EDISON

Wilex

Redefined and refined

Partnership agreements; Q214

Pharma & biotech

Wilex has fulfilled its target of establishing global licence deals for Mesupron, opening up the opportunity to confirm its potential across a range of oncology indications. The new, leaner Wilex is focusing on its antibody drug conjugate ADC technology and targets additional alliances along the lines of its existing tie-up with Roche. It also seeks partners for the clear cell renal cancer programme. Our valuation is €46m, which could increase to €116m if Wilex can out-license Rencarex and Redectane.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
11/12	17.8	(9.4)	(36.2)	0.0	N/A	N/A
11/13	19.1	(5.0)	(16.1)	0.0	N/A	N/A
11/14e	4.0	(5.0)	(64.1)	0.0	N/A	N/A
11/15e	2.0	(4.0)	(51.2)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments.

New global partners for Mesupron

Wilex has sealed global licensing development and commercialisation deals in oncology for Mesupron. In March it out-licensed the uPA-inhibitor to Link Health, for China, Hong Kong, Taiwan and Macao, and in June, Israeli company RedHill Biopharma in-licensed rights for all other territories. The deal terms include US$1m upfront plus tiered royalties from RedHill and an upfront fee, €7m in milestones plus royalties from Link Health. These partners will conduct large-scale Phase II/III studies with Mesupron, which was shown to enhance the activity of chemotherapy in Phase II trials in breast and pancreatic cancer.

Focus on internal R&D with ADC technology

Wilex will return rights to oncology candidates WX-037, WX-554 and all other projects to UCB Pharma, which will waive a €2.5m loan conditional on final transfer in H214. Following IBA's return of commercial and production rights for Redectane in April, Wilex is free to search for partners for the clear cell renal cancer diagnostic and for antibody therapy Rencarex. The R&D focus is now on identifying new preclinical candidates, either in house, through its alliance with Roche, or other potential partners, using its proprietary ADC toxin-linker technology.

Costs pared back, cash reach extended into H215

Post-restructuring, we estimate that Wilex's FY14 total operating expenses will fall by c 60% from FY13. Q214 gross cash of €2.8m gives an estimated 12-month cash reach including c €1.5m from new deals and settlement from former partners. Wilex has completed a (4:1) capital reduction, scaling back its equity to 7.8m shares.

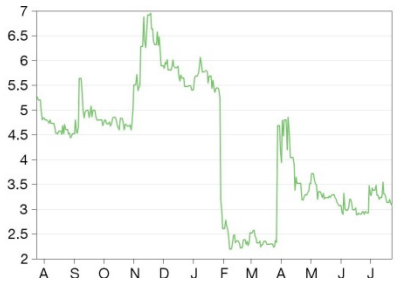
Valuation: Upside catalysts ADC or new deals

Our valuation of Wilex is €46m. There is upside scope to €116m if the company is able to form agreements for the renal cancer programmes. Other potential catalysts could include progress or news of a new alliance through the ADC platform.

24 July 2014

Price	**€3.2**
Market cap	**€25m**
Net cash at 31 May 2014	€0.3m
Shares in issue	7.8m
Free float	13%
Code	WL6
Primary exchange	FRA
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	12.3	(8.0)	(38.3)
Rel (local)	14.3	(11.2)	(47.8)
52-week high/low		€7.0	€2.2

Business description

Wilex is focusing on the novel antibody drug conjugate (ADC) technology and contract research at its Heidelberg Pharma subsidiary. The company recently out-licensed Mesupron to Link Health (China, HK, Taiwan, Macao) and to RedHill Biopharma (RoW). It requires partners to progress its clear cell renal cancer programmes: Redectane, a diagnostic, and Rencarex, an adjuvant therapy.

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Working from a new base

Wilex has stabilised its position after a challenging period of restructuring and has succeeded in arranging licence deals for Mesupron in oncology across all geographies. After a series of cost-cutting initiatives, Wilex has rebased itself and has extended its cash reach into Q315. It is now focusing on securing new deals using its ADC technology, and on identifying new candidates in house or through the Roche collaboration. Progress with Mesupron or news on a deal for the renal cancer pipeline would also be significant catalysts. Our valuation of the newly rebased Wilex is €46m, with upside to €116m if Wilex secures partners for the renal cancer programme.

Partners will take Mesupron forward, internal focus is on ADC technology

Wilex has signed two partnership deals that will cover the global development of Mesupron with Link Health for China, Hong Kong, Taiwan and Macao and with RedHill for all other territories including Europe and the US. Wilex has carried out eight Phase I studies on the small molecule Mesupron in over 150 patients in breast, pancreatic and head and neck cancers and a further two Phase II studies in HER-2 negative breast cancer and in pancreatic cancer. Mesupron is a non-cytotoxic, anti-metastatic compound, which has the potential to block cell invasion, metastasis and growth in a broad range of solid tumours. Link Health is likely to initiate studies in China and consequently, it might use the data for approval filing in Hong Kong, Taiwan and Macao. RedHill has scope to develop Mesupron across all oncology indications, although its specialisation is in gastrointestinal therapies. The company has indicated that RedHill will resume studies with Mesupron at the Phase IIb stage.

