PTC Therapeutics, Inc (PTCT)

Rating	**OUTPERFORM* [V]**
Price (21 Jan 14, US$)	28.96
Target price (US$)	24.00[1]
52-week price range	29.32 - 13.59
Market cap. (US$ m)	721.60
Enterprise value (US$ m)	575.16

**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

SMA Program Enters Phase I -- Likely Future Driver of Significant Value

PTCT announced the initiation of a Phase I trial for its novel oral drug for the treatment of spinal muscular atrophy (SMA). The program is partnered with Roche and the SMA Foundation. The initiation of the trial is on the early side of its 2014 guidance; it triggers a $7.5M milestone from Roche, and it sets up PTCT with a third value driver in addition to Ataluren for DMD and CF.

- **SMA program:** PTCT's SMA program is the most advanced oral treatment for this disease. It acts on the RNA of the SMN2 gene to upregulate the production of the fully functional protein. Significant in vitro and animal models demonstrate this biochemical activity and subsequent clinical activity.
- **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 $135M in development milestones and $325M in sales milestones. PTCT will receive royalties on WW net sales that are tiered in the single digits to the mid-teens.
- **SMA program is not in our valuation:** Our current valuation does not include the SMA program or earlier stage programs. With any proof of concept data, this program could drive significant upside from current levels.
- **Modest changes to model:** We are updating our model to include the $7.5M milestone payment in Q1:14. Previously we had conservatively forecast the milestone in Q1:15. The result is an increase in 2014 EPS and a decrease in 2015.

Financial and valuation metrics

Year	12/12A	12/13E	12/14E	12/15E
EPS (CS adj.) (US$)	42.50	-3.68	-2.47	-1.92
Prev. EPS (US$)	—	—	-2.77	-1.77
P/E (x)	0.7	-7.9	-11.7	-15.1
P/E rel. (%)	3.9	-47.5	-77.6	-110.8
Revenue (US$ m)	33.9	36.3	18.5	22.0
EBITDA (US$ m)	-24.1	-37.4	-55.9	-60.0
OCFPS (US$)	NM	-3.27	-2.12	-1.46
P/OCF (x)	—	-8.9	-13.7	-19.9
EV/EBITDA (current)	-23.4	-15.1	-10.1	-9.4
Net debt (US$ m)	2	-146	-88	-222
ROIC (%)	160.91	497.33	3,849.25	2,533.89

Number of shares (m)	24.92	IC (current, US$ m)	-16.66
BV/share (Next Qtr., US$)	-13.0	EV/IC (x)	-71.9
Net debt (Next Qtr., US$ m)	-146.4	Dividend (current, US$)	—
Net debt/tot cap (Next Qtr., %)	-105.8	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates

SMA Program – Updates from Oct. 2013 Analyst Day

At the October 2013 analyst day, PTCT provided a comprehensive review of its SMA program, and guided for a Phase I start in 2014. The January initiation of the Phase I program is on the very early side of guidance. The program is in collaboration with Roche.

Some of the topics reviewed at the analyst meeting were previously reported and included in our initiation report. Highlights from the October 2013 meeting included:

- **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.

SMA Program – 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.

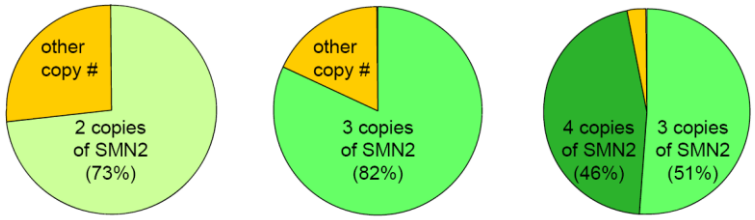
- SMN1 gene is the primary source of the SMN protein. Mutations in the SMN1 gene lead to the development of SMA, as the other gene SMN2 is not sufficient.
- SMN2 gene can also produce functional SMN protein, but the message it encodes is more frequently spliced into an alternative form (70-90% of the 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

