a Benefit in Time to Persistent 10% 6MWD (nominal p=0.039) in a Pre-Specified ITT Population



Kaplan-Meier curve illustrates time to persistent (unrecovered) 10% loss in 6MWD.
Evaluates rates of disease stabilization and progression between treatment arms and controls variability.

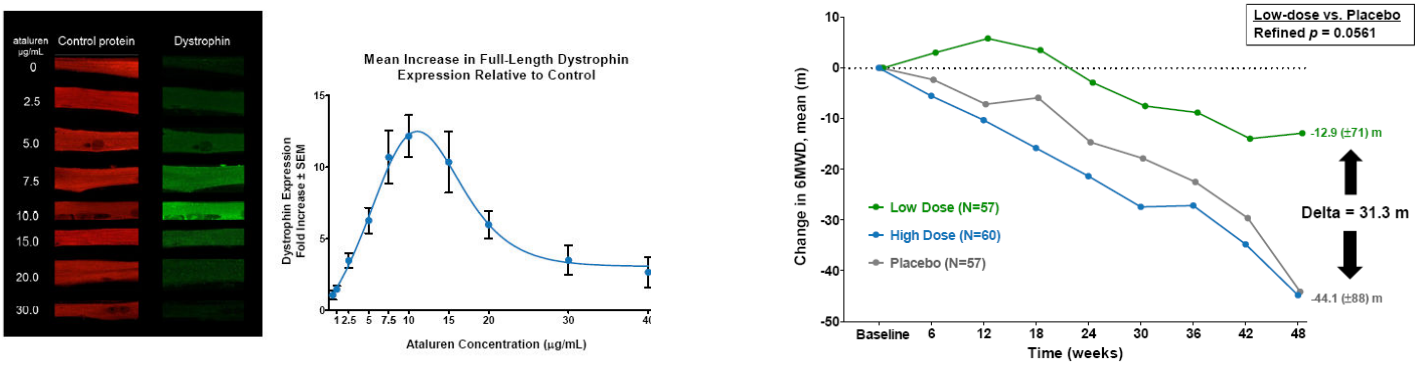
Source: Company data, Wedbush Securities, Inc.

Bell-Shaped Dose Response Curve

High Dose vs. Low Dose Efficacy Explained

Ataluren demonstrated a bell-shaped dose response curve in clinical and pre-clinical assessments made by PTC. The most significant manifestation of this dose response occurred in the Phase IIb trial in which patients on high dose (20, 20, 40 mg/kg) demonstrated no benefit in 6MWT measure vs. placebo. Importantly, patients on low dose (10, 10, 20 mg/kg) showed a near-statistically significant 31.3 m benefit (p=0.0561) (Figure 6). In pre-clinical studies, PTC also demonstrated that ataluren resulted in dystrophin production in nm human myotubes and that this production was also dose-dependent in a bell-shaped fashion (Figure 6).

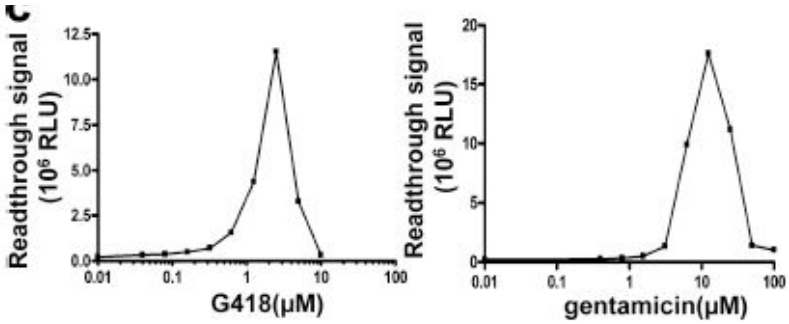
Figure 3: Pre-Clinical (Left) and Clinical Evidence of Ataluren's Bell-Shaped Dose Response



Source: Company data, Wedbush Securities, Inc.

Beyond the substantial clinical and pre-clinical data provided by PTC and independent studies, other compounds that promote read-through also have a similar "bell-shaped" dose-response curve (Figure 7). Past studies of aminoglycosides, compounds known to promote nonsense mutation read-through have demonstrated bell-shaped dose response curves (Figure 6-7).

