

PTC Therapeutics, Inc (PTCT)

SMALL & MID CAP RESEARCH

Q3 Results: EMA To Convene SAG Meeting - Modest Positive

We believe the announcement of the planned EMA Scientific Advisory Group (SAG) to discuss the ataluren conditional application for DMD is a slight positive, and suggests to us that the agency is at least thoughtfully considering the application, for which the Street gives PTCT no credit. A decision on the application is now expected in Q1:14. We assign no value for an early approval, which could represent meaningful upside to PTCT (potentially reach the market 2 years earlier than our estimates).

■ **SAG to discuss ataluren for DMD:** The EMA will select a group of experts to review the application, including a presentation by PTCT in a closed-door meeting. The SAG will make a recommendation to the CHMP. We do not expect any disclosures to follow this meeting, and PTCT now expects the CHMP decision in Q1:14 vs. prior YE:13.

■ **Catalysts:** (1) CHMP decision on EU conditional approval for ataluren in DMD in Q1:14, (2) File for conditional approval for ataluren in CF in Q1:14 (pushed slightly from YE:13 pending CHMP decision on DMD), (3) DMD Phase III read out in mid:2015, and 4) CF Phase III read out in 2016, and (5) Advancement of PTCT's SMA program with partner Roche 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	-3.68	-2.77	-1.77
Prev. EPS (US\$)	—	-3.48	-2.74	-1.76
P/E (x)	0.4	-4.3	-5.7	-9.0
P/E rel. (%)	2.2	-27.4	-40.3	-69.5
Revenue (US\$ m)	33.9	36.3	11.0	27.0
EBITDA (US\$ m)	-24.1	-37.4	-63.4	-55.0
OCFPS (US\$)	NM	-3.27	-2.39	-1.32
P/OCF (x)	—	-4.8	-6.6	-12.0
EV/EBITDA (current)	-9.9	-6.4	-3.8	-4.3
Net debt (US\$ m)	2	-146	-81	-219
ROIC (%)	160.91	497.33	4,344.44	2,325.51
Number of shares (m)	24.92	IC (current, US\$ m)		-16.66
BV/share (Next Qtr., US\$)	-13.0	EV/IC (x)		-31.1
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

Rating	OUTPERFORM* [V]
Price (14 Nov 13, US\$)	15.87
Target price (US\$)	24.00 ¹
52-week price range	22.48 - 13.63
Market cap. (US\$ m)	395.43
Enterprise value (US\$ m)	248.99

*Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.

¹Target 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

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Closer Look at SAG Meeting

The SAG will be composed of a group of experts that will have the background necessary to opine on the data package for DMD. However, PTCT does not know who will be part of the group. A SAG is similar to an FDA advisory committee, although the discussion is held behind closed doors and its decision is not released until the CHMP releases its decision.

PTCT is not certain when the SAG will convene, but it seems likely that it would have to be December or January to give the agency sufficient time to come to a decision in Q1:14. PTCT will present to the committee, along with DMD advocacy groups.

We view this development positively, and we believe the EMA is taking its diligence seriously. Given that there are no approved products for nmDMD and the drug has been safely administered to several hundred patients, the risk/reward benefit could be viewed in favor of ataluren.

Q3:13 Beat vs. CS Estimates

PTCT reported an EPS loss of (\$0.19) vs. our estimate of (\$0.32). The primary driver of the upside was the full recognition of the \$10M milestone from Roche for selection of the SMA clinical candidate. We had the revenue spread over Q3 and Q4. We have pulled forward the \$5M in Q4.

Our EPS estimates for 2013, 2014, and 2015 change slightly based on Q3 results and modest changes to our share count, to (\$3.68), (\$2.77), and (\$1.77) from (\$3.48), (\$2.74), and (\$1.76).

Exhibit 1: Q3 Variance Table

Income Statement	Actual	CS Estimate	Difference
Collaboration revenue	15.5	10.0	5.5
Grant revenue	0.8	1.0	(0.2)
Total Revenues	16.3	11.0	5.3
COGS	0.0	0.0	0.0
Research and Development Expenses	13.9	11.5	2.4
Sales, General and Administrative Expenses	6.7	6.5	0.2
Total Costs and Expenses	20.6	18.0	2.6
Operating Income (Loss)	(4.3)	(7.0)	2.7
Interest Expense, net	0.0	(0.1)	0.1
Other income, net	(0.2)	(1.0)	0.8
Income (Loss) before Tax	(4.4)	(8.1)	3.7
Provision for Income Tax (benefit)	0.0		0.0
Net income (loss)	(4.4)	(8.1)	3.7
Net income attributable to common shareholders	(4.4)	(8.1)	3.7
Basic Loss per Common Share	(0.19)	(0.32)	0.13
Diluted Loss per Common Share	0.0	0.0	0.0
Shares Outstanding, Basic	23.8	25.0	(1.2)
Shares Outstanding, Diluted*	23.8	27.0	(3.2)

Source: Company data, Credit Suisse estimates

Exhibit 2: PTCT News Flow

Timing	Event
Duchenne Muscular Dystrophy	
H2:13	Seek early access programs for DMD in select territories
Q1:14	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	
Q1:14	EMA conditional approval filing
H1:14	Dose first patient in confirmatory 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 2017	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 3: 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 4: 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	8.0	23.0	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	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	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)	(65.8)	(55.8)	(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)	(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)	(4.4)	(13.5)	(47.2)	(69.8)	(59.8)	(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)	(69.8)	(59.8)	(91.1)	(14.9)	84.2
EPS - diluted	4.55	42.50	(6,527)	(5.51)	(0.19)	(0.54)	(3.68)	(2.77)	(1.77)	(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

Companies Mentioned (Price as of 14-Nov-2013)

PTC Therapeutics, Inc (PTCT.OQ, \$15.87, OUTPERFORM[V], TP \$24.0)
Roche (ROG.VX, SFr254.2)

Disclosure Appendix

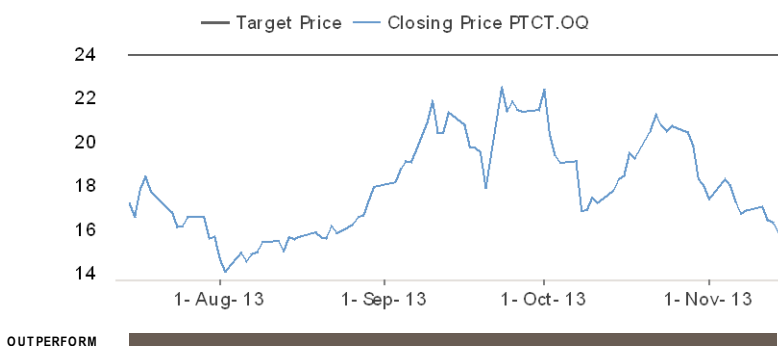
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3-Year Price and Rating History for PTC Therapeutics, Inc (PTCT.OQ)

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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