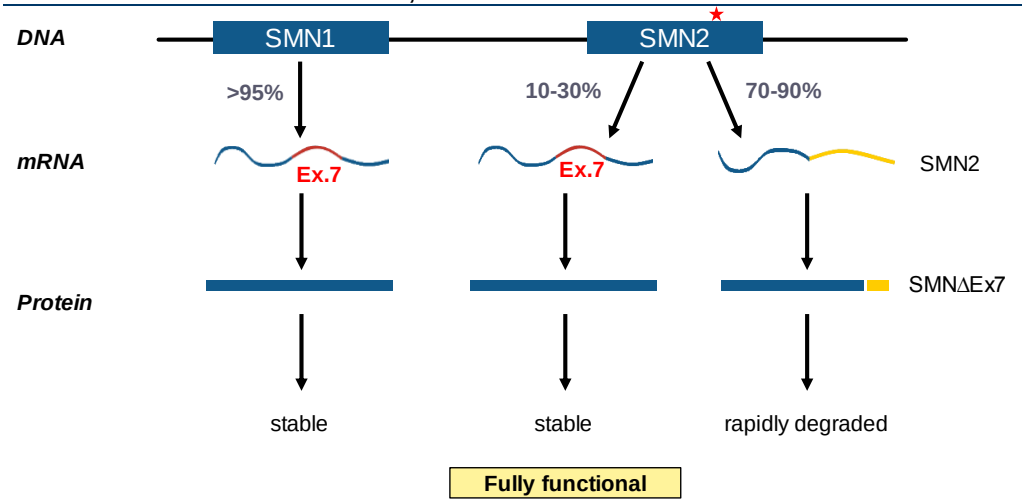
PTCT Targets Increased SMN2

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 to preferentially 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.

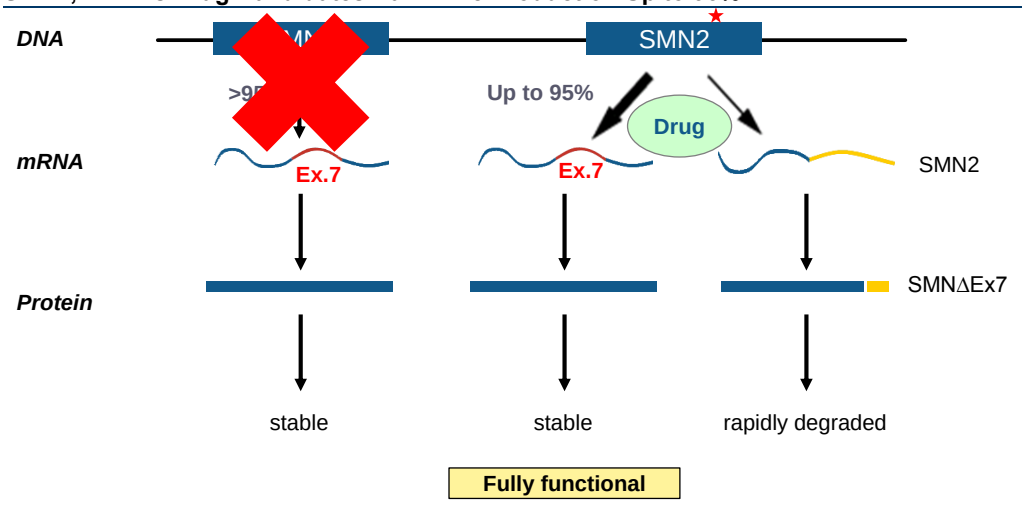
- **Evidence of Mechanism:** RNA from the brain or muscle of diseased mice shows that treatment with PTCT's SMA candidate increases production of the "normal" full-length RNA (see Exhibit 4, left panel) and increases production of the SMN protein in target tissues. (See Exhibit 4, right panel.)
- **Evidence 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



