PTC Therapeutics, Inc (PTCT)

SMALL & MID CAP RESEARCH

PTCT Selects SMA Drug Candidate & Receives $10M Milestone From Partner Roche

The selection of the lead candidate indicates that the SMA program is progressing as planned and could lead to the initiation of a clinical study in 2014. SMA represents an unmet medical need, potentially allowing for an expedited registration path for this indication. This program highlights the depth of PTCT technology beyond the Ataluren programs in DMD and CF.

- **PTCT selects SMA candidate:** The selection triggers a $10M milestone payment to PTCT, which we had modeled for Q3. Assuming preclinical toxicology is clean, we expect that the chosen candidate could enter human clinical testing in 2014, likely triggering another cash milestone to PTCT.
- **Overview of Roche Partnership:** PTCT and Roche entered into a deal in November 2011 for the worldwide rights to the SMA program. PTCT received $30M upfront and is eligible for $125M in development milestones (in addition to the $10M announced today) and $325M in sales milestones. PTCT will receive tiered royalties on worldwide net sales (single digits to the mid-teens).
- **Our $24 TP Is Supported by a Probability-Weighted DCF Analysis 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 risk-lowering Phase III results, advancement of its pipeline, or potential ex-U.S. partnership(s). The SMA program is not in our valuation.
- **Q2:13 Earnings call 8/12 at 4:30 PM EST:** 877-303-9216 pwd: 24942756.

Rating	**OUTPERFORM* [V]**
Price (07 Aug 13, US$)	14.86
Target price (US$)	24.00[1]
52-week price range	18.40 - 13.63
Market cap. (US$ m)	351.86
Enterprise value (US$ m)	202.54

**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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Financial and valuation metrics

Year	12/12A	12/13E	12/14E	12/15E
EPS (CS adj.) (US$)	42.50	-2.26	-2.19	-1.64
Prev. EPS (US$)	—	—	—	—
P/E (x)	0.3	-6.6	-6.8	-9.1
P/E rel. (%)	2.1	-43.0	-49.2	-72.5
Revenue (US$ m)	33.9	30.1	20.0	27.0
EBITDA (US$ m)	-24.1	-37.6	-54.2	-55.0
OCFPS (US$)	-2.98	-2.00	-2.12	-1.31
P/OCF (x)	—	-7.4	-7.0	-11.3
EV/EBITDA (current)	-12.7	-8.1	-5.6	-5.6
Net debt (US$ m)	2	-149	-91	-229
ROIC (%)	160.91	358.28	2,118.33	1,605.00

Number of shares (m)	23.68	IC (current, US$ m)	-16.66
BV/share (Next Qtr., US$)	-19.9	EV/IC (x)	-13.8
Net debt (Next Qtr., US$ m)	-169.5	Dividend (current, US$)	—
Net debt/tot cap (Next Qtr., %)	-108.5	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates

SMA Program Could Become a Driver in 2014/2015

PTCT has partnered with Roche to develop drugs for the treatment of spinal muscular atrophy. This neurodegenerative disease affects approximately 10,000 children in the United States and is the leading genetic cause of infant death.

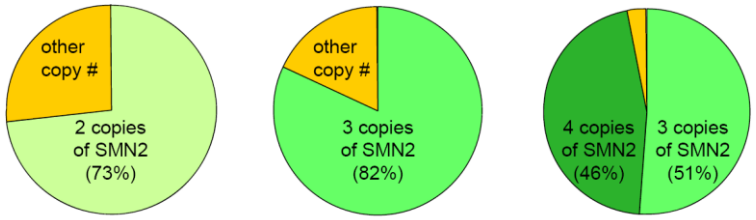
The disease is caused by an inadequate production of a protein called SMN, which is necessary for motor neuron survival. This protein can be produced by one of two genes.

- SMN1 gene is the primary source of the SMN protein. Mutations in the SMN1 gene lead to the development of SMA, as the other gene SMN2 is not sufficient.
- SMN2 gene can also produce functional SMN protein, but the message it encodes is more frequently spliced into an alternative form (70-90% of the time), which codes for a protein that is rapidly degraded and therefore inadequate. (See Exhibit 1)

The goal of many therapies for SMA is to increase the product from the SMN2 gene to compensate for the loss of SMN1. Human data clearly show that the severity of disease in SMA patients correlates with the copy number of the SMN2 gene. (See Exhibit 1) The most severe form (Type I) is associated with lower copy number of SMN2 (bottom panel), and the least severe form (Type III) is associated with higher copy number of SMN2. This forms the primary rationale for trying to increase SMN2 activity as a therapeutic intervention.

