

# Paion

Q318 update

## Near-term filings in the US and Japan on track

Paion is approaching several important milestones, with partners on track to file for approval of remimazolam in the US, Japan and Russia in the next few months. Its Phase III study of remimazolam in general anaesthesia (GA) in Europe is progressing well and is on track to complete recruitment in 2019, while partner R-Pharm recently completed a successful Phase III in GA in Russia. The filings will be an important step towards establishing Paion as a leader in acute and critical care. We have made minor revisions to the timing of R&D expenditure in line with revised guidance and rolled forward our DCF model, which lifts our valuation to €291m or €4.56/share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/16	4.3	(25.1)	(37.8)	0.0	N/A	N/A
12/17	5.8	(15.9)	(20.5)	0.0	N/A	N/A
12/18e	3.1	(13.6)	(17.9)	0.0	N/A	N/A
12/19e	10.5	(9.4)	(10.2)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding, exceptionals and share-based payments.

## Filings on track in the US and Japan

Remimazolam is Paion's ultra-short-acting intravenous (IV) sedative/anaesthetic which combines the best features of the approved IV agents Midazolam and Propofol. Partner Cosmo is on track to file for US approval in procedural sedation, as planned, in Q418 or Q119. Mundipharma is on track to file for approval in Japan towards year-end. Paion expects to receive ~€2m in milestones following a filing in Japan and €7.5m for the US filing.

## Progressing GA phase III in Europe

The European Phase III study of remimazolam in 500 elderly or unwell patients undergoing GA for elective surgery is on track to complete recruitment in 2019. The primary endpoint is non-inferiority compared to propofol in successfully completing the procedure. A key secondary endpoint is to show fewer episodes of low blood pressure, which can lead to negative outcomes in these patients.

## Partners progressing development in other territories

The company's partner R-Pharm intends to file for approval of Remimazolam in Russia in Q119, having successfully completed its Phase III in GA. Hana Pharm has completed recruitment in a GA Phase III in South Korea and expects to file for approval in 2020 after production has been established in that country. Partners in several other territories plan to file based on the US or Japanese dossier.

## Valuation: Lifted to €291m

We roll forward our DCF model and lift our valuation to €291m, or €4.56/share, from €283m, or €4.44/share. Paion has lowered its guidance for R&D spend in 2018 by €3m to €12-14m to reflect some items of expenditure that have been deferred until 2019. As a consequence, we have revised our forecast R&D spend down by €3m in 2018 and up by €3m in 2019. Paion is funded until H120 assuming the filings in the US and Japan proceed as planned. A further €10m would be required until filing in Europe (we model these funds coming from approval milestones).

## Pharma & biotech

12 November 2018

**Price** €2.27

**Market cap** €145m

US\$1.10/€

Net cash (€m) at end September 2018 19.8

Shares in issue 63.9m

Free float 75%

Code PA8

Primary exchange Frankfurt (Xetra)

Secondary exchange N/A

## Share price performance



% 1m 3m 12m

Abs (8.2) (13.6) (14.6)

Rel (local) (4.7) (5.0) (2.3)

52-week high/low €2.7 €2.0

## Business description

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

## Next events

Japan filing for GA by Mundipharma Q418

US filing for procedural sedation by Cosmo Q418/  
Q119

Russia filing for GA by R-Pharm Q119

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**Exhibit 1: Financial summary**

	€'000s	2015	2016	2017	2018e	2019e
Year end 31 December						
<b>PROFIT &amp; LOSS</b>						
Revenue		61	4,262	5,811	3,100	10,475
Cost of sales		0	0	0	0	0
Gross profit		61	4,262	5,811	3,100	10,475
R&D expenditure		(29,385)	(23,408)	(17,854)	(13,000)	(16,000)
General, administrative & selling		(5,729)	(5,129)	(3,828)	(3,820)	(3,935)
Other		965	(807)	(2)	51	51
Operating profit		(34,088)	(25,841)	(16,219)	(14,069)	(9,709)
Depreciation and amortisation		0	(759)	(347)	(400)	(300)
Share-based payments		0	0	0	0	0
Exceptionals		0	0	0	0	0
EBITDA		(34,088)	(25,082)	(15,872)	(13,669)	(9,409)
Operating profit (before GW and except)		(34,088)	(25,082)	(15,872)	(13,669)	(9,409)
Net interest		42	21	20	20	20
Profit before tax (norm)		(34,046)	(25,061)	(15,852)	(13,649)	(9,389)
Profit before tax (reported)		(34,046)	(25,061)	(15,852)	(13,649)	(9,389)
Tax		5,834	4,944	3,759	2,470	2,880
Profit after tax (norm)		(28,212)	(20,118)	(12,093)	(11,179)	(6,509)
Profit after tax (reported)		(28,212)	(20,118)	(12,093)	(11,179)	(6,509)
Average number of shares outstanding (m)		50.7	53.2	59.1	62.5	63.9
EPS - normalised (c)		(55.7)	(37.8)	(20.5)	(17.9)	(10.2)
EPS - reported (c)		(55.7)	(37.8)	(20.5)	(17.9)	(10.2)
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
<b>BALANCE SHEET</b>						
Fixed assets		3,417	2,855	2,529	2,529	2,529
Intangible assets		3,362	2,688	2,415	2,415	2,415
Tangible assets		56	167	114	114	114
Refund from assumption of dev costs		0	0	0	0	0
Other		0	0	0	0	0
Current assets		40,051	35,128	29,357	23,245	16,736
Stocks		0	0	0	0	0
Debtors		0	0	37	25	25
Cash		32,680	30,111	24,839	18,739	12,230
Other		7,371	5,017	4,481	4,481	4,481
Current liabilities		(7,901)	(13,040)	(6,656)	(6,656)	(6,656)
Trade payables		(7,332)	(6,353)	(5,921)	(5,921)	(5,921)
Short-term borrowings		0	0	0	0	0
Provisions		(224)	(555)	(391)	(391)	(391)
Finance lease liabilities		0	0	0	0	0
Other current liabilities		(305)	(359)	(325)	(325)	(325)
Current deferred income		(39)	(5,774)	(19)	(19)	(19)
Long-term liabilities		(6)	0	0	0	0
Long-term borrowings		0	0	0	0	0
Provisions		0	0	0	0	0
Long-term deferred income		(6)	0	0	0	0
Deferred taxes		0	0	0	0	0
Other long-term liabilities		0	0	0	0	0
Net assets		35,562	24,943	25,229	19,117	12,608
<b>CASH FLOW</b>						
Operating cash flow		(28,212)	(17,135)	(22,318)	(13,657)	(9,409)
Net interest		43	19	20	20	20
Tax		2,575	5,529	4,577	2,470	2,880
Capex		0	7	0	0	0
Purchase of intangibles		(33)	0	0	0	0
Acquisitions/disposals		0	(199)	(25)	0	0
Equity Financing		22	9,212	12,494	5,067	0
Dividends		0	0	0	0	0
Other		0	0	0	0	0
Net cash flow		(25,605)	(2,567)	(5,251)	(6,100)	(6,509)
Opening net debt/(cash)		(58,912)	(32,680)	(30,111)	(24,839)	(18,739)
Effect of exchange rate changes		(66)	(2)	(22)	0	0
Other		-560	0	0	0	0
Closing net debt/(cash)		(32,680)	(30,111)	(24,839)	(18,739)	(12,230)

Source: Edison Investment Research, Paion accounts

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