

Paion

Q317 update

US and Japan filings and EU Phase III on track

Paion remains on track to file for approval of Remimazolam in 2018 for procedural sedation (via partner Cosmo Pharmaceuticals in the US) and general anaesthesia (GA) in Japan. Remimazolam's excellent safety profile and shorter procedure times than midazolam are expected to drive uptake if it gains market approval. Preparations are underway for an EU Phase III study for GA in general surgery patients to start in 2018 (subject to funding). Recently granted formulation and dosing patents will strengthen market exclusivity in the EU and Japan until 2033, which sees us lift our valuation to €260m (vs €245m) or €4.25/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 potential study last hurdle before US filing

Paion has conducted Phase I studies to assess the pharmacodynamics of intranasal administration of remimazolam and whether it can be abused as a knockout cocktail combined with alcohol. It will hold discussions with the FDA in Q417 ahead of a second intranasal study to be able to comprehensively understand the potential for abuse. Contingent on study results and FDA discussions, Paion expects to complete the human abuse liability programme in H118. Partner Cosmo expects to file for approval in H218.

Dosing patent, partnering discussions in Japan

Paion has been granted a dosing patent which strengthens exclusivity of remimazolam in Japan until 2033. Preparation of the regulatory dossier is ongoing ahead of an expected filing for approval for GA in Japan in mid-2018. Paion plans to partner in Japan during or following the preparation of the dossier.

Phase III for GA in Europe planned for 2018

Based on a recently-completed Phase I study and existing data in GA, the company estimates that ~500 patients would be required for the Phase III study in GA in the EU that is planned for 2018. The study is expected to target sicker and elderly patients who will gain the greatest benefit from the capacity of remimazolam to reduce the incidence of hypotension. Paion estimates that the Phase III clinical programme in Europe will cost ~€25m until filing for approval. As a first step €8m funds were raised in July.

Valuation: Increased to €260m or €4.25 per share

Our valuation is increased to €260m (from €245m) or €4.25/share (vs €4.02/share), due to the extended market exclusivity in the EU and Japan. Paion confirmed its previous guidance in the Q317 results presentation; end-Q317 cash of €29.6m extends Paion's cash reach into H219 (without considering potential milestone revenue or the cost of EU Phase III trial).

Pharma & biotech

10 November 2017

Price €2.61

Market cap €160m

US\$1.10/€

Net cash (€m) at 30 September 2017 29.6

Shares in issue 61.1m

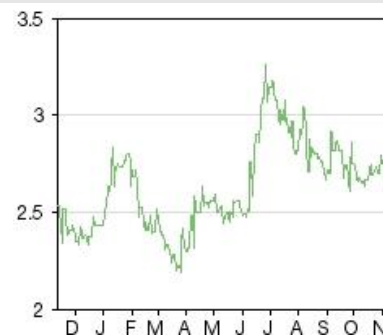
Free float 75%

Code PA8

Primary exchange Frankfurt (Xetra)

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (1.4) (10.6) 6.7

Rel (local) (3.0) (17.6) (13.8)

52-week high/low €3.3 €2.2

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 | | | | | | |
| PROFIT & LOSS | | | | | | |
| 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 |
| 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 | 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 |
| CASH FLOW | | | | | | |
| 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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