Paion

Q117 results update

On track for two filings by mid-2018

Pharma & biotech

Paion has completed patient recruitment in its pivotal bronchoscopy study of its ultra-fast-acting sedative remimazolam. Results are likely by mid-2017 and, if positive, would put it on track to file for US approval for procedural sedation in mid-2018. Paion is also preparing a dossier for a filing for general anaesthesia (GA) in Japan in a similar time frame. It has also outlined a programme that could see it restart Phase III studies in GA in Europe (estimated cost €20-25m). Paion has sufficient cash to fund operations beyond end 2018, but would need additional funds to complete the Europe development programme. We leave our valuation unchanged at €214m ahead of the key bronchoscopy trial results.

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)	(23.2)	0.0	N/A	N/A
12/18e	3.1	(13.3)	(19.2)	0.0	N/A	N/A

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

Bronchoscopy data likely in June

On 27 March Paion announced full recruitment in the confirmatory Phase III trial of remimazolam for procedural sedation in bronchoscopy patients, with headline data expected in mid-2017. Based on consultation with the FDA, Paion will initiate additional Phase I studies to further assess abuse potential. A pre-NDA meeting is planned for the end of 2017, with a US filing by partner Cosmo expected in mid-2018 (pending positive trial results).

Getting serious about Europe

Paion will shortly commence a Phase I trial using EEGs to measure the depth of anaesthesia, to help determine the number of patients that would be required for an EU Phase III study for GA in general surgery patients. The Phase III could start in 2018, but would require €20-25m in additional funding up to filing.

Japan filing potentially mid-2018

Paion has begun to prepare a dossier for a potential mid-2018 filing for remimazolam for general anaesthesia in Japan. Paion will validate commercial-scale production of remimazolam for the Japanese market and will use an experienced contract research organisation to prepare the dossier. Paion is in ongoing discussions as it seeks to partner in the Japanese market.

Valuation: Unchanged at €214m

Our forecasts and valuation are unchanged at €214m (€3.68/share). Paion has sufficient cash to fund operations beyond end 2018, which would allow it to complete filings in the US (via partner Cosmo) and Japan. However, it would need ~€20-25m of additional funds to complete development of remimazolam in Europe (funds could potentially come from Cosmo milestones and a licence deal in Japan).

12 May 2017

Price	**€2.44**
Market cap	**€142m**
	US$1.10/€
Net cash (€m) at 31 March 2017	28.7
Shares in issue	58.2m
Free float	75%
Code	PA8
Primary exchange	Frankfurt
Secondary exchange	Xetra

Share price performance

%	1m	3m	12m
Abs	(3.9)	(3.1)	25.0
Rel (local)	(8.2)	(11.1)	(1.9)
52-week high/low		€2.96	€1.66

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

Bronchoscopy Phase III results	Q217
Pre-NDA meeting with FDA	Q417
Potential filing in Japan	Mid-2018

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Edison profile page

Paion is a research client of Edison Investment Research Limited

Exhibit 1: Financial summary

	€'000s	2014	2015	2016	2017e	2018e
Year end 31 December						
PROFIT & LOSS						
Revenue		3,456	61	4,262	5,874	3,100
Cost of sales		(4)	0	0	0	0
Gross profit		3,452	61	4,262	5,874	3,100
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)	(13,763)
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)	(13,363)
Operating profit (before GW and except)		(11,546)	(34,088)	(24,323)	(16,375)	(13,363)
Net interest		(66)	42	21	20	20
Profit before tax (norm)		(11,612)	(34,046)	(24,302)	(16,355)	(13,343)
Profit before tax (reported)		(11,704)	(34,046)	(25,061)	(16,855)	(13,743)
Tax		2,468	5,834	4,944	3,135	2,145
Profit after tax (norm)		(9,143)	(28,212)	(19,359)	(13,220)	(11,198)
Profit after tax (reported)		(9,236)	(28,212)	(20,118)	(13,720)	(11,598)
Average number of shares outstanding (m)		39.9	50.7	53.2	57.0	58.2
EPS - normalised (c)		(22.9)	(55.7)	(36.4)	(23.2)	(19.2)
EPS - reported (c)		(23.2)	(55.7)	(37.8)	(24.1)	(19.9)
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
BALANCE SHEET						
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	20,925	9,727
Stocks		0	0	0	0	0
Debtors		467	0	0	25	25
Cash		58,912	32,680	30,111	15,883	4,685
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	16,014	4,416
CASH FLOW						
Operating cash flow		(12,044)	(28,212)	(17,135)	(22,174)	(13,363)
Net interest		(66)	43	19	20	20
Tax		0	2,575	5,529	3,135	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	4,790	0
Dividends		0	0	0	0	0
Other		0	0	0	0	0
Net cash flow		45,482	(25,605)	(2,567)	(14,229)	(11,198)
Opening net debt/(cash)		(13,292)	(58,912)	(32,680)	(30,111)	(15,883)
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)	(15,883)	(4,685)

Source: Edison Investment Research, Paion accounts

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