PTC Therapeutics, Inc (PTCT)

Rating	**OUTPERFORM* [V]**
Price (25 Oct 13, US$)	20.71
Target price (US$)	24.00[1]
52-week price range	22.48 - 13.63
Market cap. (US$ m)	516.06
Enterprise value (US$ m)	368.29

**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).

Research Analysts
Jason Kantor, PhD
415 249 7942
jason.kantor@credit-suisse.com
Jeremiah Shepard, PhD
415 249 7933
jeremiah.shepard@credit-suisse.com
Ravi Mehrotra PhD
212 325 3487
ravi.mehrotra@credit-suisse.com
Lee Kalowski
212 325 9683
lee.kalowski@credit-suisse.com
Koon Ching PhD
212 325 6286
koon.ching@credit-suisse.com
Anuj Shah
212 325 6931
anuj.shah@credit-suisse.com

SMALL & MID CAP RESEARCH

PTCT Highlights Deep Pipeline at R&D Day

The bulk of PTCT's R&D day presentation was focused on its technology platform and core expertise in post-transcriptional RNA regulation and its ability to generate drug candidates for a variety of genetic disorders, including DMD, CF, SMA, cancer, and others. While most of the discussion was not new (to us), we do not believe this platform was the focus for investors during the IPO, nor is it reflected in the current stock price. While significant upside from current levels can be driven solely by Ataluren, we believe the investment thesis for PTCT is much broader and significant long term value creation will likely come from its pipeline/technology.

- **PTCT provides a better insight into its deep pipeline:** We go through each program discussed at the R&D day in this report including new opportunities for ataluren, SMA, Huntington's disease, cancer, and others.
- **Catalysts:** A CHMP decision on EU conditional approval for ataluren in DMD is expected by year-end 2013. Two Phase III trials in DMD and CF could read out in 2015 and 2016. Further advancement of PTCT's SMA program with partner Roche is expected in 2014.
- **Our $24 TP is supported by a probability-weighted DCF 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). The SMA program, other opportunities for Ataluren, and earlier stage programs are 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	-6.0	-7.5	-11.8
P/E rel. (%)	2.9	-37.8	-53.1	-91.3
Revenue (US$ m)	33.9	36.0	11.0	27.0
EBITDA (US$ m)	-24.1	-35.1	-63.4	-55.0
OCFPS (US$)	NM	-2.98	-2.37	-1.31
P/OCF (x)	—	-6.9	-8.7	-15.8
EV/EBITDA (current)	-19.5	-13.4	-7.4	-8.5
Net debt (US$ 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$)	-115.7	EV/IC (x)	-35.2
Net debt (Next Qtr., US$ m)	-162.9	Dividend (current, US$)	—
Net debt/tot cap (Next Qtr., %)	-106.6	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates

Highlights from Each Program

GEMS platform

There is a great deal of interest in finding drugs that specifically target genetic diseases. Much of the focus in the industry has been on anti-sense, siRNA, and other oligo-based technologies such as exon-skipping and others.

PTCT has a unique approach that is validated by its lead program and is highlighted by its very broad earlier stage pipeline. If these programs emerge as active clinical candidates, we believe investors will begin to assign significant value to the platform.

What's in a name: PTC stands for Post Transcription Control and GEMS stands for Gene Expression Modulation by Small-molecules. The ability to find effective and highly selective small molecule drugs that induce very specific changes in the expression of genes is a unique core competency at PTC and a true technology platform.

The advantages of small molecules compared to other approaches include:

- **Ease of administration** – potentially delivered orally
- **Broad tissue distribution** – potential to impact the disease in all tissues
- **Potential broader activity** – By targeting the "process" rather than a specific gene sequence, these drugs may be amenable to treating multiple diseases with similar genetic aberrations (e.g. Ataluren for DMD and CF)

Follow-on ataluren programs

Ataluren has demonstrated benefit in numerous disease models (in addition to DMD and CF) based on its ability to induce read through of premature stop codons. PTCT plans to identify the top five diseases that will be best suited for targeting with ataluren within the next year, and from these five, one will be selected for the next ataluren program. Genetic diseases with nonsense mutations that have been independently shown to be potentially addressable with ataluren include:

Muscle disease - Miyoshi myopathy

Neurological disorders - Infantile neuronal ceroid lipofuscinoses, late infantile ceroid lipofuscinoses, ataxia telangiectasia, Usher syndrome

Skin diseases - pseudoxanthoma elasticum

Eye disorders – choroideremia and aniridia

Pulmonary disease – heritable pulmonary arterial hypertension

Metabolic diseases – canitine palmitoyltransferase 1A deficiency, methylmalonic aciduria (MA), propionic acidemia (PA), maroteaux-lamy syndrome (MPS VI), Hurler's syndrome (MPS I).

