

Paion

2018 results

Near-term EU sedation filing added to the list

Following discussions with the EMA, Paion has added filing for procedural sedation (PS) in Europe to the list of potential near-term filings for remimazolam. Mundipharma filed for approval in general anaesthesia (GA) in Japan in December 2018, while Cosmo is expected to file for PS in the US shortly. Paion's GA Phase III in Europe is on track to complete recruitment by the end of 2019. The filings will be an important step towards commercialising remimazolam and establishing Paion as a leader in acute and critical care. We have made minor revisions to expenditure in line with guidance, accelerated early ramp-up of sales in Europe and rolled forward our DCF model, which lifts our valuation to €303m or €4.74/share.

| Year end | Revenue (€m) | PBT* (€m) | EPS* (c) | DPS (c) | P/E (x) | Yield (%) |
|----------|--------------|-----------|----------|---------|---------|-----------|
| 12/17 | 5.8 | (15.9) | (20.5) | 0.0 | N/A | N/A |
| 12/18 | 2.8 | (12.4) | (15.9) | 0.0 | N/A | N/A |
| 12/19e | 10.5 | (8.6) | (9.3) | 0.0 | N/A | N/A |
| 12/20e | 20.0 | 5.8 | 11.8 | 0.0 | N/A | N/A |

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

Clinical data likely sufficient for PS filing in Europe

After a successful pre-submission meeting with the European Medicines Authority (EMA) in February, Paion assumes that the existing data package will be sufficient for filing in Europe (ie no extra trials needed). It will meet with an EMA rapporteur and anticipates updating the market as to potential timing with the H1 report. We understand that converting a US dossier into a format acceptable to the EMA is complex, and expect that it would take six to 12 months to prepare an EU filing submission if, as we assume, Paion decides to proceed.

Early introduction to EU clinicians and regulators

While initial sales of remimazolam in PS in Europe may be modest, in our view a filing in this indication would be an excellent opportunity to familiarise regulators, anaesthesiologists and other clinicians with the product. It could also bring an early start to the process of getting remimazolam listed on hospital formularies. These factors should lead to a faster uptake of remimazolam in GA (if approved).

US filing expected shortly – other territories to follow

Partner Cosmo has missed its target to file for US approval in PS by the end of Q119, but Paion expects it to complete the submission soon. Paion expects to receive €7.5m in milestones for the US filing. R-Pharm plans to file for GA in Russia by the end of 2019. Partners plan to file in Canada and Turkey based on the US or Japanese dossiers. Hana Pharm plans to file in South Korea in 2020.

Valuation: Lifted to €303m

We roll forward our DCF model and lift our valuation to €303m, or €4.74/share, from €291m, or €4.56/share. We have adjusted our near-term forecasts in line with guidance (R&D down ~€2m, SG&A up ~€0.5m), but have then added €0.5m to R&D spend in each of 2019 and 2020 to cover filing in PS in Europe. Paion is funded until H120 assuming the US filing proceeds as planned. A further €10m would be needed until filing in Europe (we model the funds coming from approval milestones from signed milestone agreements).

Pharma & biotech

1 April 2019

Price €2.2

Market cap €141m

US\$1.10/€

Net cash (€m) at end December 2018 17.2

Shares in issue 63.9m

Free float 75%

Code PA8

Primary exchange Frankfurt (Xetra)

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (6.4) 2.3 (2.2)