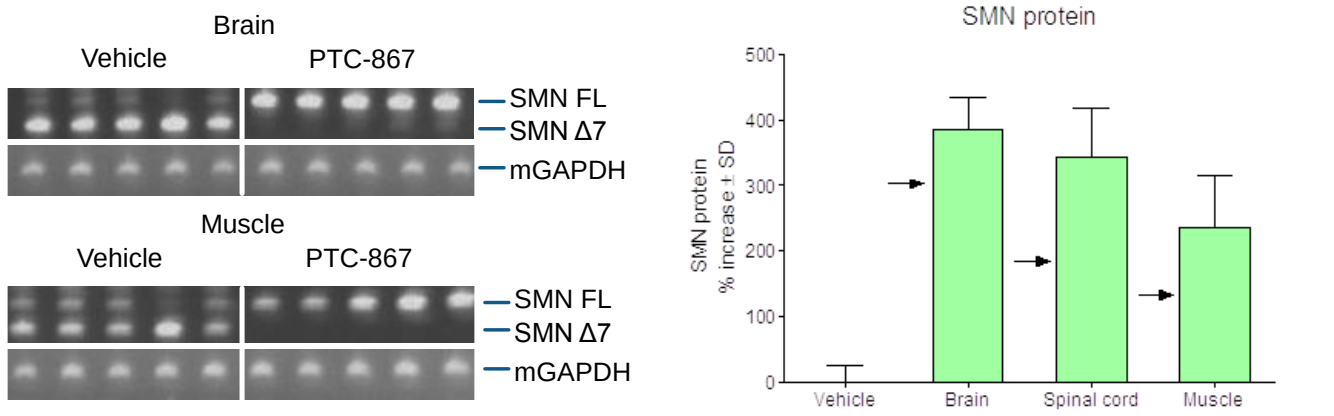
Source: Company data

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%



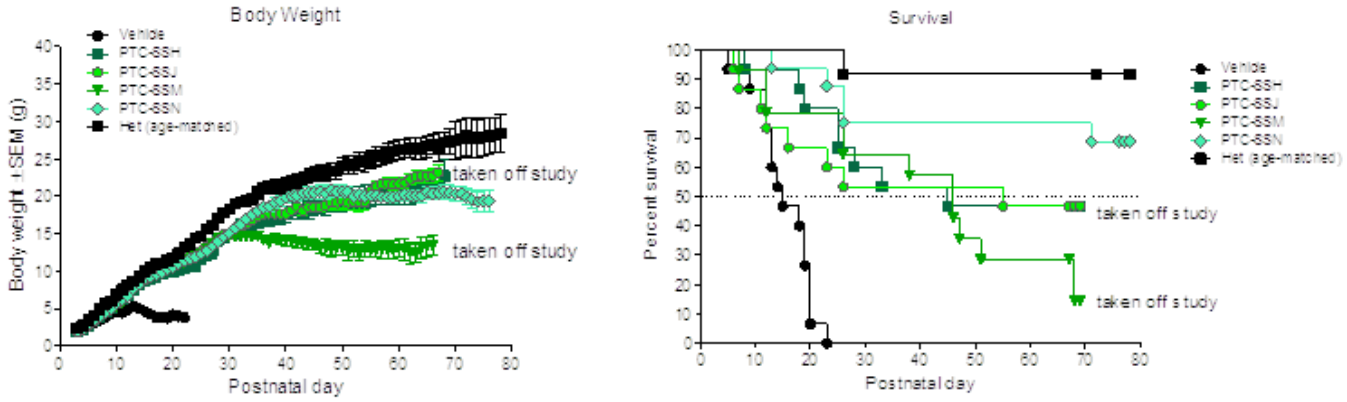
Source: Company data

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

Terms of the SMA Deal

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 $135M in development milestones and $325M in sales milestones. PTCT will receive royalties on WW net sales that are tiered in the single digits to the mid-teens.

