

# Paion

H117 update

## Remimazolam set for commercialisation in 2019

Paion is well positioned to commercialise Remimazolam in 2019 for procedural sedation (via partner Cosmo Pharmaceuticals in the US) and general anaesthesia (Japan); successful Phase III studies confirmed an excellent safety profile and shorter procedure times than midazolam. Paion is conducting additional Phase I studies to further assess abuse potential of remimazolam, which will guide its scheduling under the Controlled Substances Act in the US. Cosmo has advised that it expects to file for US approval in H218 vs prior guidance of a mid-2018 filing. The recent €8m capital raise has extended the funding runway for current activities to at least H219. We adjust our valuation to €245m (vs €240m) or €4.02/share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/15	0.1	(34.0)	(55.7)	0.0	N/A	N/A
12/16	4.3	(24.3)	(36.4)	0.0	N/A	N/A
12/17e	5.9	(16.4)	(21.2)	0.0	N/A	N/A
12/18e	3.5	(12.9)	(17.7)	0.0	N/A	N/A

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

## Abuse studies ongoing, US filing expected H218

Paion is undertaking additional Phase I studies to assess whether remimazolam can be abused intranasally and whether it could be used as a knock-out cocktail in combination with alcohol. Paion expects that the FDA will classify remimazolam as a lower-abuse-potential schedule IV drug under the Controlled Substance Act, the same classification as midazolam. Paion has clarified the expected timeline for a potential US filing by partner Cosmo, with filing expected in H218 vs prior guidance of mid-2018. Encouragingly, Canadian regulators have advised partner Pharmascience that the current data package is adequate for filing in that country, without any further data from the current abuse potential trials.

## Japan filing likely mid-2018, GA Phase I underway

Paion is preparing for a potential mid-2018 filing for remimazolam for general anaesthesia (GA) in Japan, and is in ongoing discussions as it seeks to partner in the Japanese market. It has initiated a Phase I trial to collect data to aid the design of an EU Phase III study for GA in general surgery patients. Paion expects the Phase III programme to cost €20-25m – the recent €8m capital raise will contribute to this funding requirement and will enable it to accelerate Phase III preparations. The Phase III could start in 2018, subject to securing the additional funding.

## Valuation: Adjusted to €245m or €4.02 per share

Our valuation is increased to €245m (from €240m) due to the €8m capital raise in July, partly offset by a modest reduction in forecast sales of remimazolam in 2019 due to an anticipated launch date later in the course of the year. The increased share count sees valuation per share decline to €4.02/share (vs €4.13/share). H117 results confirmed that Paion is trimming expenditure in line with guidance; end-H117 cash of €27.1m combined with the €8m capital raise extends Paion's cash reach into H219 (without considering potential milestone payments).

### Pharma & biotech

14 August 2017

**Price** €2.71

**Market cap** €165m

US\$1.10/€

Net cash (€m) at 30 June 2017 27.1

Shares in issue 61.1m

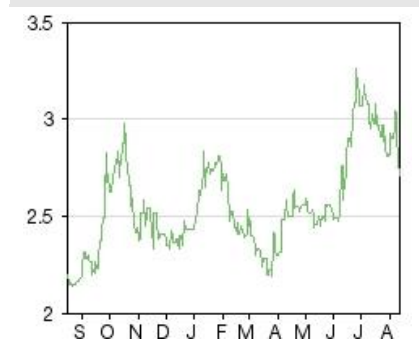
Free float 75%

Code PA8

Primary exchange Frankfurt (Xetra)

Secondary exchange N/A

### Share price performance



% 1m 3m 12m

Abs (8.9) 10.8 27.0

Rel (local) (5.7) 17.2 13.5

52-week high/low €3.3 €2.1

### Business description

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

### Next events

Complete abuse potential studies H118

Japan PMDA filing mid 2018

FDA filing H218

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**Exhibit 1: Financial summary**

