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PTC Therapeutics (PTCT - OUTPERFORM): Roche Call Highlights PTC SMA Candidate Collaboration - RG7800 in the Clinic, Potential Mechanistic Validation in Healthy Volunteers

Price: $26.83 **12-Month Price Target: $55**

- **On their Q4:13 earnings call Roche, PTCT's SMA candidate collaborator, highlighted additional details on the recently initiate Phase I trial. PTC/Roche's SMA candidate (RG7800), is entering the clinic in a 48-patient, placebo controlled single ascending dose trial in healthy volunteers investigating the safety and PK parameters of RG7800.** We anticipate the first patient will be dosed in Q1:14 and full results from the trial will be presented in 2015. PTC is eligible for double-digit royalties and $442.5M in remaining milestone payments on RG7800.

- **We highlight results from the Phase I trial may in addition to safety and PK data, yield initial signals of mechanistic efficacy through the measurement SMN transcript levels in healthy patients blood plasma.** Recall that RG7800 is designed to increase the levels of full length SMN2 transcripts, and thus SMN protein levels, compared to the alternatively spliced SMN2Δ7 transcript that produces dysfunctional protein. We would anticipate that decreased levels of SMNΔ7 transcript in blood plasma cells may be indicative of the drugs mechanistic activity in healthy volunteers.

- **Importantly we note that Roche and PTCT is also running an SMA biomarker trial (NCT01910168) which we believe may further expedite the clinical development of this compound**. The biomarker trial enrolled 40 patients with 5q autosomal recessive spinal muscular atrophy (SMA) type I, II or III as judged by their neurologist upon diagnosis. The trial measure SMN1/SMN2 in blood by mRNA as well as SMN protein levels in blood and lymphocytes.

- **PTC/Roche's oral SMA compound demonstrated impressive systemic efficacy in SMA mouse models, prolonging survival and reducing phenotypic abnormalities.** In addition to demonstrating a dose-dependent increase in SMN protein, PTCT showed that early therapy (day-0) with their compound appears to result in optimal restoration of near-normal life span and phenotypic characteristics. Demonstration of systemic impact of their SMA candidate, imparted by excellent bioavailability, included prevention of tail necrosis, as well as reduction in paw edema in SMA Type III mice.

- **We believe that as an orally bioavailable small molecule, PTCT/Roche's SMA candidate is differentiated from the ISIS/BioGen Idec (ISIS:not covered, BIIB:not covered) and PMO approaches for SMA.** We highlight that ease and safety of systemic delivery of PTCT's compound may be preferential over intrathecally delivered compounds, and may better facilitate delivery very early in life, a time during which animal models of SMA suggest maximum therapeutic benefit may be conferred.

- **We anticipate that the next catalysts for PTCT shares will include an update on full enrollment in the Phase III trial of ataluren in nmDMD and additional SMA data updates.** PTCT is also expected to announce a new indication for ataluren in 2014 as well as the start of enrollment in a Phase III trial for ataluren in cystic fibrosis (nmCF). New indications for ataluren's clinical development are to be selected in 2014 and may offer rapid routes to registration supported by excellent safety and tolerability from the current 600-patient strong clinical data set.

- **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.

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 non-sense mutations. Ataluren may also be effective in treating 2500 other rare diseases and certain cancers caused by non-sense 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 ongoing 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 Q1:14, a scenario which would result in a 2014 launch and 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 is 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 Q1:14 remains upside to our price target. 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

~~Q4/Q1:14~~	~~CHMP SAG meeting regarding potential conditional approval for ataluren for nmDMD in the EU~~
~~Jan. 20-24~~	~~Potential conditional approval of ataluren for nmDMD in the EU~~
Q1:14	Initiation of a Phase III trial of ataluren in nmCF
Q1:14	MAA filing for conditional approval of ataluren for nmCF in the EU
~~H1:14~~	~~Initiation of Phase I/II trials of SMN2 candidate for SMA~~
Q2:14	Potential new opinion following a re-examination of the negative opinion regarding conditional approval of ataluren for nmDMD in the EU
Mid:14	Full enrollment in the confirmatory Phase III trial of ataluren in nmDMD
2014	Open label trial updates for ataluren as nmDMD at a scientific conference (US study safety only, EU efficacy at 0, 6,12,18 months)
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
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	Data from initial trials of PTCT's and Roche's SMA candidate
Late 2015	Potential accelerated approval of candidate for SMA
H1:16	FDA and MAA filing for full approval of ataluren for nmCF

Figure 1: Trial Update from Roche's Presentation

Molecule	**SMN2 splicing modifier** (RG7800)
Patient population	**Spinal muscular atrophy**
Phase	**Phase I**
# of patients	N=48
Design	Healthy volunteer study ▪**ARM A:** RG7800 Single ascending dose ▪**ARM B:** Placebo
Primary endpoint	▪ Safety, PK
Status	▪ FPI Q1 2014
Collaborator	▪ PTC Therapeutics/ SMA Foundation

Source: Company data, Wedbush Securities, Inc.

Analyst Certification
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Company	Disclosure
PTC Therapeutics	1,3,4,5

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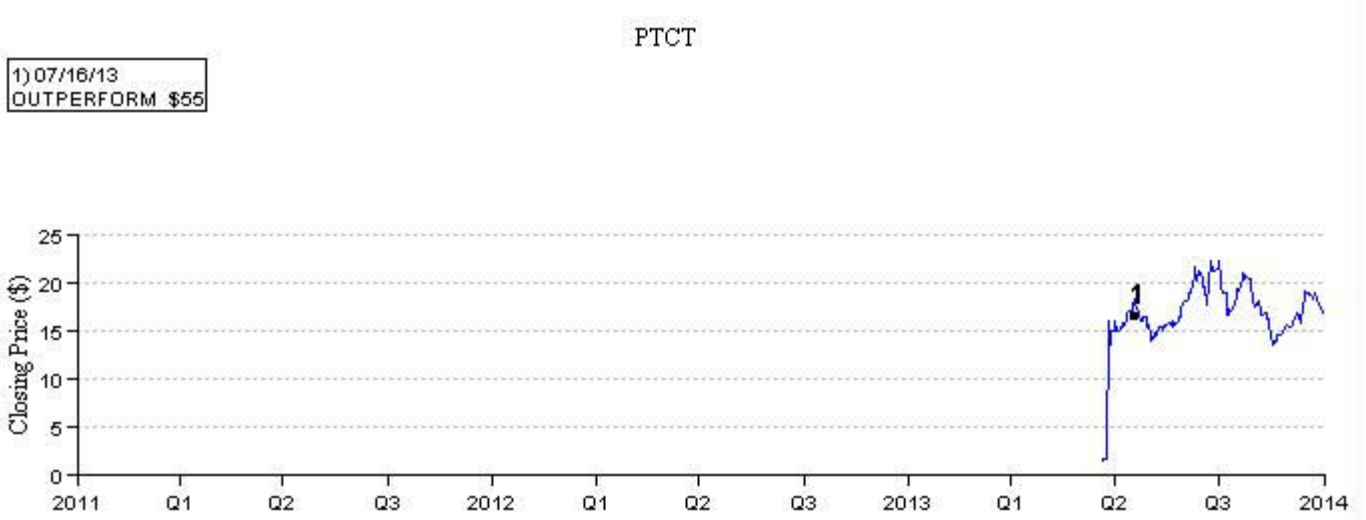

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