While PTCT would not commit to which program would be the next one selected, the company did highlight Miyoshi myopathy, Hurler's Syndrome, and Usher syndrome in its presentation.

Spinal Muscle Atrophy Program – Exon Inclusion

PTCT provided a comprehensive review of its SMA program. PTCT is still guiding to initiating a Phase I study in 2014 in collaboration with its partner Roche. New highlights from the SMA program include:

- **Good oral bioavailability** – the lead compound has a promising plasma level profile from a single oral dose (10mg/kg) in mice. The SMN full length protein found in the

blood follows a similar curve as the drug's plasma levels, and the SMN full length protein found in brain follows a delayed, but similarly shaped curve. This demonstrates good PK for convenient dosing, good tissue distribution, and a positive impact on the target protein in the organ of interest (brain).

- **Dose dependent increases in SMN protein** – When mice are dosed continuously for 10 days at 3 different doses, there is a dose dependent increase in the SMN protein in the brain and the blood. Increased SMN protein expression was also observed in the heart, liver, skin, spinal cord, and muscle.

- **Notable improvements in phenotypic abnormalities in SMN III mice** – This highlights the significance of the broad tissue distribution of PTCT's small molecule, and that its drug candidate could help alleviate potentially substantial complications in SMN patients outside of the nervous system. This also suggests that peripheral complications may not be adequately addressed with the ISIS' SMNRx, which is an antisense oligo delivered intrathecally. PTCT's drug candidate is further differentiated from ISIS' SMNRx by the ease of administration of an orally bioavailable compound versus an intrathecal injection.

- **Approach validated in cells from SMA patients** – PTCT treated cells isolated from SMA patients with increasing amounts of its compound. A dose dependent increase in the SMN full length transcript and protein was observed in these experiments. This shows that the drug works in the genetic environment of human cells. Provided the tissue distribution and PK are similar in humans as in the animals, this should be highly predictive of a positive clinical response.

DMD – Exon 51 Skipping

The SMA program validates the GEMS platform being utilized to study therapeutics that can modify alternative splicing. PTCT has used this system to examine other alternative splicing events that can be altered with small molecules, including exon 51 skipping in DMD.

Targeting Exon 51 skipping is the same therapeutic approach being utilized by SRPT/RNA to correct mutated DMD pre-mRNAs such that the transcripts have the proper reading frame downstream of the mutation. However, the key difference is that PTCT's compound is expected to have broad tissue distribution, different from the limited distribution of antisense oligos. We speculate that the improved tissue distribution could enhance the efficacy of the exon 51 skipping beyond what is possible with antisense oligos.

Importantly, this small molecule approach could be applicable to other DMD mutations that could benefit from exon skipping (ie exon 45, 53, etc) being studied with antisense oligos.

Exon Skipping – Myostatin Gene

Myostatin is negative regulator of skeletal muscle fiber size, and the protein is already the target of several antibody programs at other companies. It is also possible to target myostatin genetically by inducing exon skipping to disrupt the reading frame and knock down the production of the protein.

There are many diseases that involve muscle weakness or loss of muscle, such as different forms of muscular dystrophy (ie DMD), cancer wasting, age-related muscle wasting, muscle atrophy following immobility or injury, and others. Novartis' myostatin antibody has been granted breakthrough designation for a rare muscle wasting disorder called sporadic inclusion body myositis. A muscle inducing drug that lacks the side effects of steroids would be therapeutically valuable.

PTCT has identified an early compound that causes exon 2 in the myostatin transcript to be skipped, which would yield a nonfunctional transcript, which would down-regulate myostatin protein levels. This approach may be trickier than the gain of function exon

skipping drugs for DMD because the efficiency of the drug would likely need to be much higher to inhibit a process compared to the amount of protein that needs to be produced in DMD or other diseases to see a functional improvement.

