

Paion

Positive data in high-risk patients

Paion has taken an important step towards its goal of US approval for its ultra-fast-acting sedative, remimazolam with the announcement of positive top line results from a safety study in high risk colonoscopy patients. It is approaching another important milestone, with the confirmatory Phase III in bronchoscopy patients expected to complete recruitment soon; top line results are likely about two months later. Paion is on track to file for approval in both the US (in procedural sedation via partner Cosmo Pharmaceuticals) and Japan (for general anaesthesia) by mid-2018.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/15	0.1	(34.0)	(55.7)	0.0	N/A	N/A
12/16	4.3	(24.3)	(36.4)	0.0	N/A	N/A
12/17e	5.9	(16.4)	(23.2)	0.0	N/A	N/A
12/18e	3.1	(13.3)	(19.2)	0.0	N/A	N/A

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

Safety confirmed in high-risk colonoscopy patients

Paion reported positive headline data from a safety study in high-risk colonoscopy patients (American Society of Anesthesiologists (ASA) class III or IV patients with severe systemic disease who are mostly treated in a hospital environment). The primary objective of the trial was to assess the safety of remimazolam compared to placebo with midazolam rescue. Paion reported that remimazolam demonstrated good respiratory and cardiovascular stability compared to placebo with midazolam rescue; no adverse events of concern were observed in either group. While commercial use of remimazolam is likely to be targeted at lower-risk ASA I/II patients, this trial is an important part of the development programme agreed with the FDA because it confirms that remimazolam can be used safely in high-risk patients.

Efficiency gains similar to colonoscopy Phase III

Secondary outcome measures that compared remimazolam to placebo and to an open label arm treated with midazolam according to the US label confirmed time savings with the use of remimazolam. Induction of and recovery from sedation was faster with remimazolam than midazolam (median induction time 5.0 vs 19.0 minutes, and time to full recovery 3.0 vs 7.0 minutes for the two groups, respectively. Recovery times to full alertness were similar to the results reported last year from the comparable groups in the Phase III trial in low-risk colonoscopy patients (4.0 and 19.0 minutes, respectively); recovery to full alertness took longer in all groups in the phase III (7.2 and 15.7 minutes, respectively) – the use of lower doses may have led to faster recovery in the high-risk patients.

Valuation: Unchanged at €214m

Our valuation is unchanged at €214m (€3.68/share). Paion has sufficient cash to fund operations beyond end 2018, which would allow it to complete filings in the US (via partner Cosmo) and Japan. However, it would need ~€20-25m of additional funds should it choose to restart development of remimazolam in Europe (funds could potentially come from Cosmo milestones and a licence deal in Japan).

Headline trial results

Pharma & biotech

27 March 2017

Price €2.19

Market cap €127m

US\$1.10/€

Net cash (€m) at 31 December 2016 30.1

Shares in issue 58.2m

Free float 75%

Code PA8

Primary exchange Frankfurt

Secondary exchange Xetra

Share price performance



% 1m 3m 12m

Abs (9.0) (11.5) (0.1)

Rel (local) (10.9) (16.0) (18.4)

52-week high/low €2.96 €1.66

Business description

Paion is an emerging specialty pharma company developing anaesthesia products. Lead product remimazolam is undergoing US Phase III trials and is partnered with Cosmo (US), Yichang (China), Hana Pharma (South Korea), Pendopharm (Canada) and R-Pharm (CIS, Turkey, MENA).