Figure 4: Bell-Shaped Dose Response Curves Also Occur with Other Read-Through Compounds



Source: Du et al. J Exp Med 2009

Given the fact that ataluren is not based upon an aminoglycoside scaffold and that at the molecular mechanisms of read-through are poorly understood, it is understandable that PTC identified the bell-shaped dose response curve later in the development cycle.

Financial Model

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Christopher N. Marai Ph.D.

8/20/2013

PTC Therapeutics, Inc.

Annual Financial Results & Projections
($ in thousands except per share data)
Ticker: PTCT (Nasdaq)

	FY:12A	Q1:13	Q2:13	Q3:13	Q4:13	FY:13E	FY:14E	FY:15E	FY:16E	FY:17E	FY:18E	FY:19E
Revenue:												
Ataluren Sales US - DMD	0	0	0	0	0	0	0	0	49,618	216,553	313,599	335,577
Ataluren Sales EU - DMD	0	0	0	0	0	0	0	0	35,543	185,637	310,494	345,451
Ataluren Sales ROW - DMD	0	0	0	0	0	0	0	0	715	10,692	47,266	93,713
Ataluren Sales US - CF	0	0	0	0	0	0	0	0	0	94,984	267,911	344,683
Ataluren Sales EU - CF	0	0	0	0	0	0	0	0	0	37,354	185,142	367,238
Ataluren Sales ROW - CF	0	0	0	0	0	0	0	0	0	0	1,010	12,187
Grant and other revenues	5,167	1,070	986	11,100	1,100	14,256	5,600	4,000	0	0	0	0
Collaboration revenue	28,779	6,072	5,868	5,868	5,000	22,808	20,500	18,000	1,000	1,000	1,000	1,000
Total Revenues	**$33,946**	**$7,142**	**$6,854**	**$16,968**	**$6,100**	**$37,064**	**$26,100**	**$22,000**	**$86,876**	**$546,221**	**$1,126,423**	**$1,499,849**
Cost and Expenses:												
Costs of goods sold	0	0	0	0	0	0	0	0	8,588	54,522	112,542	149,885
Research and Development	46,139	11,257	14,712	12,000	12,000	49,969	51,000	57,000	62,305	66,497	67,837	69,204
Sales, General and Administrative	14,615	4,461	6,595	6,000	6,500	23,556	30,000	31,500	43,000	52,000	53,313	55,478
Other	0	0	0	0	0	0	0	0	0	0	0	0
Total Costs and Expenses	**$60,754**	**$15,718**	**$21,307**	**$18,000**	**$18,500**	**$73,525**	**$81,000**	**$88,500**	**$113,893**	**$173,019**	**$233,692**	**$274,566**
Operating Income (loss)	(26,808)	(8,576)	(14,453)	(1,032)	(12,400)	(36,461)	(54,900)	(66,500)	(27,017)	373,202	892,731	1,225,283
Net Interest Income (Expense)	(1,210)	(6,162)	(114)	497	492	(5,287)	1,551	1,127	1,813	3,062	8,989	18,400
Other income / (Expense)	1,783	53	(19)	0	0	34	0	0	0	0	0	0
Income Before Income Taxes	(26,235)	(14,685)	(14,587)	(535)	(11,908)	(41,715)	(53,349)	(65,373)	(25,204)	376,264	901,719	1,243,683
Net Income	**$133,341**	**($14,685)**	**($14,587)**	**($535)**	**($11,908)**	**($41,715)**	**($53,349)**	**($65,373)**	**($25,204)**	**$350,648**	**$707,468**	**$932,762**
GAAP Net Income	**$133,341**	**($29,543)**	**($14,587)**	**($535)**	**($11,908)**	**($56,573)**	**($53,349)**	**($65,373)**	**($25,204)**	**$340,648**	**$697,468**	**$922,762**
GAAP Basic EPS with sFAS123	**#REF!**	**(3244.59)**	**(5.51)**	**(0.02)**	**(0.44)**	**(3.18)**	**(2.13)**	**(2.50)**	**(0.93)**	**12.83**	**25.80**	**33.89**
GAAP Diluted EPS with sFAS123	**#REF!**	**(3244.59)**	**(5.51)**	**(0.02)**	**(0.44)**	**(2.95)**	**(1.97)**	**(2.32)**	**(0.86)**	**11.95**	**24.03**	**31.57**
Weighted shares outstanding	3	5	2,649	24,934	24,959	13,137	24,984	26,121	27,221	27,321	27,421	27,521
Fully diluted shares outstanding	17	5	2,649	26,954	26,979	14,147	27,041	28,141	29,241	29,341	29,441	29,541
Cash Burn	(26,808)	(14,685)	(14,587)	(535)	(11,908)	(41,715)	(53,349)	(65,373)	(25,204)	-	-	-
Cash Balance	2,726	50,247	165,678	163,983	151,075	151,075	96,301	114,847	174,577	509,349	1,202,032	2,127,506