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
Novartis	BVS857	NA	Phase II
PTC/Roche	Small molecule	SMN2 splicing augmentation	Phase I
Pfizer/Repligen	RG3039	Impact mRNA metabolism	Phase I
Genethon	AAV with SMN1	Gene therapy	Preclinical

Source: Company data, ClinicalTrials.gov

Exhibit 7: PTCT News Flow

Product/ Event	Indication	Catalyst	Expected Date	Price Sensitivity
Ataluren	Duchenne Muscular Dystrophy	Potential conditional EU approval	Q1:14	High
Ataluren	Cystic Fibrosis	EMA conditional approval filing	Q1:14	Low
Ataluren	Cystic Fibrosis	Dose first patient in confirmatory CF Phase III study	H1:14	Low
Ataluren	Duchenne Muscular Dystrophy	Complete enrollment in confirmatory DMD Phase III study	Mid-2014	Low
Ataluren	Duchenne Muscular Dystrophy	Potential data from EU open-label extension study	H2:14	High
Ataluren	Cystic Fibrosis	Potential conditional EU approval	YE 2014	High
SMA program	Spinal muscular atrophy	Additional SMA data	YE 2014	Medium
SMA program	Spinal muscular atrophy	Complete Phase I	YE:2014	Low
Ataluren	Duchenne Muscular Dystrophy	Potential data from confirmatory DMD Phase III study	Mid-2015	High
Ataluren	Cystic Fibrosis	Complete enrollment in confirmatory CF Phase III study	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	Potential data from confirmatory CF Phase III study	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 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	Phase I	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	Q2:13A	Q3:13A	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	15.5	5.0	32.4	15.5	18.0	16.0	16.0	12.0
Grant revenue	6.5	5.2	1.1	1.0	0.8	1.0	3.9	3.0	4.0			
Total Revenues	105.4	33.9	7.1	6.9	16.3	6.0	36.3	18.5	22.0	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	13.9	12.0	51.9	50.8	53.8	63.0	70.0	77.0
Sales, General and Administrative Expenses	16.2	14.6	4.5	6.6	6.7	6.5	24.2	26.0	29.0	67.0	101.0	119.2
Total Costs and Expenses	74.8	60.8	15.7	21.3	20.6	18.5	76.1	76.8	82.8	132.3	183.5	219.9
Operating Income (Loss)	30.6	(26.8)	(8.6)	(14.5)	(4.3)	(12.5)	(39.8)	(58.3)	(60.8)	(87.1)	(10.9)	88.2
Interest Expense, net	(2.4)	(1.2)	(6.2)	(0.1)	0.0	(0.0)	(6.3)					
Other income, net	0.5	1.8	0.1	(0.0)	(0.2)	(1.0)	(1.1)	(4.0)	(4.0)	(4.0)	(4.0)	(4.0)
Income (Loss) before Tax	28.6	(26.2)	(14.7)	(14.6)	(4.4)	(13.5)	(47.2)	(62.3)	(64.8)	(91.1)	(14.9)	84.2
Provision for Income Tax (benefit)	2.3											
Net income (loss)	30.9	(26.2)	(14.7)	(14.6)	(4.4)	(13.5)	(47.2)	(62.3)	(64.8)	(91.1)	(14.9)	84.2
Net income attributable to common shareholders	0.0	0.7	(29.5)	(14.6)	(4.4)	(13.5)	(47.2)	(62.3)	(64.8)	(91.1)	(14.9)	84.2
EPS - diluted	4.55	42.50	(6,527)	(5.51)	(0.19)	(0.54)	(3.68)	(2.47)	(1.92)	(2.64)	(0.42)	2.16
Shares Outstanding - basic	0.001	0.003	0.005	2.65	23.80	24.92	12.84	25.23	33.80	34.48	35.17	35.88
Shares Outstanding - diluted	0.006	0.017	0.005	2.65	23.80	27.04	13.37	27.46	36.21	37.09	38.00	38.94

Source: Company data, Credit Suisse estimates

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Companies Mentioned *(Price as of 21-Jan-2014)*

Biogen Idec (BIIB.OQ, $310.5)
Isis Pharma (ISIS.OQ, $48.0)
Novartis (NOVN.VX, SFr74.15)
PTC Therapeutics, Inc (PTCT.OQ, $28.96, OUTPERFORM[V], TP $24.0)
Pfizer (PFE.N, $31.23)
Repligen (RGEN.OQ, $12.98)
Roche (ROG.VX, SFr248.4)