Rel (local) (6.4) (6.3) 2.6

52-week high/low €2.6 €2.0

Business description

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

Next events

US filing for procedural sedation by Cosmo Q219

Update on timing for EU filing for PS June 2019

Russia filing for GA by R-Pharm 2019

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 | 2016 | 2017 | 2018 | 2019e | 2020e |
|--|--------|----------|----------|----------|----------|----------|
| Year end 31 December | | | | | | |
| PROFIT & LOSS | | | | | | |
| Revenue | | 4,262 | 5,811 | 2,766 | 10,475 | 20,003 |
| Cost of sales | | 0 | 0 | 0 | 0 | 0 |
| Gross profit | | 4,262 | 5,811 | 2,766 | 10,475 | 20,003 |
| R&D expenditure | | (23,408) | (17,854) | (12,167) | (14,500) | (9,500) |
| General, administrative & selling | | (5,129) | (3,828) | (3,408) | (4,601) | (4,739) |
| Other | | (807) | (2) | 354 | 51 | 51 |
| Operating profit | | (25,841) | (16,219) | (12,711) | (8,875) | 5,515 |
| Depreciation and amortisation | | (759) | (347) | (256) | (300) | (300) |
| Share-based payments | | 0 | 0 | 0 | 0 | 0 |
| Exceptionals | | 0 | 0 | 0 | 0 | 0 |
| EBITDA | | (25,082) | (15,872) | (12,455) | (8,575) | 5,815 |
| Operating profit (before GW and except) | | (25,082) | (15,872) | (12,455) | (8,575) | 5,815 |
| Net interest | | 21 | 20 | 6 | 20 | 20 |
| Profit before tax (norm) | | (25,061) | (15,852) | (12,449) | (8,555) | 5,835 |
| Profit before tax (reported) | | (25,061) | (15,852) | (12,449) | (8,555) | 5,835 |
| Tax | | 4,944 | 3,759 | 2,510 | 2,610 | 1,710 |
| Profit after tax (norm) | | (20,118) | (12,093) | (9,939) | (5,945) | 7,545 |
| Profit after tax (reported) | | (20,118) | (12,093) | (9,939) | (5,945) | 7,545 |
| Average number of shares outstanding (m) | | 53.2 | 59.1 | 62.5 | 63.9 | 63.9 |
| EPS - normalised (c) | | (37.8) | (20.5) | (15.9) | (9.3) | 11.8 |
| EPS - reported (c) | | (37.8) | (20.5) | (15.9) | (9.3) | 11.8 |
| 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 | | 2,855 | 2,529 | 2,286 | 2,286 | 2,286 |
| Intangible assets | | 2,688 | 2,415 | 2,212 | 2,212 | 2,212 |
| Tangible assets | | 167 | 114 | 74 | 74 | 74 |
| Refund from assumption of dev costs | | 0 | 0 | 0 | 0 | 0 |
| Other | | 0 | 0 | 0 | 0 | 0 |
| Current assets | | 35,128 | 29,357 | 22,037 | 16,093 | 23,638 |
| Stocks | | 0 | 0 | 0 | 0 | 0 |
| Debtors | | 0 | 37 | 1,500 | 25 | 25 |
| Cash | | 30,111 | 24,839 | 17,227 | 12,757 | 20,302 |
| Other | | 5,017 | 4,481 | 3,311 | 3,311 | 3,311 |
| Current liabilities | | (13,040) | (6,656) | (3,501) | (3,501) | (3,501) |
| Trade payables | | (6,353) | (5,921) | (2,218) | (2,218) | (2,218) |
| Short-term borrowings | | 0 | 0 | 0 | 0 | 0 |
| Provisions | | (555) | (391) | (630) | (630) | (630) |
| Finance lease liabilities | | 0 | 0 | 0 | 0 | 0 |
| Other current liabilities | | (359) | (325) | (654) | (654) | (654) |
| Current deferred income | | (5,774) | (19) | 0 | 0 | 0 |
| Long-term liabilities | | 0 | 0 | 0 | 0 | 0 |
| Long-term borrowings | | 0 | 0 | 0 | 0 | 0 |
| Provisions | | 0 | 0 | 0 | 0 | 0 |
| Long-term deferred income | | 0 | 0 | 0 | 0 | 0 |
| Deferred taxes | | 0 | 0 | 0 | 0 | 0 |
| Other long-term liabilities | | 0 | 0 | 0 | 0 | 0 |
| Net assets | | 24,943 | 25,229 | 20,822 | 14,878 | 22,423 |
| CASH FLOW | | | | | | |
| Operating cash flow | | (17,135) | (22,318) | (16,547) | (7,100) | 5,815 |
| Net interest | | 19 | 20 | 5 | 20 | 20 |
| Tax | | 5,529 | 4,577 | 3,729 | 2,610 | 1,710 |
| Capex | | 7 | 0 | 0 | 0 | 0 |
| Purchase of intangibles | | 0 | 0 | 0 | 0 | 0 |
| Acquisitions/disposals | | (199) | (25) | (13) | 0 | 0 |
| Equity Financing | | 9,212 | 12,494 | 5,214 | 0 | 0 |
| Dividends | | 0 | 0 | 0 | 0 | 0 |
| Other | | 0 | 0 | 0 | 0 | 0 |
| Net cash flow | | (2,567) | (5,251) | (7,612) | (4,470) | 7,545 |
| Opening net debt/(cash) | | (32,680) | (30,111) | (24,839) | (17,227) | (12,757) |
| Effect of exchange rate changes | | (2) | (22) | (0) | 0 | 0 |
| Other | | 0 | 0 | 0 | 0 | 0 |
| Closing net debt/(cash) | | (30,111) | (24,839) | (17,227) | (12,757) | (20,302) |

Source: Edison Investment Research, Paion accounts

General disclaimer and copyright

This report has been commissioned by Paion and prepared and issued by Edison, in consideration of a fee payable by Paion. Edison Investment Research standard fees are £49,500 pa for the production and broad dissemination of a detailed note (Outlook) following by regular (typically quarterly) update notes. Fees are paid upfront in cash without recourse. Edison may seek additional fees for the provision of roadshows and related IR services for the client but does not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: 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 and have not sought for this information to be independently verified. Opinions contained in this report represent those of the Edison analyst at the time of publication. 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.

Exclusion of Liability: To the fullest extent allowed by law, Edison shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out of or in connection with the access to, use of or reliance on any information contained on this note.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, 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 securities described in the report may not be eligible for sale in all jurisdictions or to certain categories of investors.

Investment in securities mentioned: Edison has a restrictive policy relating to personal dealing and conflicts of interest. 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, subject to Edison's policies on personal dealing and conflicts of interest.

Copyright: Copyright 2019 Edison Investment Research Limited (Edison). All rights reserved FTSE International Limited ("FTSE") © FTSE 2019. "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.

Australia

Edison Investment Research Pty Ltd (Edison AU) is the Australian subsidiary of Edison. Edison AU is a Corporate Authorised Representative (1252501) of Myonlineadvisers Pty Ltd who holds an Australian Financial Services Licence (Number: 427484). This research is issued in Australia by Edison AU and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by Edison AU is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

New Zealand

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. 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 (i.e. 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.

United Kingdom

Neither this document and associated email (together, the "Communication") constitutes or form part of any offer for sale or subscription of, or solicitation of any offer to buy or subscribe for, any securities, nor shall it or any part of it form the basis of, or be relied on in connection with, any contract or commitment whatsoever. Any decision to purchase shares in the Company in the proposed placing should be made solely on the basis of the information to be contained in the admission document to be published in connection therewith.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document (nor will such persons be able to purchase shares in the placing).

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States

The Investment Research is a publication distributed in the United States by Edison Investment Research, Inc. Edison Investment Research, Inc. is registered as an investment adviser with the Securities and Exchange Commission. Edison 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. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Edison does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1,185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia