

# Paion

Phase III data

## GA data enable an application for surgical use

The Remimazolam Phase III general anaesthesia (GA) trial in Europe has released initial data. Remimazolam was as effective as propofol in maintaining anaesthesia in major surgery so met the primary endpoint. More importantly, fewer hypotensive episodes were noted on average in the remimazolam arm; these are common and may lead to post-surgical morbidity. For at risk patients (ASA Class III or IV), this safety gain could be critical in justifying remimazolam's price premium over propofol. In the US, remimazolam (ByFavo) is expected to be launched soon for procedural sedation (PS). Paion indicates that it has cash until H221. Our valuation remains €283m.

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	5.9	0.0	46.6	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.

## Superior haemodynamic stability in at risk patients

The European GA Phase III has reported data on 365 patients. The data showed an anaesthesia score of 60 or below for 95.7% of the time with remimazolam and 99.1% with propofol. This was statistically the same effect ( $p=0.0001$ ). The number of hypotensive events within 15 minutes of surgical incision occurred on average 62.62 times per patient ( $\pm 39.46$ , 270 patients) using remimazolam compared to 71.03 times using propofol ( $\pm 41.12$ , 95 patients). After statistical adjustments, this was significant ( $p=0.015$ ).

## Market potential relative to generic propofol

Remimazolam is undergoing a European Medicines Agency review for PS with the initial (CHMP) opinion now expected by Paion by the end of January with formal approval in H121. A GA abbreviated filing will then follow. GA is potentially the larger remimazolam indication in Europe, according to Paion management. We note that most anaesthesia (well over 90%) uses anaesthetic gas to maintain sedation after propofol is used to induce anaesthesia; it is uncommon to use a continuous infusion of propofol. Nonetheless, for Class III and IV patients who are more likely to receive only propofol, remimazolam appears to be haemodynamically safer.

## Valuation: Unchanged at €283m

Paion expects royalties to be under €1m in 2020 and the US Q420 ByFavo launch will be 'soft' due to COVID-19. In Europe, Paion hopes to license other products to sustain a direct European salesforce in some Northern territories or, if this is not feasible, remimazolam will be partnered elsewhere. Paion had €24.5m in cash (30 September) after receiving the €15m US approval milestone in Q3. Paion also has an EIB loan facility of up to €20m. Our indicative value remains €283m.

### Pharma & biotech

27 November 2020

**Price** €2.75

**Market cap** €182m

US\$1.10/€

Cash (€m) at 30 September 2020 24.5

Shares in issue (8 July 2020) 66.2m

Free float 92%

Code PA8

Primary exchange Frankfurt

Secondary exchange Xetra

### Share price performance



%	1m	3m	12m
Abs	18.0	5.4	38.9
Rel (local)	8.2	4.6	38.4
52-week high/low		€3.16	€1.40

### Business description

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

### Next events

CHMP opinion on remimazolam Late January 2021

FY20 results March 2021

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**Exhibit 1: Financial summary**

	€'000s	2018	2019	2020e	2021e
Year end 31 December					
<b>PROFIT &amp; LOSS</b>					
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 (norm)		(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	1,500	0
Profit after tax (norm)		(9,939)	(6,916)	3,924	(20,882)
Profit after tax (reported)		(9,939)	(7,016)	3,730	(21,076)
Average number of shares outstanding (m)		62.5	63.9	66.0	67.0
EPS - normalised (c)		(15.9)	(10.8)	5.9	(31.2)
EPS - reported (c)		(15.9)	(11.0)	5.7	(31.5)
Dividend per share (c)		0.0	0.0	0.0	0.0
Gross margin (%)		N/A	N/A	N/A	N/A
EBITDA margin (%)		N/A	N/A	N/A	N/A
Operating margin (before GW and except.) (%)		N/A	N/A	N/A	N/A
<b>BALANCE SHEET</b>					
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
<b>CASH FLOW</b>					
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: Company data, Edison Investment Research

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