Disclosure Appendix

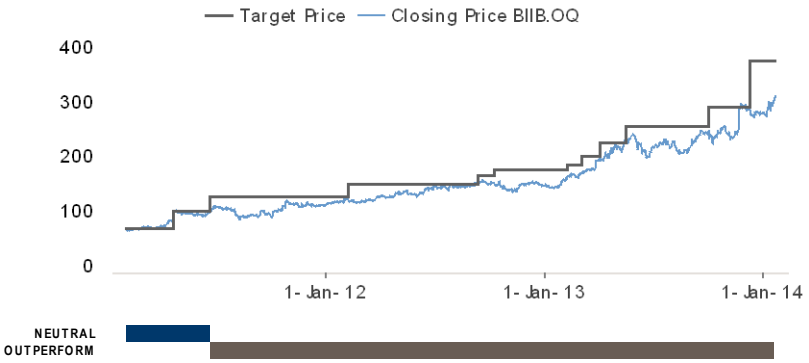
Important Global Disclosures

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 Biogen Idec (BIIB.OQ)

BIIB.OQ Date	Closing Price (US$)	Target Price (US$)	Rating
02-Feb-11	66.15	69.00	N
22-Apr-11	99.70	100.00	
22-Jun-11	99.47	126.00	O
08-Feb-12	119.60	150.00	
12-Sep-12	152.26	165.00	
08-Oct-12	151.22	175.00	
08-Feb-13	164.44	185.00	
04-Mar-13	169.96	200.00	
04-Apr-13	195.68	225.00	
17-May-13	226.85	255.00	
02-Oct-13	246.23	290.00	
10-Dec-13	285.23	375.00	

** Asterisk signifies initiation or assumption of coverage.*



3-Year Price and Rating History for Novartis (NOVN.VX)

NOVN.VX Date	Closing Price (SFr)	Target Price (SFr)	Rating
04-Oct-11	51.08	63.92	O
19-Oct-11	52.30	61.89	
22-Feb-12	52.96		*
13-Apr-12	50.58	61.00	O
20-Apr-12	51.95	61.89	
25-Apr-12	50.68	61.00	
14-Jan-13	60.05	70.00	
22-Apr-13	67.55	79.00	
20-Jan-14	73.80	87.00	

** Asterisk signifies initiation or assumption of coverage.*

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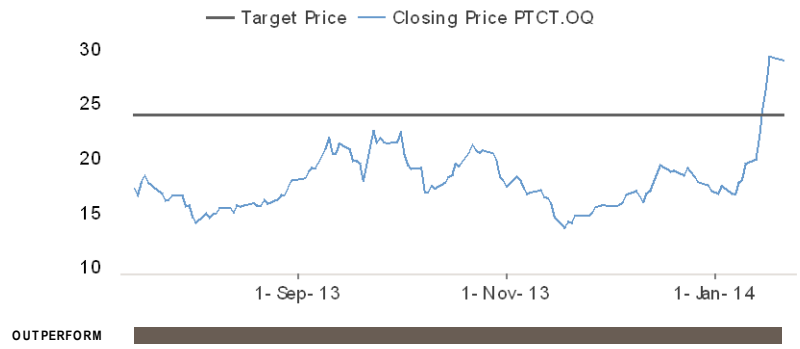
3-Year Price and Rating History for PTC Therapeutics, Inc (PTCT.OQ)

PTCT.OQ	Closing Price	Target Price	
Date	(US$)	(US$)	Rating
15-Jul-13	17.17	24.00	O *

