Paion

License agreement/H112 results

Edison investment research

Sealing the deal in China

Biotech & pharma

Formalisation of Paion's out-licensing agreement with Yichang for the Chinese rights to short-acting anaesthetic remimazolam brings a modest financial benefit and provides some flexibility while the company identifies suitable new assets to add to its anaesthetics and critical care portfolio. Acquisition of German distribution rights to the first of these additional assets, ultra-short acting anaesthetic remifentanil, were recently announced. The increase in the proportion of day-case and minimally invasive surgeries is driving the use of short-acting general anaesthetics such as remimazolam. We have increased our valuation to €54m from €44m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/10	4.5	(8.4)	(32.1)	0.0	N/A	N/A
12/11	3.2	(6.9)	(25.9)	0.0	N/A	N/A
12/12e	24.9	16.1	54.0	0.0	N/A	N/A
12/13e	1.2	(8.2)	(31.0)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation and exceptional items.

Yichang, a specialty channel for remimazolam

Paion has confirmed it has licensed Chinese development, manufacturing and commercialisation rights for remimazolam to Yichang Humanwell Pharmaceuticals. The deal provides staged upfront payments totalling €3m, plus ongoing royalties and milestones up to €4m. Yichang is potentially well placed to develop and commercialise the product, which could be complementary to the short-acting analgesic remifentanil that it markets in China for day-case surgery and ICU use.

Sharpening the focus

The deal represents progress in the reinforcement of its specialty niche in anaesthesia and sedation, leveraging the positive Phase IIb safety and efficacy data from Ono's study in colonoscopy patients. The Chinese deal should accelerate the development of remimazolam and improves the probability of attracting partners in other territories.

New products and further deals needed for remimazolam

The deal extends Paion's cash runway further into 2014. While the upfront payments are relatively modest, they allow additional flexibility for the company while it identifies complementary products to add to its anaesthesia and critical care portfolio – the first of these being remifentanil – and could attract new development partners for remimazolam. The H1 cash position stood at €21.7m; we forecast €17.2m for FY12.

Valuation: Raised to €54m in recognition of progress

We value Paion on an NPV basis using a 12% WACC. We value its two key programmes solulin and remimazolam at €39m and add Q2 net cash of c €15m. We have reduced the risk adjustment to reflect the improved status of remimazolam. This progress, and receipt of the upfront payments from Yichang, result in an increase in our valuation from €44m to €54m, which compares favourably to the current market capitalisation of €25m.

9 August 2012

Price	€0.97
Market cap	€25m

Shares in issue	25.4m
Free float	79%
Code	PA8
Primary exchange	Xetra

Share price performance

%	1m	3m	12m
Abs	34.3	7.4	(53.7)
Rel (local)	31.6	10.8	(46.9)
52-week high/low		€1.70	€0.53

Business description

Paion is a biopharmaceutical company specialising in the development of products for anaesthesia and critical care. Lead programme, remimazolam, is partnered with Ono Pharmaceutical in Japan and Yichang Humanwell Pharmaceutical in China.

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Partnering deal for lead programme remimazolam

Formalisation of the option agreement on Chinese rights for remimazolam, announced in July, is a step forward for Paion in its search for ex-Japanese partners for the programme, which forms the focus of its ongoing targeting of critical care and anaesthesia. Progress into Phase III could attract further licensing deals. The deal extends the cash runway further into 2014, giving some extra leeway to negotiate new in-licensing opportunities. The first of these is the acquisition of German distribution rights to remifentanil, an ultra-short acting anaesthetic. We have increased our valuation to €54m in recognition of the advancing status of the programme.

Yichang will carry out evaluation of remimazolam to assess how to take the programme forward. There are various options available depending on its development strategy; they might include using Ono's existing Phase IIb data in procedural sedation. Remimazolam has potential in the former indication as well as in general anaesthesia and ICU sedation. Ono is preparing to start Phase III studies including a colonoscopy trial versus propofol and endoscopy versus midazolam, as well as evaluation of remimazolam during limb setting and wound dressing. Yichang can move straight into Phase III or repeat Phase II depending on the requirements of the Chinese regulatory agency, the SFDA, and its choice of indication. Progress by Yichang and further news on Ono's Phase III should increase the profile of remimazolam and improve the potential for additional partnership deals. Paion's existing R&D portfolio is summarised in Exhibit 1.