Wilex is focusing its in-house R&D activity on the largely preclinical ADC development activities through its alliance with Roche at its subsidiary, Heidelberg Pharma. The former CFO of Wilex and head of the division, Dr Jan Schmidt-Brand, has taken on the role of CEO of Wilex. Heidelberg Pharma operates a dual business model. It provides customer-specific research, chiefly for early stage biotech companies. It also has a proprietary antibody drug conjugate (ADC) technology, which has led to an alliance with Roche to gain access to Wilex's ADC technology for a range of tumour targets.

The principle of anti-cancer ADCs is to increase the efficacy of antibody therapy by introducing a toxin to the tumour cell guided by the antibody. ADCs are versatile and can potentially be used against a range of indications. Heidelberg Pharma's ADC technology is based on antibody targeted amanitin conjugates (ATACs), which use the toxin α-Amanitin from the green Death Cap mushroom *Amanita phalloides*. ATACs are designed so that the α-Amanitin is cleaved off the antibody inside a cell thus blocking RNA II polymerase, which leads to apoptosis. The technology is designed so that normal cells are not affected and enables it to act on dormant tumour cells, preventing tumour relapse and metastasis.

Wilex's subsidiary provides an independent revenue stream from its CRO services, while the licence agreement with Roche provides payments for the use of its technology and services. Furthermore, for each candidate selected, the company will receive an upfront payment and milestones to manufacture the compound. Heidelberg Pharma is developing independently early stage ADC candidates against a distinct set of targets, which it might develop in house or by forming new alliances.

Meanwhile, Wilex announced in May that it will return rights to two oncology candidates, MEK inhibitor WX-554 and PI3K inhibitor WX-037, as well as three undisclosed antibody programmes to UCB Pharma. In return UCB, a 14% shareholder in Wilex, will waive its €2.5m shareholder loan and

is due to reimburse development costs to Wilex, conditional on the final transfer of rights expected in H214.

Targeting partnerships for the renal cell cancer pipeline

Wilex requires a partner for Rencarex (girentuximab; G250), an antibody for the adjuvant (ie post-surgical) treatment of non-metastatic clear cell renal cell carcinoma (ccRCC). Separately, the company is looking to partner Redectane, the radioactively labelled form of girentuximab, which has potential as a pre-surgical diagnostic to assess whether renal masses are ccRCC.

Rencarex targets the CAIX antigen, which is expressed on the cell surface of c 90% of all clear cell renal cell carcinomas but not in normal kidney tissue. The CAIX antigen is also expressed in bladder, head and neck, and colon cancers, although the level of expression is lower in these tumours. The standard treatment in the adjuvant setting (post-nephrectomy) is watchful waiting, despite a 30-40% risk of relapse of kidney cancer in patients with localised disease. Wilex has completed three Phase I, three Phase II and one Phase III studies with Rencarex in ccRCC. The Phase III trial failed to show that patients receiving Rencarex had a survival benefit, but subgroup analysis suggested that c 30% of ccRCC patients, those expressing high levels of the carbonic anhydrase IX (CAIX) antigen, could benefit from receiving the product. The analysis showed that these patients had a 40% lower risk of recurrence of ccRCC and suggests that patients with a high CAIX score might benefit from Rencarex therapy.

Clinical studies with Redectane showed its potential as a diagnostic tool for ccRCC, which is the type of renal cancer most likely to lead to metastasis. Redectane might also be used for follow-on imaging for metastatic patients or in other forms of cancer. Wilex's Phase III study REDECT showed that ccRCC can be diagnosed using Redectane in combination with PET/CT imaging. The sensitivity (correct diagnosis of ccRCC) of Redectane in the trial with 226 nephrectomy patients was 86% ($p \leq 0.016$) and the specificity (correct negative diagnosis) was 87% ($p<0.001$). The Oncologic Drugs Advisory Committee (ODAC) voted 16:0 in favour of the clinical usefulness and diagnostic performance of Redectane. The FDA requires a final confirmatory Phase III study with Redectane.

Financials and valuation

We have updated and reinstated our forecasts following the restructuring – total revenue of €4m in FY14e includes c €1.5m in upfront payments from the licence agreements and from reimbursed development costs from UCB and IBA. We have cut operating expenses, based on company guidance, by c 60% from €20.4m in FY13, to €7.3m in FY14. These include R&D costs of €4.3m and SG&A of €3.1m (compared to €12.4m and €8.0m in FY13). The H114 gross cash position of €2.8m is forecast provide a runway into Q315. Our year-end 2014 net cash estimate is €2.4m assuming that UCB waives the €2.5m shareholder loan, which is conditional on completing the return of rights for the oncology programme. A capital reduction was recently completed, reducing the number of shares by 23.5m to 7.8m. This was an accounting measure needed to overcome the fact that the share price has traded consistently below the nominal value of €1.

