

Paion

H119 results

FDA outcome April 2020; EMA filing in Q419

Assuming a successful FDA review of remimazolam for procedural sedation (PS), with an outcome due by 5 April 2020, Paion is set for 20–25% royalties from US sales made by Cosmo. Remimazolam is a safe ultra-short-acting sedative/anaesthetic offering both rapid onset and offset of action. This profile should drive US market uptake for short, painful procedures such as colonoscopy. A European regulatory filing for PS will now be made in H219 allowing a possible European launch in 2021, an abbreviated EMA filing for general anaesthesia (GA) could be made by late 2020. We maintain our valuation of €317m (€4.96 per share).

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/17	5.8	(15.9)	(20.5)	0.0	N/A	N/A
12/18	2.8	(12.4)	(15.9)	0.0	N/A	N/A
12/19e	8.0	(11.1)	(14.2)	0.0	N/A	N/A
12/20e	25.0	10.8	19.6	0.0	11.9	N/A

Note: *PBT and EPS are normalised, excluding exceptional items.

US outcome by 5 April 2020, EU review by end Q420

The FDA review will complete by 5 April 2020 (PDUFA), which could allow an H2 2020 launch of remimazolam. Four Phase III studies in the US and Japan all met their primary endpoints and reported favourable safety data, so we use a 90% likelihood of approval. Paion now plans to file with the EMA for PS (based on the US trials) by late 2019 (and subject to EMA approval of the Paediatric Investigation Plan), potentially allowing EU sales from 2021. Recruitment to the GA Phase III (NCT03661489) is ongoing, with over 200 of 500 planned patients treated since July 2018; completion may now be in Q120 if recruitment accelerates. The Phase III data in GA could then allow a faster abbreviated follow-on filing.

H119 results show improved cash position

Paion received an H1 €7.5m milestone from Cosmo on the FDA regulatory filing, a further €0.5m related to the Japanese filing might be received in H2. In H219, UK R&D tax credits should provide €2m in cash. The company expects a reported PAT loss for FY19 of €7–10m compared to our forecast loss of €9.1m, formerly €9.3m. Our forecast revenues for 2020 (€25m) come from milestones in the US, Japan and Canada. Depending on the US and Japanese launch dates and sales growth, there might be additional royalties, but these really grow from 2021. Given the €19.2m June 19 cash plus expected income, Paion is funded into H220. Management states that a further €10m of funding will be required up to the GA EMA filing (we estimate Q420). Paion now has a European Investment Bank loan facility of €20m available until June 2021; €5m will be drawn in H219. Paion intends to market remimazolam directly in some countries in Europe but this will need investment.

Valuation: Retained at €317m

We expect the higher patient throughput achievable with remimazolam in PS procedures such as colonoscopy to be a key factor driving US market uptake from late 2020. We retain our valuation of €317m or €4.96/share. Use of the European Investment Bank loan of €20m will reduce the potential dilution requirement.

Pharma & biotech

15 August 2019

Price €2.33

Market cap €149m

US\$1.10/€

Cash (€m) at 30 June 2019 19.2

Shares in issue 63.9m

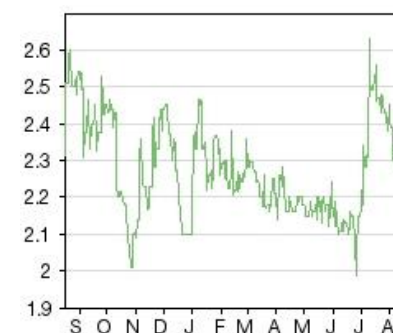
Free float 75%

Code PA8

Primary exchange Frankfurt

Secondary exchange Xetra

Share price performance



% 1m 3m 12m

Abs (6.4) 5.9 (2.3)

Rel (local) 0.3 10.5 5.1

52-week high/low €2.6 €2.0

Business description

Paion is an emerging specialty pharma company developing anaesthesia products. Lead product remimazolam has been filed for approval in the US, Japan and China and is partnered with Cosmo (US), Mundipharma (Japan), Yichang (China), Hana Pharma (South Korea), Pharmascience (Canada) and R-Pharm (CIS, Turkey, MENA).