Exhibit 1: More SMN2 Is Associated with Less Severe SMA (Rationale for Upregulating SMN2)

Type	Age of onset	Life expectancy	Highest function	SMN2 gene copy #[1]	SMN protein % of carrier[2]
I	0 - 3 months	< 2 years	Unable to sit, respiratory insufficiency	~2	~30-40%
II	6 -18 months	> 2 years	Able to sit, cannot stand or walk unaided	~3	~50-60%
III	After 2 years	Adult	Able to sit, stand and walk with restrictions	~ 3 to 4	~60-80%



Charts - courtesy of SMA Foundation

[1] The SMN2 copy number does not always predict SMA type.

[2] SMN protein measured using Western blot in SMA patient fibroblasts (PTC data)

Source: Company data

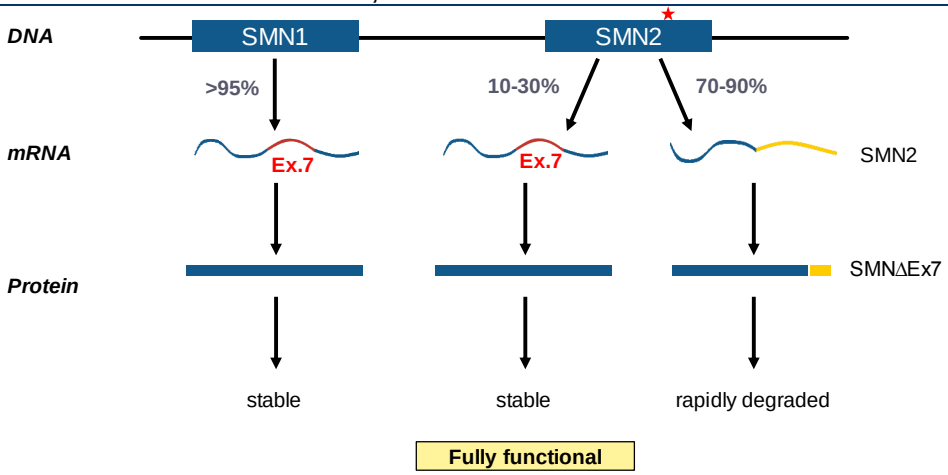
PTCT Targets Increased SMN2

PTCT in collaboration with Roche and the SMA Foundation is developing drugs that increase the production of "normal" protein from the SMN2 gene. PTCT's lead candidates act on the SMN2 message and cause it preferentially to splice into the active form. Normally, SMN2 is spliced correctly 10-30% of the time (see Exhibit 2), but in the presence of PTCT's compound, correct splicing occurs up to 95% of the time (see Exhibit 3), producing enough SMN protein significantly to alter the development of the disease in animal models of SMA.

Evidence for the efficacy of this compound comes from in vivo studies in disease models.

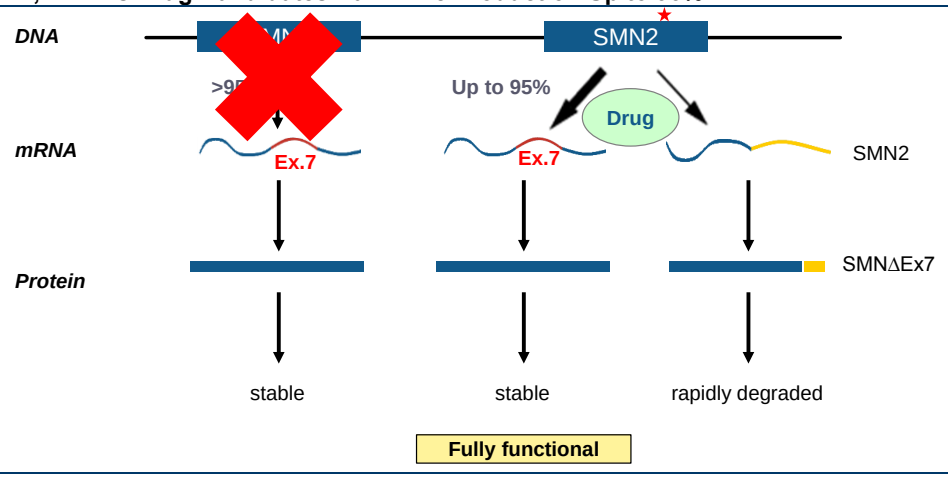
- **Evidence of Mechanism:** RNA from the brain or muscle of diseased mice shows that treatment with PTCT's SMA candidate increases production of the "normal" full-length RNA (see Exhibit 4, left panel) and increases production of the SMN protein in target tissues. (See Exhibit 4, right panel.)
- **Evidence of Activity:** In animal models of SMA, PTCT's candidates promote long-term survival, while untreated animals die within three weeks. (See Exhibit 5.)

