

Paion

Q218 update

Progressing towards filings in US and Japan

Paion and partner Cosmo took an important step towards a US filing for its ultra-short-acting sedative/anaesthetic remimazolam, with the completion of a successful pre-NDA meeting in July. Filing in Japan (via partner Mundipharma) is expected before the end of 2018. Paion took a step towards its goal of self-commercialising remimazolam in Europe with the initiation of a Phase III study in general anaesthesia (GA) in July. The company is funded beyond top-line data from the EU Phase III trial expected in 2019. We lift our valuation to €283m or €4.44 per share.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/16	4.3	(25.1)	(37.8)	0.0	N/A	N/A
12/17	5.8	(15.9)	(20.5)	0.0	N/A	N/A
12/18e	3.1	(16.6)	(21.8)	0.0	N/A	N/A
12/19e	10.5	(6.4)	(6.4)	0.0	N/A	N/A

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

Successful pre-NDA meeting: US filing Q418 or Q119

Partner Cosmo has completed a successful pre-NDA meeting with the US FDA and remains on track to file for approval of remimazolam for procedural sedation in Q418 or Q119. Paion would receive a €7.5m milestone upon filing in the US.

Japan filing in 2018, progress in other territories

Partner Mundipharma has advised Paion that it is on track to file for approval of remimazolam for GA in Japan before the end of 2018. Partners in Russia and South Korea are expected to complete Phase III remimazolam studies in GA in 2018; R-Pharm expects to file for approval in Russia in 2018. Yichang Humanwell is conducting a Phase III in procedural sedation and a Phase II in GA in China. Partners in multiple other territories plan to file based on US or Japan dossiers.

Phase III for GA in Europe underway

Paion initiated a Phase III trial in GA in Europe on schedule in July. The primary endpoint of the randomised, single blind, confirmatory study in ~500 elderly or unwell (ASA III/IV) patients is to demonstrate non-inferiority to propofol, which is the standard of care. A secondary endpoint is to show fewer instances of a drop in blood pressure, which can lead to negative outcomes in these patients who are already in poor overall health. Recruitment is expected to complete in 2019.

Well funded beyond 2019 and EU Phase III data

Paion raised €5.2m (gross) from the issue of 2.6m shares in a private placement in June. It had cash and equivalents of €23.3m at 30 June, giving it cash reach beyond the end of 2019 in our forecasts, and past the expected reporting of data from the European Phase III trial. No change to guidance in the half-yearly report.

Valuation: Lifted to €283m

We increase our valuation to €283m, or €4.44 per share, from €269m or €4.40 per share, to account for the increase in cash and shares in issue following the capital raise in June and from rolling forward our model. Our assumptions are unchanged.

Pharma & biotech

13 August 2018

Price €2.55

Market cap €162m

US\$1.10/€

Net cash (€m) at end June 2018 23.3

Shares in issue 63.7m

Free float 75%

Code PA8

Primary exchange Frankfurt (Xetra)

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 9.4 9.0 (8.3)

Rel (local) 11.1 14.2 (11.3)

52-week high/low €2.9 €2.0

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), Mundipharma (Japan), Yichang (China), Hana Pharma (South Korea), Pendopharm (Canada) and R-Pharm (CIS, Turkey, MENA).

Next events

Japan filing for GA by Mundipharma H218

 US filing for procedural sedation by Cosmo Q418/
Q119

Russia filing for GA by R-Pharm H218

Analysts

Dr Dennis Hulme +61 (0)2 8249 8345

Dr Susie Jana +44 (0)20 3681 2527

healthcare@edisongroup.com
[Edison profile page](#)

