

Paion

2016 results update

On track to file in US and Japan by mid-2018

Paion has successfully accelerated recruitment in the confirmatory pivotal bronchoscopy study of its ultra-fast-acting sedative remimazolam in procedural sedation and has raised funds to support filing for general anaesthesia (GA) in Japan, putting it on track to file for approval in both the US (via partner Cosmo Pharmaceuticals) and Japan by mid-2018. It has also outlined a programme that could see it restart Phase III studies in GA in Europe (estimated cost €20-25m). Paion has sufficient cash to fund operations beyond end 2018 but would need additional funds to restart the Europe development programme (potentially from Cosmo milestones and a licence deal in Japan). We lift our valuation slightly to €214m (vs €208m).

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.

Bronchoscopy Phase III close to full recruitment

Paion has successfully accelerated patient recruitment in the confirmatory Phase III trial of remimazolam for procedural sedation in bronchoscopy patients; recruitment is expected to complete shortly. A safety study in high-risk colonoscopy patients completed recruitment in December, with headline data expected soon. Based on consultation with the FDA, Paion will initiate additional Phase I studies to further assess abuse potential. A pre-NDA meeting is planned for the end of 2017, with a US filing by partner Cosmo expected in mid-2018 (pending positive trial results).

Japan filing expected mid-2018

Paion raised €5m in February to fund a GA filing for remimazolam in Japan. Paion will validate commercial-scale production of remimazolam for the Japanese market and will use an experienced contract research organisation to prepare the dossier for filing by mid-2018. Paion is in ongoing discussions as it seeks to partner in the Japanese market during or after dossier preparation.

Europe GA Phase III could start 2018

Paion has identified a study design in general surgery patients (similar to the successful Japan Phase III completed by former partner Ono in Japan) that will allow it to resume European development of remimazolam for GA. A Phase I study this year will determine the required trial size for a Phase III in general surgery. Phase III could start in 2018, but requires €20-25m in additional funding until filing.

Valuation: Modest increase to €214m

We lift our valuation to €214m (vs €208m), with the €5m (gross) rights issue cash and lower forecast SG&A costs (2017 guidance is for a ~25% fall) partly offset by higher near-term R&D spend (2017 forecast €19m vs prior €10m). The extra shares in issue result in the valuation per share falling to €3.68/share (vs €3.74/share).

Pharma & biotech

20 March 2017

Price €2.28

Market cap €133m

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 (5.4) (4.3) (1.0)

Rel (local) (8.0) (9.8) (19.0)

52-week high/low €3.0 €1.7

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

High-risk colonoscopy safety study results Q217

Bronchoscopy Phase III results Q317

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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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