Exhibit 2: Under Normal Conditions, SMN1 Produces Sufficient SMN Protein



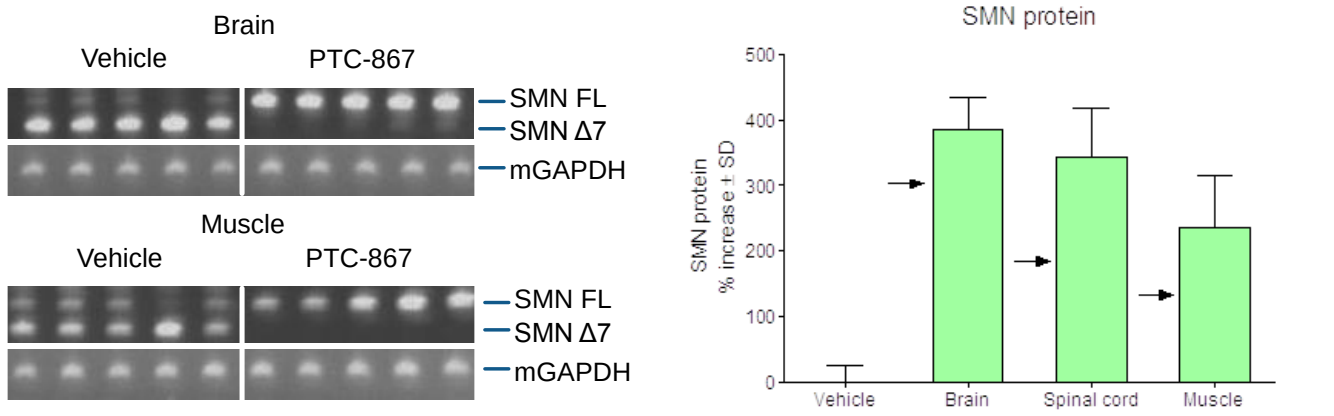
Source: Company data

Exhibit 3: When SMN1 Gene Function Is Lost, SMN Is Produced at Low Levels from SMN2; PTCT's Drug Candidates Can Drive Production Up to 95%