Huntington's – Nucleotide Repeat Diseases

Huntington's disease (HD) is caused by nucleotide repeat expansion that leads to inclusion of protein motifs that induce cellular toxicity. The nucleotide repeat can also induce non-ATG dependent translation initiation, which leads to uncontrolled, overproduction of the harmful protein. PTCT is working to identify small molecules using its GEMS platform that can down regulate the expression of the deleterious protein in HD. Currently it has 3-5 scaffolds that it will use to optimize a lead compound.

There are several well characterized diseases caused by nucleotide repeat expansions (in addition to Huntington's disease) that might be treatable with a small molecule therapeutic, including: 1) spinal and bulbar muscular atrophy, 2) Fragile-X syndrome, 3) Jacobson syndrome, 4) spinocerebellar ataxia, 5) autosomal dominant cerebellar ataxia, 6) myotonic dystrophy, 7) Fiedreich ataxia, 8) dentatorubral-pallidoluysian atrophy, and 9) myoclonus epilepsy of the Unverricht-Lundborg type.

Cancer program – PTC596 targeting BMI1

BMI1 has been shown to be a negative prognostic factor for specific cancers and is believed to be associated with cancer stem cells. There is evidence that BMI1 can induce immortality and resistance to tumor cells via different mechanisms. PTCT has identified a lead compound, PTC596, that selective induces the phosphorylation of BMI1, leading to degradation of the protein. PTC596 has demonstrated single agent activity in several animal models, including an orthotopic glioblastoma model. When compared to the standard-of-care, temozolomide, in the glioblastoma model, PTC596 was significantly better at improving survival in the mice.

PTC596 is orally bioavailable and has not demonstrated any putative drug-drug interactions to date. PTCT believes that this compound can be safely combined with other approved agents, as the safety profile observed in animal studies has been benign. PTCT intends to pursue glioblastoma first and it is working on IND-enabling studies for the drug candidate. This program is also compelling because it represents a combination of a biomarker that could be analyzed with a diagnostic test and a selective agent that can target that could possible target the tumor stem cells.

Antibiotic program – DNA synthesis inhibitors

PTCT has a program developing a new class of molecules that target unmet medical needs in the infectious disease space. It is developing three compounds that can address different classes of pathogens. The company spent the most time discussing its lead compound for targeting drug-resistant *Neisseria gonorrhoeae*. This compound (PTC847) can specifically target the wild type and drug resistant forms of the bacteria. In a gonorrhea mouse model, PTC847 has been shown to be as efficacious as ceftriaxone.

PTCT also has two other compounds in its antibiotic program, one targeting gram-negative bacteria (PTC280) and another targeting MRSA (PTC-082).

Exhibit 1: PTCT News Flow

Timing	Event
Duchenne Muscular Distrophy	
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	DR gonorrhea, Gram (-) bacteria, MRSA	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 25-Oct-2013)*

PTC Therapeutics, Inc (PTCT.OQ, $20.71, OUTPERFORM[V], TP $24.0)
Prosensa (RNA.OQ, $4.31)
Roche (ROG.VX, SFr248.7)
Sarepta Theprcs (SRPT.OQ, $42.78)

Disclosure Appendix

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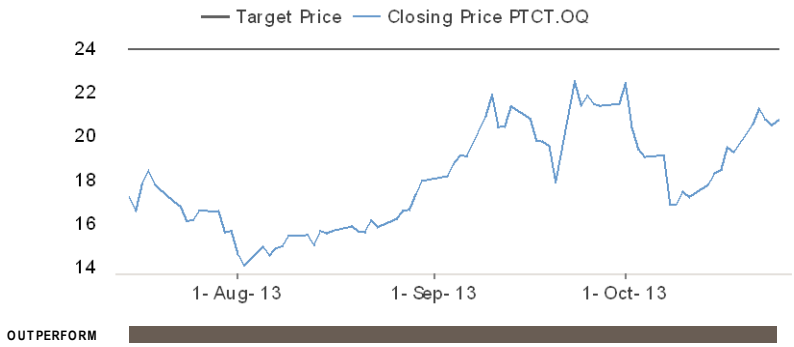
3-Year Price and Rating History for PTC Therapeutics, Inc (PTCT.OQ)

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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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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