Exhibit 1: Paion's R&D portfolio

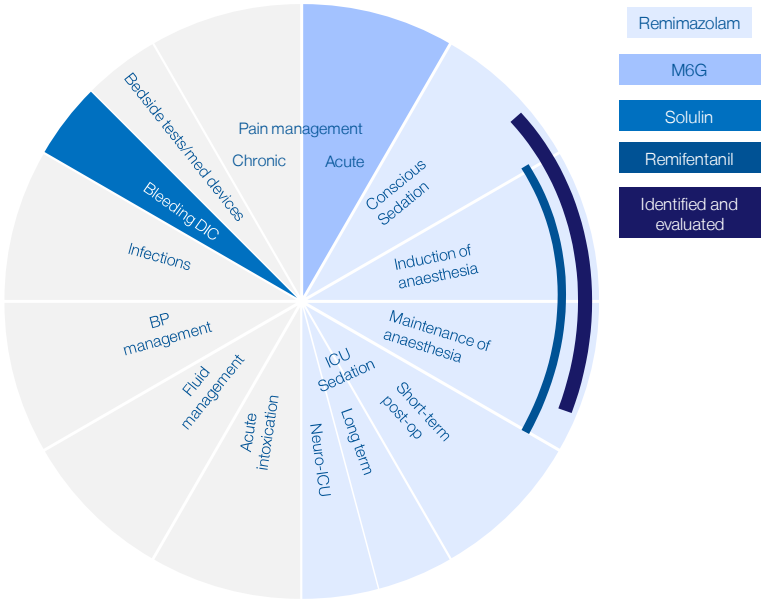
Programme	Indication	Licensee	Development stage/notes
Remimazolam (CNS-7056; ONO-2745)	Short-acting sedation (Phase IIb)	Licensed to Ono Pharmaceutical for Japan and Yichang Pharmaceutical for China. Additional ex-Japan partner(s) sought.	Fast-onset/short-duration anaesthetic, suitable for procedural sedation, induction/maintenance of anaesthesia and ICU sedation. Phase IIa in upper GI endoscopy and Phase Ib in colonoscopy volunteers completed. 160-pt Phase IIb trial in colonoscopy met its objective of showing a higher procedure success rate for the three treatment groups cf the gold-standard agent midazolam. Phase III programme will include colonoscopy trial vs propofol, endoscopy trial vs midazolam, and short-procedures study evaluating use in trauma, limb resetting and wound dressing.
M6G (morphine-6-glucuronide)	Peri-operative pain (Phase III)	Further development dependent on partnering.	Opioid (new chemical entity). 769-pt meta-analysis from two Phase II and two Phase III studies confirmed analgesic effect, showed 28% reduction of nausea/ vomiting cf morphine in key six to 24 hours after treatment (p=0.018).
Solulin	Haemophilia (Phase Ib) and possibly radiation injury	Licensed from Bayer.	Human thrombomodulin. Natural modulator of coagulation and fibrinolysis. Open-label, dose-finding Phase Ib study in severe haemophilia; results due in 2012. Peak sales $200-400m; haemophilia use patent claims market exclusivity to 2030+.
GGF2 (glial growth factor 2)	Heart failure	Licensed to Acorda Therapeutics for $3.5m in development milestones ($1m received), $5m on approval and royalties.	Glial growth factor 2 (Type II neuregulin I). Double-blind, placebo-controlled Phase I study investigating a single ascending dose in 50 left ventricular dysfunction and symptomatic heart failure patients due to be completed in H1 2013. The study aims to determine maximum tolerated dose, pharmacokinetics, outcome measures and immunogenicity. Significantly improved ventricular function in a heart failure model in swine.

Source: Edison Investment Research

Paion is seeking additional in-licensing opportunities in anaesthesia and critical care to shore up the specialty niche. The first of these opportunities, German distribution rights to the highly potent short-acting opioid remifentanil, and rights to obtain marketing approvals in selected EU countries have been secured. Paion views remifentanil as an ideal companion product for remimazolam, and intends to market these products through the same sales force. First remifentanil revenues are expected in FY13.

Ongoing assessment of potentially complementary products is underway and these could include fluid management, chronic pain management, blood pressure or infection control agents. Exhibit 2 illustrates the spectrum of current and potential product categories that could fit this portfolio (including two opportunities currently under evaluation) and the breadth of remimazolam's potential markets.

Exhibit 2: Potential for Paion to fulfil the needs of a typical anaesthetist



Source: Paion presentation

Paion has initially assigned around €5m over three years to set up this speciality-focused business, and intends to finance these acquisitions using the €20.1m proceeds from its sale of desmoteplase to Lundbeck. Paion is planning to appoint around five sales and marketing staff to focus on the portfolio, which could include the German rights to remimazolam.

Financials and valuation

Paion reported H1 cash of €21.7m, and revenue of €22.8m including €20.1m from sale of desmoteplase rights, and €0.3m option payment from Yichang received in April 2012 of the total €3m upfront payable. A further €1.5m is due in Q312 together with an additional €1.2m by June 2013 at the latest, on completion of the technology transfer. All payments are received in the form of revenue. Future milestone payments up to €4m are payable on launch, depending on Yichang's development strategy, together with 10% ongoing royalties, although these longer-term payments will be included in our model as the programme progresses towards launch.