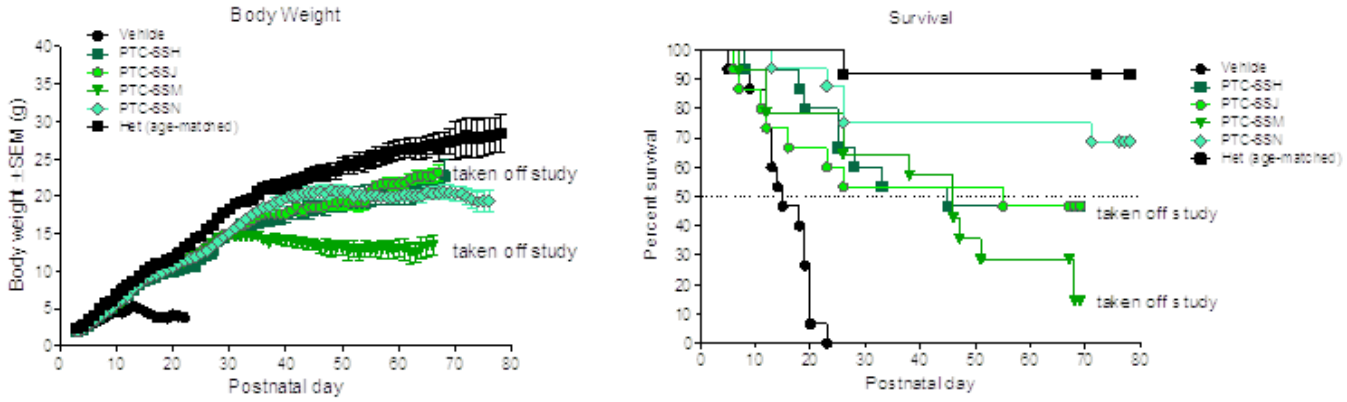
Source: Company data

Exhibit 4: Increased SMN RNA and Protein after Administration of PTCT's Drug Candidate



Source: Company data

Exhibit 5: Long-Term Dosing Leads to Weight Gain and Increased Survival with Different Drug Candidates



Source: Company data

Several Novel Drugs in Development for SMA

The molecular understanding of the cause of SMA has led several groups to develop novel approaches to increase SMN protein levels. (See Exhibit 6) The most advanced program is from Isis/Biogen's ISIS-SMNRx in Phase II. While PTCT is clearly behind, the field is still wide open, and the preclinical data so far from PTCT are compelling. Physicians we have spoken to who are familiar with these data are excited about the potential activity and its utility in SMA.

Exhibit 6: Drugs that Aim to Increase SMN Production

Company	Drug	MOA	Stage
ISIS/Biogen	ISIS-SMNRx	SMN2 splicing augmentation	Phase II
Pfizer	RG3039	Impact mRNA metabolism	Preclinical
PTC/Roche	Small molecule	SMN2 splicing augmentation	Preclinical
Genethon	AAV with SMN1	Gene therapy	Preclinical

Source: Company data, ClinicalTrials.gov

Exhibit 7: **PTCT News Flow**

Timing	Event
Duchenne Muscular Distrophy	
Sep 2013	Receive list of outstanding issues from EMA for filing
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
Q1:14	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 8: **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	MDR Gram (-) bacteria	Proprietary

Source: Company data, Credit Suisse estimates

Exhibit 9: PTCT Model

($ in MM; except per share)	2011A	2012A	Q1:13A	Q2:13E	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	5.0	5.0	10.0	26.1	16.0	23.0	16.0	16.0	12.0
Grant revenue	6.5	5.2	1.1	1.0	1.0	1.0	4.1	4.0	4.0			
Total Revenues	105.4	33.9	7.1	6.0	6.0	11.0	30.1	20.0	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	11.0	11.5	12.0	45.8	50.7	53.8	63.0	70.0	77.0
Sales, General and Administrative Expenses	16.2	14.6	4.5	7.0	6.5	6.5	24.5	26.0	29.0	67.0	101.0	119.2
Total Costs and Expenses	74.8	60.8	15.7	18.0	18.0	18.5	70.2	76.7	82.8	132.3	183.5	219.9
Operating Income (Loss)	30.6	(26.8)	(8.6)	(12.0)	(12.0)	(7.5)	(40.1)	(56.7)	(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	(1.0)	(1.0)	(1.0)	(2.9)	(4.0)	(4.0)	(4.0)	(4.0)	(4.0)
Income (Loss) before Tax	28.6	(26.2)	(14.7)	(13.1)	(13.1)	(8.5)	(49.4)	(60.7)	(59.8)	(91.1)	(14.9)	84.2
Provision for Income Tax (benefit)	2.3											
Net income (loss)	30.9	(26.2)	(14.7)	(13.1)	(13.1)	(8.5)	(49.4)	(60.7)	(59.8)	(91.1)	(14.9)	84.2
Net income attributable to common shareholders	0.0	0.7	(29.5)	(13.1)	(13.1)	(8.5)	(49.4)	(60.7)	(59.8)	(91.1)	(14.9)	84.2
EPS - diluted (proforma)	4.55	42.50	(2.08)	(0.86)	(0.52)	(0.34)	(2.26)	(2.19)	(1.64)	(2.44)	(0.39)	2.15
Shares Outstanding - basic (Proforma)	0.001	0.003	14.18	15.29	25.00	25.12	19.90	25.44	34.01	34.70	35.39	36.11
Shares Outstanding - diluted (Proforma)	0.006	0.017	16.10	17.22	27.02	27.24	21.89	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 07-Aug-2013)*