	€'000s	2014	2015	2016	2017e	2018e
Year end 31 December						
<b>PROFIT &amp; LOSS</b>						
Revenue		3,456	61	4,262	5,874	3,500
Cost of sales		(4)	0	0	0	0
Gross profit		3,452	61	4,262	5,874	3,500
R&D expenditure		(11,799)	(29,385)	(23,408)	(19,000)	(13,000)
General, administrative & selling		(3,702)	(5,729)	(5,129)	(3,800)	(3,914)
Other		411	965	(807)	51	51
Operating profit		(11,639)	(34,088)	(25,082)	(16,875)	(13,363)
Depreciation and amortisation		(93)	0	(759)	(500)	(400)
Share-based payments		0	0	0	0	0
Exceptionals		0	0	0	0	0
EBITDA		(11,546)	(34,088)	(24,323)	(16,375)	(12,963)
Operating profit (before GW and except)		(11,546)	(34,088)	(24,323)	(16,375)	(12,963)
Net interest		(66)	42	21	20	20
Profit before tax (norm)		(11,612)	(34,046)	(24,302)	(16,355)	(12,943)
Profit before tax (reported)		(11,704)	(34,046)	(25,061)	(16,855)	(13,343)
Tax		2,468	5,834	4,944	3,990	2,145
Profit after tax (norm)		(9,143)	(28,212)	(19,359)	(12,365)	(10,798)
Profit after tax (reported)		(9,236)	(28,212)	(20,118)	(12,865)	(11,198)
Average number of shares outstanding (m)		39.9	50.7	53.2	58.4	61.1
EPS - normalised (c)		(22.9)	(55.7)	(36.4)	(21.2)	(17.7)
EPS - reported (c)		(23.2)	(55.7)	(37.8)	(22.0)	(18.3)
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		3,516	3,417	2,855	2,355	1,955
Intangible assets		3,440	3,362	2,688	2,313	2,013
Tangible assets		76	56	167	42	-58
Refund from assumption of dev costs		0	0	0	0	0
Other		0	0	0	0	0
Current assets		63,032	40,051	35,128	29,187	18,389
Stocks		0	0	0	0	0
Debtors		467	0	0	25	25
Cash		58,912	32,680	30,111	24,145	13,347
Other		3,653	7,371	5,017	5,017	5,017
Current liabilities		(3,924)	(7,901)	(13,040)	(7,266)	(7,266)
Trade payables		(3,338)	(7,332)	(6,353)	(6,353)	(6,353)
Short-term borrowings		0	0	0	0	0
Provisions		(306)	(224)	(555)	(555)	(555)
Finance lease liabilities		0	0	0	0	0
Other current liabilities		(254)	(305)	(359)	(359)	(359)
Current deferred income		(26)	(39)	(5,774)	0	0
Long-term liabilities		(17)	(6)	0	0	0
Long-term borrowings		0	0	0	0	0
Provisions		0	0	0	0	0
Long-term deferred income		(17)	(6)	0	0	0
Deferred taxes		0	0	0	0	0
Other long-term liabilities		0	0	0	0	0
Net assets		62,607	35,562	24,943	24,276	13,078
<b>CASH FLOW</b>						
Operating cash flow		(12,044)	(28,212)	(17,135)	(22,174)	(12,963)
Net interest		(66)	43	19	20	20
Tax		0	2,575	5,529	3,990	2,145
Capex		0	0	7	0	0
Purchase of intangibles		(26)	(33)	0	0	0
Acquisitions/disposals		0	0	(199)	0	0
Equity Financing		57,618	22	9,212	12,198	0
Dividends		0	0	0	0	0
Other		0	0	0	0	0
Net cash flow		45,482	(25,605)	(2,567)	(5,966)	(10,798)
Opening net debt/(cash)		(13,292)	(58,912)	(32,680)	(30,111)	(24,145)
Effect of exchange rate changes		(72)	(66)	(2)	0	0
Other		210	-560	0	0	0
Closing net debt/(cash)		(58,912)	(32,680)	(30,111)	(24,145)	(13,347)

Source: Edison Investment Research, Paion accounts

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