We estimate a year-end 2012 gross cash position of €17.2m, revised down at Q1 due to a €2.4m tax accrual charge payable in 2012 on the sale of desmoteplase, but increased to include the upfront payments from Yichang with FY12 net cash forecast of €10.2m. Our year-end 2013 cash position increases to €3.8m from our last published forecast of €2.8m, showing an extension of the cash reach into 2014 and assuming repayment of its €6.9m subordinated loan in 2013.

We assume that the Chinese partnership increases the probability of launching remimazolam, both in China and other territories, and is recognition of the advancing status of this programme. We have therefore lowered our risk adjustment to reflect this. Consequently, we have increased our valuation from €44m to €54m based on lead programmes remimazolam and solulin. This total comprises NPV of €39m plus Q212 net cash of c €15m. This appears to offer potential compared to the current market capitalisation of c €25m.

Exhibit 3: Financial summary

€'000s	2010	2011	2012e	2013e
PROFIT & LOSS				
Revenue	**4,474**	**3,249**	**24,852**	**1,200**
Cost of sales	(19)	(2)	0	0
Gross profit	4,455	3,247	24,852	1,200
R&D expenditure	(9,016)	(11,825)	(4,652)	(7,000)
General, administrative & selling	(4,540)	(4,815)	(5,500)	(4,000)
Other	68	29	100	100
Operating profit	(9,033)	(13,363)	14,800	(9,700)
Depreciation and amortisation	(889)	(531)	(800)	(800)
Share-based payments	(440)	(501)	(501)	(501)
Exceptionals	0	(6,100)	0	0
EBITDA	**(7,704)**	**(6,230)**	**16,102**	**(8,399)**
Operating profit (before GW and except.)	(7,704)	(6,230)	16,102	(8,399)
Net interest	(660)	(660)	0	200
Profit before tax (norm)	(8,365)	(6,890)	16,102	(8,199)
Profit before tax (FRS 3)	(9,694)	(14,023)	14,800	(9,500)
Tax	439	339	(2,400)	340
Profit after tax (norm)	(7,925)	(6,551)	13,702	(7,859)
Profit after tax (FRS3)	(9,255)	(13,684)	12,400	(9,160)
Average number of shares outstanding (m)	24.7	25.3	25.4	25.4
EPS - normalised (c)	(32.1)	(25.9)	54.0	(31.0)
EPS - FRS 3 (c)	(37.5)	(54.1)	48.9	(36.1)
Gross margin (%)	99.6%	99.9%	100.0%	NA
Operating margin (before GW and except.) (%)	NA	NA	NA	NA
BALANCE SHEET				
Fixed assets	**10,767**	**4,180**	**3,390**	**2,590**
Intangible assets	10,571	4,013	3,263	2,503
Tangible assets	196	167	127	87
Current assets	**16,068**	**8,426**	**19,659**	**4,867**
Debtors	11	4	1,500	21
Cash	14,882	7,516	17,159	3,846
Other	1,175	906	1,000	1,000
Current liabilities	**(4,385)**	**(3,115)**	**(2,271)**	**(2,021)**
Trade payables	(1,835)	(1,493)	(1,493)	(1,493)
Short-term borrowings	0	0	(6,933)	0
Provisions	(677)	(621)	(500)	(250)
Finance lease liabilities	0	0	0	0
Other current liabilities	(407)	(278)	(278)	(278)
Current deferred income	(1,466)	(723)	0	0
Long-term liabilities	**(10,482)**	**(9,955)**	**(1,193)**	**(1,193)**
Long-term borrowings	(6,893)	(6,933)	0	0
Provisions	(1,346)	(1,193)	(1,193)	(1,193)
Long-term deferred income	(2,243)	(1,829)	0	0
Deferred taxes	0	0	0	0
Other long-term liabilities	0	0	0	0
Net assets	**11,968**	**(464)**	**19,585**	**4,243**
CASH FLOW				
Operating cash flow	**(8,582)**	**(7,896)**	**12,053**	**(6,920)**
Net interest	(517)	(480)	0	200
Tax	365	428	(2,400)	340
Capex	0	0	0	0
Purchase of intangibles	(44)	(42)	(10)	0
Acquisitions/disposals	0	0	0	0
Financing	761	621	0	0
Net cash flow	(8,018)	(7,369)	9,643	(6,380)
Opening net debt/(cash)	**(16,014)**	**(7,989)**	**(584)**	**(10,226)**
Effect of exchange rate changes	28	4	0	0
Other	(36)	(39)	0	0
Closing net debt/(cash)	**(7,989)**	**(584)**	**(10,226)**	**(3,846)**

Source: Company data, Edison Investment Research

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