

Paion

Compassionate COVID-19 ICU use in Italy

As we await the FDA verdict on ByFavo (remimazolam) for procedural sedation (PS) due 5 July 2020, Paion announced in June that it will provide remimazolam for compassionate use, supplied free, to sedate five intensive care COVID-19 patients in Milan. This has no immediate commercial implications but shows how remimazolam might be further developed. This may lead to published ICU case reports and we expect remimazolam to be an alternative to midazolam and propofol. Paion announced Q1 gross cash at €18m, down from €18.8m on 31 December, with a €15m milestone due on anticipated FDA approval. Paion has funds and loan facilities until 2022. Our indicative value remains at €270m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/18	2.77	(12.45)	(15.9)	0.0	N/A	N/A
12/19	8.00	(9.35)	(10.8)	0.0	N/A	N/A
12/20e	20.30	2.42	3.7	0.0	69.7	N/A
12/21e	4.21	(20.88)	(31.2)	0.0	N/A	N/A

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

US approval likely on 5 July with sales via Acacia

The FDA review for PS will now complete by 5 July 2020 (PDUFA). Cosmo (Paion's US partner) sublicensed US sales to Acacia, a company now selling Barhemsys for post-operative recovery. Cosmo will loan Acacia €25m on ByFavo approval to support marketing; Cosmo announced a €10m equity investment in June. We expect that Paion will receive a €15m milestone on US approval and a 20% royalty on sales. ByFavo launch is expected in Q420, but royalties will only become significant from 2021 onwards. In Japan, remimazolam (Anerem) is approved for general anaesthesia (GA) with Mundipharma planning a mid-2020 launch. Remimazolam is under EMA review for PS; the outcome is now likely in H121. The GA Phase III ([NCT03661489](#)) closed enrolment. This will allow analysis in H220, with possible launch after an abbreviated EMA application in Q421.

COVID-19 compassionate use by leading hospital

In an interesting development, a leading Italian hospital, the San Raffaele Hospital in Milan, is using Remimazolam as a sedative for five COVID-19 ICU patients. The usual sedation agents, propofol and midazolam, are in short supply; ICU use is not a current clinical application and compassionate use products are not sold commercially. However, we potentially expect published case reports and other data to emerge. Midazolam accumulates with prolonged use, which can lead to delirium, so remimazolam might have advantages for longer-term patients. As the number of SARS-CoV-2 infections falls, this specific ICU demand will drop, but more general ICU use might be a way to further expand the market in future.

Valuation: Remains at €270m with cash until H21

Paion has stated that it aims to become a profitable company within five years. It has cash (€18m at 31 March), expected milestones in 2020 (€20m) and EIB loan facilities (€20m) to cover planned expenses to H221 plus potential royalties, assuming US ByFavo approval. The company is evaluating the economics of creating a direct salesforce in key European markets. Our value remains at €270m.

Q120 results and update

Pharma & biotech

9 June 2020

Price €2.58

Market cap €170m

US\$1.10/€

Cash (€m) at 31 March 2020 17.97

Shares in issue (8 June 2020) 65.8m

Free float 75%

Code PA8

Primary exchange Frankfurt

Secondary exchange Xetra

Share price performance



% 1m 3m 12m

Abs 30.3 27.1 22.3

Rel (local) 10.8 14.4 14.9

52-week high/low €2.63 €1.40

Business description

Paion develops the fast-onset and short-recovery anaesthesia product remimazolam. This is approved in Japan and could gain US approval in July where it is sublicensed to Acacia. It is filed in the EU, China and South Korea. A European Phase III general anaesthesia has ended enrolment for a possible H121 regulatory filing.

Next events

FDA ByFavo PDUFA 5 July 2020

GA Phase III top-line data H220

Interim FY20 report 12 August 2020

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Exhibit 1: Financial summary

	€'000s	2018	2019	2020e	2021e
Year end 31 December					
PROFIT & LOSS					
Revenue		2,766	8,000	20,295	4,207
Cost of sales		0	0	(120)	(1,284)
Gross profit		2,766	8,000	20,175	2,924
Operating profit		(12,711)	(9,346)	2,210	(21,096)
Depreciation and amortisation		(256)	(120)	(214)	(214)
Share-based payments		0	0	0	0
Exceptionals		0	0	0	0
EBITDA		(12,455)	(9,226)	2,424	(20,882)
Operating profit (before amort. and except.)		(12,455)	(9,226)	2,424	(20,882)
Net Interest		6	(122)	0	0
Profit Before Tax (nom)		(12,449)	(9,348)	2,424	(20,882)
Profit before tax (reported)		(12,449)	(9,448)	2,230	(21,076)
Tax		2,510	2,432	0	0
Profit after tax (norm)		(9,939)	(6,916)	2,424	(20,882)
Profit after tax (reported)		(9,939)	(7,016)	2,230	(21,076)
Average number of shares outstanding (m)		62.5	63.9	66.0	67.0
EPS - normalised (c)		(15.9)	(10.8)	3.7	(31.2)
EPS - reported (c)		(15.9)	(11.0)	3.4	(31.5)
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		2,286	2,262	2,068	1,874
Intangible assets		2,212	2,137	1,943	1,749
Tangible assets		74	46	46	46
Refund from assumption of dev costs		0	0	0	0
Other		0	79	79	79
Current assets		22,037	22,650	23,048	12,165
Stocks		0	0	0	0
Debtors		1,500	500	0	464
Cash		17,227	18,787	22,252	10,905
Other		3,311	3,363	796	796
Current liabilities		(3,501)	(10,179)	(3,800)	(3,800)
Trade payables		(2,218)	(4,843)	(2,843)	(2,843)
Short-term borrowings		0	(4,354)	0	0
Provisions		(630)	(956)	(956)	(956)
Other current liabilities		(654)	(26)	0	0
Long-term liabilities		0	0	0	(10,000)
Long-term borrowings		0	0	0	(10,000)
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		20,822	14,733	21,316	240
CASH FLOW					
Operating cash flow		(16,547)	(5,274)	944	(21,326)
Net interest		5	(8)	0	0
Tax		3,729	2,435	2,567	0
Capex		0	(15)	(20)	(20)
Purchase of intangibles		0	0	0	0
Acquisitions/disposals		(13)	1	0	0
Equity Financing		5,214	0	4,354	0
Dividends		0	0	0	0
Other		0	4,421	(4,380)	10,000
Net cash flow		(7,612)	1,560	3,465	(11,346)
Opening net debt/(cash)		(24,839)	(17,227)	(14,433)	(22,252)
Effect of exchange rate changes		(0)	0	0	0
Other		0	(4,354)	4,354	(10,000)
Closing net debt/(cash)		(17,227)	(14,433)	(22,252)	(905)

Source: Edison Investment Research, company accounts

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