

Paion

ByFavo – poised for autumn US launch

In a breakthrough achievement for Paion, the FDA has approved ByFavo (remimazolam) for US sale for procedural sedation (PS) taking under 30 minutes – mainly 25m colonoscopy and bronchoscopy procedures. A €15m milestone is due from US partner Cosmo. Cosmo has sublicensed ByFavo to Acacia in the US; launch is indicated in autumn 2020. Paion has operational funds and loan facilities until 2022. Our valuation has been updated to reflect US approval and is now €283m vs €270m previously.

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	82.2	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.

Approved in US with sales via Acacia

The FDA approved ByFavo for PS on 2 July 2020. Cosmo (Paion's US partner) has sublicensed US sales to Acacia, a company selling Barhemsys for post-operative recovery using an. Paion will receive a €15m milestone and a 20–25% royalty; we expect a price of about \$25 per 20mg vial. Acacia states that the US colonoscopy market is 25m procedures in an overall 40m procedure market. ByFavo launch is expected by us in Q420, after Drug Enforcement agency classification (probably the same as midazolam). We forecast that royalties will become significant from H221. The market positioning, supported by the clinical trials, targets midazolam as ByFavo claims increased patient throughput due to its fast onset and shorter recovery times - so potentially giving higher clinic revenues. The US ByFavo label is based on the midazolam label with similar warnings. Acacia notes that 80% of US partial sedation procedures involve an anaesthetic provider, a group specifically targeted by the approximately 50-person Acacia salesforce.

Other indications and countries

In Japan, remimazolam (Anerem) is approved for general anaesthesia (GA), with partner Mundipharma planning a mid-2020 launch. Remimazolam is undergoing an EMA review for PS with the outcome likely in H121. The European GA Phase III closed in H120, allowing an H220 analysis with a likely abbreviated EMA application in Q421. There is some ICU use with COVID-19 patients in Italy.

Valuation: Increased to €283m with funding until 2022

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 from late 2020 and especially from 2021 given the US ByFavo and Anerem (in Japan) approvals. We have moved the US probability from 90% to 100% with the full €15m milestone. All other forecasts are unchanged. This gives an indicative value of €283m (formerly €270m).

Gain of regulatory approval

Pharma & biotech

7 July 2020

Price €3.04
Market cap €200m

US\$1.10/€

Cash (€m) at 31 March 2020 17.97

Shares in issue (8 June 2020) 65.8m

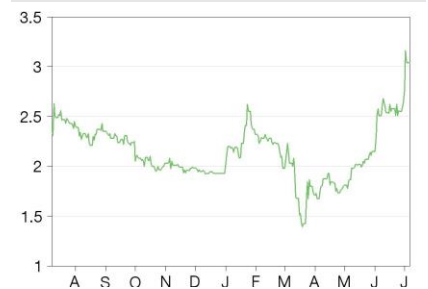
Free float 75%

Code PA8

Primary exchange Frankfurt

Secondary exchange Xetra

Share price performance



% 1m 3m 12m

Abs 21.1 71.8 33.3

Rel (local) 22.2 35.9 31.6

52-week high/low €3.16 €1.40

Business description

Paion develops the fast-onset and short-recovery anaesthesia product remimazolam. This is approved in Japan for GA and in the US for PS. ByFavo is sublicensed in the US to Acacia. It is filed in the EU, China and South Korea. A European GA filing is expected in H121. The European sales strategy needs to be confirmed.

Next events

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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