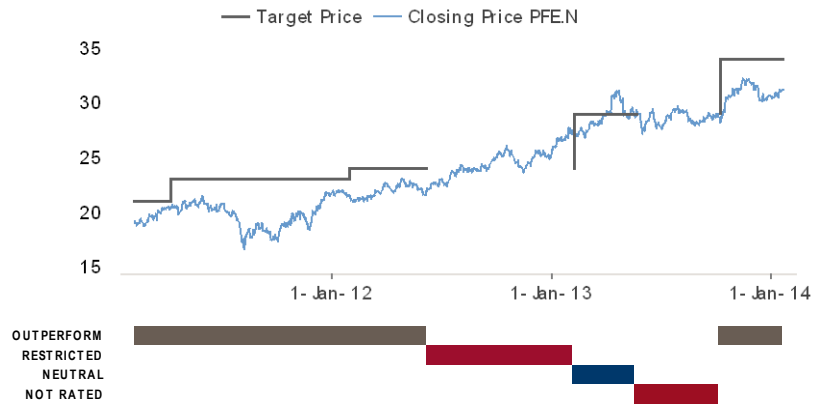
** Asterisk signifies initiation or assumption of coverage.*



3-Year Price and Rating History for Pfizer (PFE.N)

PFE.N	Closing Price	Target Price	
Date	(US$)	(US$)	Rating
07-Feb-11	19.04	21.00	O
08-Apr-11	20.46	23.00	
31-Jan-12	21.40	24.00	
07-Jun-12	21.94		R
07-Feb-13	26.96	29.00	N
22-May-13	29.30		NR
08-Oct-13	28.24	34.00	O *

** Asterisk signifies initiation or assumption of coverage.*



The analyst(s) responsible for preparing this research report received Compensation that is based upon various factors including Credit Suisse's total revenues, a portion of which are generated by Credit Suisse's investment banking activities

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Outperform (O) : The stock's total return is expected to outperform the relevant benchmark*over the next 12 months.

Neutral (N) : The stock's total return is expected to be in line with the relevant benchmark* over the next 12 months.

Underperform (U) : The stock's total return is expected to underperform the relevant benchmark* over the next 12 months.

**Relevant benchmark by region: As of 10th December 2012, Japanese ratings are based on a stock's total return relative to the analyst's coverage universe which consists of all companies covered by the analyst within the relevant sector, with Outperforms representing the most attractive, Neutrals the less attractive, and Underperforms the least attractive investment opportunities. As of 2nd October 2012, U.S. and Canadian as well as European ratings are based on a stock's total return relative to the analyst's coverage universe which consists of all companies covered by the analyst within the relevant sector, with Outperforms representing the most attractive, Neutrals the less attractive, and Underperforms the least attractive investment opportunities. For Latin American and non-Japan Asia stocks, ratings are based on a stock's total return relative to the average total return of the relevant country or regional benchmark; Australia, New Zealand are, and prior to 2nd October 2012 U.S. and Canadian ratings were based on (1) a stock's absolute total return potential to its current share price and (2) the relative attractiveness of a stock's total return potential within an analyst's coverage universe. For Australian and New Zealand stocks, 12-month rolling yield is incorporated in the absolute total return calculation and a 15% and a 7.5% threshold replace the 10-15% level in the Outperform and Underperform stock rating definitions, respectively. The 15% and 7.5% thresholds replace the +10-15% and -10-15% levels in the Neutral stock rating definition, respectively. Prior to 10th December 2012, Japanese ratings were based on a stock's total return relative to the average total return of the relevant country or regional benchmark.*

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Market Weight : The analyst's expectation for the sector's fundamentals and/or valuation is neutral over the next 12 months.

Underweight : The analyst's expectation for the sector's fundamentals and/or valuation is cautious over the next 12 months.

**An analyst's coverage sector consists of all companies covered by the analyst within the relevant sector. An analyst may cover multiple sectors.*

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Global Ratings Distribution

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Neutral/Hold*	41%	(48% banking clients)
Underperform/Sell*	14%	(43% banking clients)
Restricted	2%	

**For purposes of the NYSE and NASD ratings distribution disclosure requirements, our stock ratings of Outperform, Neutral, and Underperform most closely correspond to Buy, Hold, and Sell, respectively; however, the meanings are not the same, as our stock ratings are determined on a relative basis. (Please refer to definitions above.) An investor's decision to buy or sell a security should be based on investment objectives, current holdings, and other individual factors.*

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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).

Please refer to the firm's disclosure website at https://rave.credit-suisse.com/disclosures for the definitions of abbreviations typically used in the target price method and risk sections.

See the Companies Mentioned section for full company names

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