**Paion is a research client of
Edison Investment Research
Limited**

Exhibit 1: Financial summary

	€'000s	2015	2016	2017	2018e	2019e
Year end 31 December						
PROFIT & LOSS						
Revenue		61	4,262	5,811	3,100	10,475
Cost of sales		0	0	0	0	0
Gross profit		61	4,262	5,811	3,100	10,475
R&D expenditure		(29,385)	(23,408)	(17,854)	(16,000)	(13,000)
General, administrative & selling		(5,729)	(5,129)	(3,828)	(3,820)	(3,935)
Other		965	(807)	(2)	51	51
Operating profit		(34,088)	(25,841)	(16,219)	(17,069)	(6,709)
Depreciation and amortisation		0	(759)	(347)	(400)	(300)
Share-based payments		0	0	0	0	0
Exceptionals		0	0	0	0	0
EBITDA		(34,088)	(25,082)	(15,872)	(16,669)	(6,409)
Operating profit (before GW and except)		(34,088)	(25,082)	(15,872)	(16,669)	(6,409)
Net interest		42	21	20	20	20
Profit before tax (norm)		(34,046)	(25,061)	(15,852)	(16,649)	(6,389)
Profit before tax (reported)		(34,046)	(25,061)	(15,852)	(16,649)	(6,389)
Tax		5,834	4,944	3,759	3,040	2,340
Profit after tax (norm)		(28,212)	(20,118)	(12,093)	(13,609)	(4,049)
Profit after tax (reported)		(28,212)	(20,118)	(12,093)	(13,609)	(4,049)
Average number of shares outstanding (m)		50.7	53.2	59.1	62.4	63.7
EPS - normalised (c)		(55.7)	(37.8)	(20.5)	(21.8)	(6.4)
EPS - reported (c)		(55.7)	(37.8)	(20.5)	(21.8)	(6.4)
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		3,417	2,855	2,529	2,529	2,529
Intangible assets		3,362	2,688	2,415	2,415	2,415
Tangible assets		56	167	114	114	114
Refund from assumption of dev costs		0	0	0	0	0
Other		0	0	0	0	0
Current assets		40,051	35,128	29,357	20,815	16,766
Stocks		0	0	0	0	0
Debtors		0	0	37	25	25
Cash		32,680	30,111	24,839	16,309	12,260
Other		7,371	5,017	4,481	4,481	4,481
Current liabilities		(7,901)	(13,040)	(6,656)	(6,656)	(6,656)
Trade payables		(7,332)	(6,353)	(5,921)	(5,921)	(5,921)
Short-term borrowings		0	0	0	0	0
Provisions		(224)	(555)	(391)	(391)	(391)
Finance lease liabilities		0	0	0	0	0
Other current liabilities		(305)	(359)	(325)	(325)	(325)
Current deferred income		(39)	(5,774)	(19)	(19)	(19)
Long-term liabilities		(6)	0	0	0	0
Long-term borrowings		0	0	0	0	0
Provisions		0	0	0	0	0
Long-term deferred income		(6)	0	0	0	0
Deferred taxes		0	0	0	0	0
Other long-term liabilities		0	0	0	0	0
Net assets		35,562	24,943	25,229	16,687	12,638
CASH FLOW						
Operating cash flow		(28,212)	(17,135)	(22,318)	(16,657)	(6,409)
Net interest		43	19	20	20	20
Tax		2,575	5,529	4,577	3,040	2,340
Capex		0	7	0	0	0
Purchase of intangibles		(33)	0	0	0	0
Acquisitions/disposals		0	(199)	(25)	0	0
Equity Financing		22	9,212	12,494	5,067	0
Dividends		0	0	0	0	0
Other		0	0	0	0	0
Net cash flow		(25,605)	(2,567)	(5,251)	(8,530)	(4,049)
Opening net debt/(cash)		(58,912)	(32,680)	(30,111)	(24,839)	(16,309)
Effect of exchange rate changes		(66)	(2)	(22)	0	0
Other		(560)	0	0	0	0
Closing net debt/(cash)		(32,680)	(30,111)	(24,839)	(16,309)	(12,260)

Source: Edison Investment Research, Paion accounts

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world-renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors, advisers and stakeholders. Edison Advisors leverages our core research platform to provide differentiated services including investor relations and strategic consulting. Edison is authorised and regulated by the [Financial Conduct Authority](#). Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Pty Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. www.edisongroup.com

DISCLAIMER

Copyright 2018 Edison Investment Research Limited. All rights reserved. This report has been commissioned by Paion and prepared and issued by Edison for publication globally. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in the Investment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Investment Research Pty Ltd (Corporate Authorised Representative (1252501) of Myonlineadvisers Pty Ltd (AFSL: 427484)) and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is registered as an investment adviser with the Securities and Exchange Commission. Edison US relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. As such, Edison does not offer or provide personalised advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions. The information that we provide or that is derived from our website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. Also, our website and the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. This document is provided for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research. Edison has a restrictive policy relating to personal dealing. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report. Edison or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (ie without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision. To the maximum extent permitted by law, Edison, its affiliates and contractors, and their respective directors, officers and employees will not be liable for any loss or damage arising as a result of reliance being placed on any of the information contained in this report and do not guarantee the returns on investments in the products discussed in this publication. FTSE International Limited ("FTSE") © FTSE 2018. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.