Next events

Fully recruit bronchoscopy Phase III Q217

Bronchoscopy Phase III results Q317

Pre NDA meeting with FDA Q417

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Exhibit 1: Financial summary

	€'000s	2014	2015	2016	2017e	2018e
Year end 31 December						
PROFIT & LOSS						
Revenue		3,456	61	4,262	5,874	3,100
Cost of sales		(4)	0	0	0	0
Gross profit		3,452	61	4,262	5,874	3,100
R&D expenditure		(11,799)	(29,385)	(23,408)	(19,000)	(13,000)
General, administrative & selling		(3,702)	(5,729)	(5,129)	(3,800)	(3,914)
Other		411	965	(807)	51	51
Operating profit		(11,639)	(34,088)	(25,082)	(16,875)	(13,763)
Depreciation and amortisation		(93)	0	(759)	(500)	(400)
Share-based payments		0	0	0	0	0
Exceptionals		0	0	0	0	0
EBITDA		(11,546)	(34,088)	(24,323)	(16,375)	(13,363)
Operating profit (before GW and except)		(11,546)	(34,088)	(24,323)	(16,375)	(13,363)
Net interest		(66)	42	21	20	20
Profit before tax (norm)		(11,612)	(34,046)	(24,302)	(16,355)	(13,343)
Profit before tax (reported)		(11,704)	(34,046)	(25,061)	(16,855)	(13,743)
Tax		2,468	5,834	4,944	3,135	2,145
Profit after tax (norm)		(9,143)	(28,212)	(19,359)	(13,220)	(11,198)
Profit after tax (reported)		(9,236)	(28,212)	(20,118)	(13,720)	(11,598)
Average number of shares outstanding (m)		39.9	50.7	53.2	57.0	58.2
EPS - normalised (c)		(22.9)	(55.7)	(36.4)	(23.2)	(19.2)
EPS - reported (c)		(23.2)	(55.7)	(37.8)	(24.1)	(19.9)
Dividend per share (c)		0.0	0.0	0.0	0.0	0.0
Gross margin (%)		NA	NA	NA	NA	NA
EBITDA margin (%)		NA	NA	NA	NA	NA
Operating margin (before GW and except.) (%)		NA	NA	NA	NA	NA
BALANCE SHEET						
Fixed assets		3,516	3,417	2,855	2,355	1,955
Intangible assets		3,440	3,362	2,688	2,313	2,013
Tangible assets		76	56	167	42	-58
Refund from assumption of dev costs		0	0	0	0	0
Other		0	0	0	0	0
Current assets		63,032	40,051	35,128	20,925	9,727
Stocks		0	0	0	0	0
Debtors		467	0	0	25	25
Cash		58,912	32,680	30,111	15,883	4,685
Other		3,653	7,371	5,017	5,017	5,017
Current liabilities		(3,924)	(7,901)	(13,040)	(7,266)	(7,266)
Trade payables		(3,338)	(7,332)	(6,353)	(6,353)	(6,353)
Short-term borrowings		0	0	0	0	0
Provisions		(306)	(224)	(555)	(555)	(555)
Finance lease liabilities		0	0	0	0	0
Other current liabilities		(254)	(305)	(359)	(359)	(359)
Current deferred income		(26)	(39)	(5,774)	0	0
Long-term liabilities		(17)	(6)	0	0	0
Long-term borrowings		0	0	0	0	0
Provisions		0	0	0	0	0
Long-term deferred income		(17)	(6)	0	0	0
Deferred taxes		0	0	0	0	0
Other long-term liabilities		0	0	0	0	0
Net assets		62,607	35,562	24,943	16,014	4,416
CASH FLOW						
Operating cash flow		(12,044)	(28,212)	(17,135)	(22,174)	(13,363)
Net interest		(66)	43	19	20	20
Tax		0	2,575	5,529	3,135	2,145
Capex		0	0	7	0	0
Purchase of intangibles		(26)	(33)	0	0	0
Acquisitions/disposals		0	0	(199)	0	0
Equity Financing		57,618	22	9,212	4,790	0
Dividends		0	0	0	0	0
Other		0	0	0	0	0
Net cash flow		45,482	(25,605)	(2,567)	(14,229)	(11,198)
Opening net debt/(cash)		(13,292)	(58,912)	(32,680)	(30,111)	(15,883)
Effect of exchange rate changes		(72)	(66)	(2)	0	0
Other		210	-560	0	0	0
Closing net debt/(cash)		(58,912)	(32,680)	(30,111)	(15,883)	(4,685)

Source: Edison Investment Research, Paion accounts

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