Our sum-of-the-parts DCF valuation is €46m, using a 12.5% WACC, which is based on a review of our assumptions compared to our previous base case valuation of €47m. If Wilex is able to partner Rencarex and Redectane, our valuation would increase to €116m. The main changes to our valuation assumptions include:

- greater probability of success in developing Mesupron due to the new partnerships; risk adjustment increased from 25% to 30% to reflect progression;

- our global peak sales estimate for Mesupron is based on those of other non-blockbuster oncology drugs such as Erbitux (colorectal cancer) and Abraxane (pancreatic cancer). We use an average royalty rate of 15%;
- shift of the estimated timeline for the launch of Mesupron from 2018 to 2021;
- addition of risk-adjusted milestone payments up to €7m from Link Health payable over the development period; and
- we have removed the value of UCB candidates, WX-037 and WX-554, plus all associated R&D costs.

A summary of our valuation is shown in Exhibit 1.

Exhibit 1: Sum-of-the-parts DCF valuation

Driver	Value per share €	Value €m
Mesupron	6.4	50.2
Heidelberg Pharma (CRO revenue only)	0.4	3.1
Expenses	(0.5)	(3.7)
Tax	(0.4)	(3.5)
Net cash	0.04	0.3
Total	**5.9**	**46.4**
Rencarex	5.1	39.7
Redectane	3.8	30.0
Total	**14.9**	**116.1**
Number of shares		7.8

Source: Edison Investment Research. Note: Rencarex and Redectane values are shown inclusive of tax.

The valuation of Heidelberg Pharma includes only services revenue as the preclinical nature of the pipeline and limited visibility on the timing and nature of milestone payments prevents us from valuing the ADC collaboration.

Future catalysts could include news of progress through the development alliance with Roche, for example a new drug candidate being identified, or new licence deals for the ADC technology. Other potential news flow includes progress in the clinical development of Mesupron or success in partnering discussions with the ccRCC programmes.

Exhibit 1: Financial summary

€000s	2012	2013	2014e	2015e
Year end 30 November	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	17,842	19,107	3,971	1,979
Cost of Sales	(6,746)	(3,678)	(1,476)	(1,184)
Gross Profit	11,096	15,429	2,494	795
EBITDA	(8,237)	(3,247)	(4,500)	(3,731)
Operating Profit (before GW and except.)	(8,909)	(4,963)	(4,866)	(4,012)
Intangible Amortisation	0	0	0	0
Other	0	0	0	0
Exceptionals	0	0	0	0
Operating Profit	(8,909)	(4,963)	(4,866)	(4,012)
Net Interest	(478)	(77)	(101)	7
Other	0	0	2,500	0
Profit Before Tax (norm)	(9,387)	(5,039)	(4,968)	(4,006)
Profit Before Tax (FRS 3)	(9,387)	(5,039)	(2,468)	(4,006)
Tax	(3)	(0.12)	(47.2)	(0.0)
Deferred tax	0	0	0	0
Profit After Tax (norm)	(9,390)	(5,039)	(5,015)	(4,006)
Profit After Tax (FRS 3)	(9,390)	(5,039)	(2,515)	(4,006)
Average Number of Shares Outstanding (m)	25.9	31.3	7.8	7.8
EPS - normalised (c)	(36.2)	(16.1)	(64.1)	(51.2)
EPS - FRS 3 (c)	(36.2)	(16.1)	(32.2)	(51.2)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	62.2	80.7	62.8	40.2
EBITDA Margin (%)	-46.2	-17.0	-113.3	-188.6
Operating Margin (before GW and except.) (%)	-49.9	-26.0	-122.6	-202.8
BALANCE SHEET				
Fixed Assets	12,532	12,805	12,550	12,221
Intangible Assets	10,218	9,182	9,033	8,869
Tangible Assets	2,087	1,324	1,216	1,052
Other	228	2,298	2,301	2,301
Current Assets	25,189	9,507	3,526	1,598
Stocks	258	78	52	52
Debtors	832	402	867	867
Cash	23,363	8,920	2,510	583
Other	735	106	96	96
Current Liabilities	(16,739)	(7,285)	(3,492)	(4,992)
Creditors	(14,102)	(4,647)	(3,429)	(3,429)
Short term borrowings	(2,638)	(2,638)	(63)	*(1,563)
Long Term Liabilities	(1,061)	(77)	(13)	(13)
Long term borrowings	0	0	0	0
Other long term liabilities	(1,061)	(77)	(13)	(13)
Net Assets	19,921	14,950	12,570	8,814
CASH FLOW				
Operating Cash Flow	(4,632)	(14,358)	(6,097)	(3,317)
Net Interest	(478)	(94)	(176)	7
Tax	3	0	47	(0)
Capex	(244)	(172)	(194)	(117)
Acquisitions/disposals	0	0	0	0
Financing	33,420	0	0	0
Dividends	0	0	0	0
Other	(306)	(224)	(50)	(47)
Net Cash Flow	27,762	(14,848)	(6,471)	(3,474)
Opening net debt/(cash)	7,128	(20,726)	(6,283)	(2,448)
HP finance leases initiated	0	0	0	0
Exchange rate movements	48	(406)	136	0
Other	44	811	2500	47
Closing net debt/(cash)	(20,726)	(6,283)	(2,448)	979

Source: Company accounts, Edison Investment Research. Note: *FY15 funding requirement shown as short-term borrowings.

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