Next events

Japan approval decision Q419/H120

Fully recruit GA Phase III in Europe Q120

FDA decision on PS 5 April 2020

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Exhibit 1: Financial summary

	€'000s	2017	2018	2019e	2020e
Year end 31 December					
PROFIT & LOSS					
Revenue		5,811	2,766	8,000	25,003
Cost of sales		0	0	0	0
Gross profit		5,811	2,766	8,000	25,003
R&D expenditure		(17,854)	(12,167)	(14,500)	(9,500)
General, administrative & selling		(3,828)	(3,408)	(4,601)	(4,739)
Other		(2)	354	0	0
Operating profit		(16,219)	(12,711)	(11,401)	10,464
Depreciation and amortisation		(347)	(256)	(300)	(300)
Share-based payments		0	0	0	0
Exceptionals		0	0	0	0
EBITDA		(15,872)	(12,455)	(11,101)	10,764
Operating profit (before amort. and except.)		(15,872)	(12,455)	(11,101)	10,764
Net Interest		20	6	20	20
Profit Before Tax (norm)		(15,852)	(12,449)	(11,081)	10,784
Profit before tax (reported)		(15,852)	(12,449)	(11,081)	10,784
Tax		3,759	2,510	2,000	1,710
Profit after tax (norm)		(12,093)	(9,939)	(9,081)	12,494
Profit after tax (reported)		(12,093)	(9,939)	(9,081)	12,494
Average number of shares outstanding (m)		59.1	62.5	63.9	63.9
EPS - normalised (c)		(20.5)	(15.9)	(14.2)	19.6
EPS - reported (c)		(20.5)	(15.9)	(14.2)	19.6
Dividend per share (c)		0.0	0.0	0.0	0.0
Gross margin (%)		NA	NA	NA	NA
EBITDA margin (%)		NA	NA	NA	NA
Operating margin (before GW and except.) (%)		NA	NA	NA	NA
BALANCE SHEET					
Fixed assets		2,529	2,286	2,286	2,286
Intangible assets		2,415	2,212	2,212	2,212
Tangible assets		114	74	74	74
Refund from assumption of dev costs		0	0	0	0
Other		0	0	0	0
Current assets		29,357	22,037	12,957	25,451
Stocks		0	0	0	0
Debtors		37	1,500	25	25
Cash		24,839	17,227	9,621	22,115
Other		4,481	3,311	3,311	3,311
Current liabilities		(6,656)	(3,501)	(3,501)	(3,501)
Trade payables		(5,921)	(2,218)	(2,218)	(2,218)
Short-term borrowings		0	0	0	0
Provisions		(391)	(630)	(630)	(630)
Finance lease liabilities		0	0	0	0
Other current liabilities		(325)	(654)	(654)	(654)
Current deferred income		(19)	0	0	0
Long-term liabilities		0	0	0	0
Long-term borrowings		0	0	0	0
Provisions		0	0	0	0
Long-term deferred income		0	0	0	0
Deferred taxes		0	0	0	0
Other long-term liabilities		0	0	0	0
Net assets		25,229	20,822	11,742	24,236
CASH FLOW					
Operating cash flow		(22,318)	(16,547)	(9,626)	10,764
Net interest		20	5	20	20
Tax		4,577	3,729	2,000	1,710
Capex		0	0	0	0
Purchase of intangibles		0	0	0	0
Acquisitions/disposals		(25)	(13)	0	0
Equity Financing		12,494	5,214	0	0
Dividends		0	0	0	0
Other		0	0	0	0
Net cash flow		(5,251)	(7,612)	(7,606)	12,494
Opening net debt/(cash)		(30,111)	(24,839)	(17,227)	(9,621)
Effect of exchange rate changes		(22)	(0)	0	0
Other		0	0	0	0
Closing net debt/(cash)		(24,839)	(17,227)	(9,621)	(22,115)

Source: Edison Investment Research, company accounts

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