Source:Wedbush Securities and PacGrow Life Sciences

Analyst Biography

Chris Marai is an Analyst covering the Biotechnology/Biopharmaceuticals/BioDefense sector. Prior to Wedbush PacGrow Life Sciences, Dr. Marai was at Morgan Stanley where he specialized in quantitative modeling; he has also consulted for structure-based drug design companies and biotechnology startups.
Dr. Marai holds a B.S. in Chemistry from Trinity College, University of Toronto and a Ph.D. in Biochemistry and Structural Biology from Stony Brook University, New York.
Christopher's Edge: Dr. Marai has a strong quantitative background and has covered a wide range of disease areas including gastrointestinal, CNS, oncology and rare diseases. His quantitative background has translated into an exceptional track record predicting binary events and assessing risk as a sell-side analyst.

Analyst Certification
I, Christopher N. Marai, Ph.D., Gregory R. Wade, Ph.D., David M. Nierengarten, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Company	Disclosure
PTC Therapeutics	1,3,5,7

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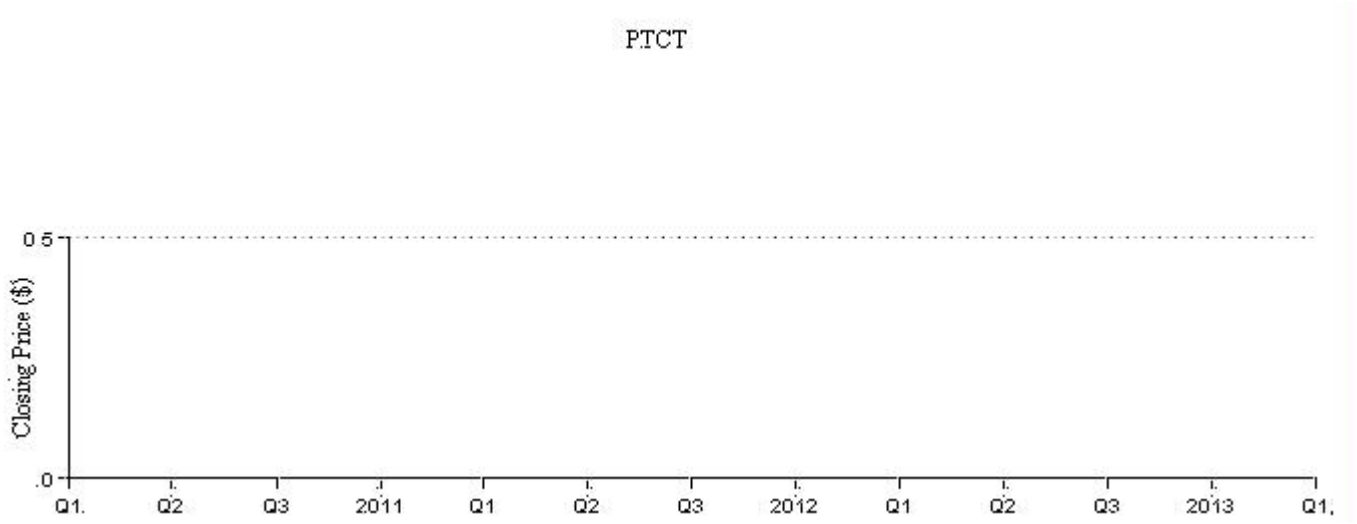

* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.
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