

Paion

Three, two, one, go

Clinical update

Pharma & biotech

Paion has launched its self-funded US Phase III programme, a head-to-head study in colonoscopy comparing remimazolam with the gold-standard midazolam, measuring clinical endpoints and also various outputs to determine the economic viability of the fast-acting sedative. Previous studies showed a faster onset and recovery as well as an excellent side-effect profile. We maintain our DCF valuation of €176m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/13	4.2	(2.6)	(7.2)	0.0	N/A	N/A
12/14	3.5	(11.3)	(22.2)	0.0	N/A	N/A
12/15e	0.0	(30.1)	(49.6)	0.0	N/A	N/A
12/16e	1.0	(21.8)	(38.9)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments.

US Phase III programme off the blocks

Paion has initiated the first of two pivotal Phase III trials planned in 2015 in the lead US indication procedural sedation. The double-blind [midazolam and placebo-controlled study](#) will enrol 460 patients undergoing colonoscopy. While the key endpoint is successful sedation, speed of onset, time to full recovery and the rate of adverse events will be compared to the midazolam arm, to confirm the potential clinical and economic rationale for remimazolam. Paion seeks a label comparable to midazolam, the gold standard for short-term and procedural sedation; around 20m colonoscopies are performed per year in the US. Potentially remimazolam can be used without an anaesthetist, a key cost advantage over approved sedatives.

Clinical studies

A second Phase III US study in bronchoscopy is expected to start during H115, to study sedation using remimazolam in a frailer patient group, along with three Phase I safety studies. The combined US studies are to support US approval filing for remimazolam in procedural sedation across all patient groups. Paion is also finalising the protocol for the European pivotal study (lead indication general anaesthesia) ahead of an H115 start, which should be sufficient for approval filing.

Cash reach to end 2017

Paion's end-2014 net cash stood at €58.9m. Our forecasts suggest that Paion has sufficient cash resources to fund trials in the US and in Europe. Our peak sales estimate in the US is \$240m. The start of the US Phase III programme could support the company's Japanese strategy, which may include a new partnership.

Valuation: Maintained at €176m

We reiterate our DCF valuation of €176m or €3.5 per share, using a 12.5% discount rate. The c 25% four-week share price move reflects progress with the clinical programme but we anticipate additional inflection points ahead, including news on the Japanese strategy and further trial starts in the US.

13 April 2015

Price €2.63
Market cap €133m

Cash (€m) at end December 2014	58.9
Shares in issue	50.6m
Free float	78%
Code	PA8
Primary exchange	Frankfurt
Secondary exchange	Xetra

Share price performance



Business description

Paion, a specialty pharma company, develops anaesthesia products. Its lead product, remimazolam, is partnered with Yichang in China, Hana Pharma in South Korea, Pendopharm in Canada and R-Pharm in CIS, Turkey & MENA.

Next events

US Phase III trial starts: bronchoscopy	Q115/Q215
European Phase III study start: general anaesthesia	H115
News on Japanese strategy	2015

Analysts

Emma Ulker	+44 (0)20 3077 5738
Dr Mick Cooper	+44 (0)20 3077 5734

healthcare@edisongroup.com

[Edison profile page](#)

Exhibit 1: Financial summary

	€000s	2013	2014	2015e	2016e
Year-end 31 December					
PROFIT & LOSS					
Revenue		4,228	3,456	0	1,000
Cost of sales		0	(4)	0	0
Gross profit		4,228	3,452	0	1,000
R&D expenditure		(4,583)	(11,799)	(25,500)	(20,000)
General, administrative & selling		(3,314)	(3,702)	(5,000)	(3,199)
Other		860	411	50	51
Operating profit		(2,810)	(11,639)	(30,450)	(22,148)
Depreciation and amortisation		(390)	(246)	(245)	(244)
Share-based payments		0	0	0	0
Exceptionals		0	0	0	0
EBITDA		(2,420)	(11,393)	(30,205)	(21,904)
Operating profit (before GW and except)		(2,420)	(11,393)	(30,205)	(21,904)
Net interest		(170)	66	90	90
Profit before tax (norm)		(2,590)	(11,327)	(30,115)	(21,814)
Profit before tax (FRS 3)		(2,980)	(11,573)	(30,360)	(22,058)
Tax		768	2,468	5,000	2,100
Profit after tax (norm)		(1,822)	(8,859)	(25,115)	(19,714)
Profit after tax (FRS3)		(2,212)	(9,105)	(25,360)	(19,958)
Average number of shares outstanding (m)		25.4	39.9	50.6	50.6
EPS - normalised (c)		(7.2)	(22.2)	(49.6)	(38.9)
EPS - FRS 3 (c)		(8.7)	(22.8)	(50.1)	(39.4)
Dividend per share (c)		0.0	0.0	0.0	0.0
Gross margin (%)		100.0%	99.9%	NA	100.0%
EBITDA margin (%)		NA	NA	NA	NA
Operating margin (before GW and except.) (%)		NA	NA	NA	NA
BALANCE SHEET					
Fixed assets		3,583	3,516	3,271	3,027
Intangible assets		3,494	3,440	3,207	2,975
Tangible assets		89	76	64	52
Refund from assumption of dev costs		0	0	0	0
Other		0	0	0	0
Current assets		14,433	63,032	35,264	15,550
Stocks		0	0	0	0
Debtors		0	467	23	24
Cash		13,292	58,912	34,241	14,526
Other		1,141	3,653	1,000	1,000
Current liabilities		(4,659)	(3,924)	(3,840)	(3,839)
Trade payables		(1,914)	(3,338)	(3,338)	(3,338)
Short-term borrowings		0	0	0	0
Provisions		(2,508)	(306)	(248)	(247)
Finance lease liabilities		0	0	0	0
Other current liabilities		(225)	(254)	(254)	(254)
Current deferred income		(11)	(26)	0	0
Long-term liabilities		(28)	(17)	0	0
Long-term borrowings		0	0	0	0
Provisions		0	0	0	0
Long-term deferred income		(28)	(17)	0	0
Deferred taxes		0	0	0	0
Other long-term liabilities		0	0	0	0
Net assets		13,329	62,607	34,695	14,738
CASH FLOW					
Operating cash flow		(1,746)	(12,044)	(29,761)	(21,905)
Net interest		(170)	63	90	90
Tax		75	0	5,000	2,100
Capex		0	0	0	0
Purchase of intangibles		(5)	(26)	0	0
Acquisitions/disposals		0	0	0	0
Financing		0	57,618	0	0
Dividends		0	0	0	0
Other		0	0	0	0
Net cash flow		(1,847)	45,610	(24,671)	(19,715)
Opening net debt/(cash)		(15,361)	(13,292)	(58,912)	(34,241)
Effect of exchange rate changes		(130)	(72)	0	0
Other		-92	82	0	0
Closing net debt/(cash)		(13,292)	(58,912)	(34,241)	(14,526)

Source: Edison Investment Research, company accounts

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