Biogen Idec (BIIB.OQ, $217.76)
Isis Pharma (ISIS.OQ, $27.45)
PTC Therapeutics, Inc (PTCT.OQ, $14.86, OUTPERFORM[V], TP $24.0)
Pfizer (PFE.N, $29.26)
Roche (ROG.VX, SFr232.6, OUTPERFORM, TP SFr270.0)

Disclosure Appendix

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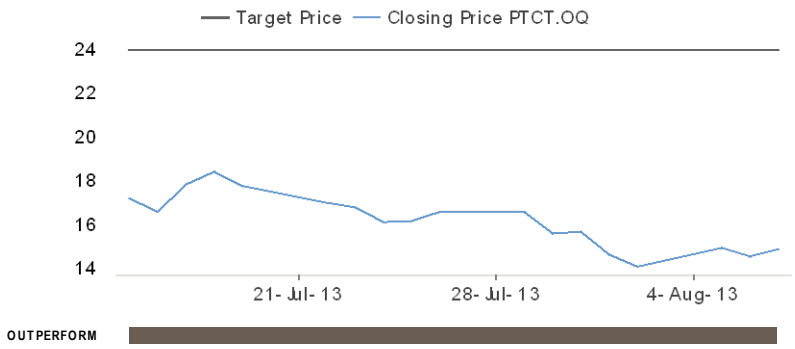
Jason Kantor, PhD, Ravi Mehrotra PhD and Lee Kalowski each certify, with respect to the companies or securities that the individual analyzes, that (1) the views expressed in this report accurately reflect his or her personal views about all of the subject companies and securities and (2) no part of his or her compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this report.

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 *

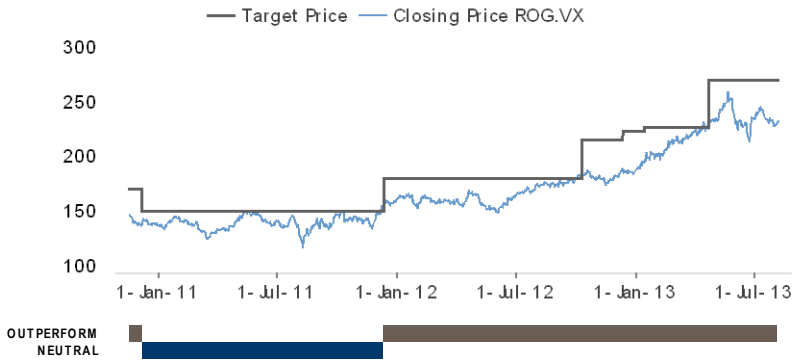
** Asterisk signifies initiation or assumption of coverage.*



3-Year Price and Rating History for Roche (ROG.VX)

ROG.VX	Closing Price	Target Price	
Date	(SFr)	(SFr)	Rating
18-Nov-10	146.50	170.00	O
07-Dec-10	138.00	150.00	N
12-Dec-11	153.90	180.00	O
11-Oct-12	181.20	215.00	
12-Dec-12	187.20	223.00	
14-Jan-13	194.60	227.00	
22-Apr-13	225.10	270.00	

** Asterisk signifies initiation or assumption of coverage.*



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Underperform/Sell*	15%	(39% banking clients)
Restricted	3%	

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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).

Price Target: (12 months) for Roche (ROG.VX)

Method: We value Roche on a PE relative basis to the European markets modulated by our PharmaValues NPV methdology. Our European Major Pharma 2013 PE market relative assumption is 135% and our sector PE relative for Roche is 105%, giving a price target of SFr 270 per share. Roche 's 3 year historical average PE sector relative is 97%.

Risk: In the Pharma business the key risks centre on the high price structure of leading oncology drugs (Avastin, Herceptin and MabThera) and the outcome of future clinical trials that will be necessary to expand their clinical use. In Diagnostics intensifying pricing and competitive pressures may also pose a threat. For the business as a whole general market and sector risk is also important.

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See the Companies Mentioned section for full company names

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