

# 4SC

## Core focus on track despite disappointing results

4SC has announced that its partner Yakult Honsha did not reach the primary endpoint in its Asian liver cancer trial with all-comer patients. As a result, it will not be progressing resminostat to a pivotal study. These results do not affect 4SC's core focus on the launch of its pivotal EU Phase II resminostat study in CTCL and progression of its earlier pipeline. A positive partnership with Link Health (4SC-205) and data at ASCO (4SC-202) underline this. Removal of the Japan HCC contribution reduces our rNPV to €104m (vs €145m).

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/14	7.1	(8.8)	(0.88)	0.0	N/A	N/A
12/15	3.3	(8.4)	(0.59)	0.0	N/A	N/A
12/16e	3.8	(11.4)	(0.60)	0.0	N/A	N/A
12/17e	4.0	(10.2)	(0.53)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

## Disappointing Phase II results from partner Yakult

Japanese partner Yakult Honsha (Yakult) has completed the Phase II part of a Phase I/II study of resminostat in combination with sorafenib in advanced liver cancer (HCC). The Phase II part (170 Asian patients) did not meet its primary endpoint of prolonged time to disease progression (TTP) compared to sorafenib monotherapy. Yakult has confirmed that it will not progress to a pivotal study in all-comer patients. However, early data appear to show that patients with certain expression levels of the ZFP64 biomarker at baseline had longer TTP when treated in combination with resminostat, a potentially positive indication. Further clinical trials in Japan are ongoing in NSCLC, pancreatic cancer and bile duct cancer.

## Core focus – CTCL Phase II trial remains on track

The pivotal Phase II trial of resminostat in CTCL is on track to start in Europe in mid-2016. This 150-patient, double-blind, randomised controlled study will be conducted in 50 centres, across 10 countries. Initial results could be available in FY18.

## Positive progress with early-stage pipeline

4SC has entered into a licensing and development partnership with Link Health in China for its oncology Eg5 inhibitor, 4SC-205. Link Health will undertake clinical development and the regulatory process, while 4SC will receive developmental milestones (€76m) and double-digit royalties. Also, further positive data have been presented ([ASCO 2016](#)) for its epigenetic compound, 4SC-202, demonstrating with preclinical evidence that it is an effective combination partner for checkpoint inhibitor therapies.

## Valuation: Reduced to €104m, but potential upside

Our rNPV-based valuation reduces to €104m or €5.5 per share (previously €145m or €7.67/share), as we remove the Japan HCC rNPV contribution following Yakult's decision not to progress in this indication. Nevertheless, we see some upside to our valuation as the pivotal Phase II CTCL trial is initiated later this year.

## Clinical progress update

### Pharma & biotech

13 June 2016

**Price** €2.41  
**Market cap** €46m

Net cash (€m) at 31 March 2016	17.1
Shares in issue	19.0m
Free float	38.1%
Code	VSC
Primary exchange	Frankfurt
Secondary exchange	N/A

### Share price performance



%	1m	3m	12m
Abs	(25.0)	(30.1)	(46.3)
Rel (local)	(23.4)	(32.5)	(38.5)
52-week high/low		€5.0	€2.4

### Business description

4SC is a Munich-based cancer R&D company. Epigenetic compound resminostat (HDAC inhibitor) is the lead candidate for CTCL (Phase II planned in H216), partnered with Yakult Honsha (Japan) and Menarini (Asia ex-Japan). 4SC is partnered with Link Health for a Phase I oncology asset. It is seeking partners for a Phase I oncology asset and a Phase IIb autoimmune asset.

### Next events

Resminostat Phase II EU CTCL starts	H216
Interim 2016 results	11 August 2016
Phase II data in NSCLC Japan (Yakult)	End 2016

### Analysts

Dr Linda Pomeroy	+44 (0)20 3077 5738
Lala Gregorek	+44 (0)20 3681 2527

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

[Edison profile page](#)

**4SC is a research client of  
Edison Investment Research  
Limited**

## Valuation

We have reduced our rNPV of 4SC's product portfolio to €104m (vs €145m), predominantly due to the removal of the Yakult HCC rNPV of €39m, or €2 per share, alongside a reduction in the probability of success (to 20%) for resminostat in the US and EU territories. This follows the announcement that the primary endpoint of the Phase II part of the trial was not met and therefore 4SC's partner Yakult would not be taking it forward into a pivotal Phase III trial.

This is offset slightly by an increase in the rNPV value of the 4SC-205 product to €20m (or €1 per share) following its partnership with Link Health to develop and commercialise it in China, Hong Kong and Macau. The deal enables Link Health to clinically develop 4SC-205 and to have responsibility for taking it through the regulatory process in China. As a result, 4SC is entitled to developmental milestones of €76m and double-digit royalty payments on product sales. In addition, 4SC receives all the data, which could be useful in securing partnerships for other territories in the future. We do not currently include the milestone payments in our forecasts as the company has indicated that they do not have an immediate impact on cash flow and we have no visibility at this time as to how and when Link Health will progress the programme.

Our overall valuation for 4SC is now €104m (vs €145m previously), or €5.5 per share (vs €7.67 per share). Our other key assumptions remain unchanged. However, we see some upside potential to our valuation as the Phase II trial in CTCL is initiated later this year.

**Exhibit 1: rNPV sum-of-the-parts valuation**

Product	Indication	Region	Status	Partner	NPV (€m)	Prob. of success	rNPV (€m)	rNPV/ share (€)	Launch	Peak sales (€m)	Net royalty estimate
Resminostat	First-line HCC	China	Phase I	Menarini	86.1	20%	17.2	0.91	2022	259	15%
		US	Phase II	-	59.0	20%	11.8	0.62	2021	191	20%
		EU	Phase II	-	62.2	20%	12.4	0.66	2021	201	20%
Resminostat	Second-line NSCLC	Japan	Phase II	Yakult Honsha	63.6	10%	6.4	0.34	2021	204	17.5%
Resminostat	Second-line CTCL	EU	Phase II	-	50.1	20%	10.0	0.53	2020	123	25.0%
4SC-202	Haematological/solid tumours	WW	Phase II-ready	-	209.6	15%	34.4	1.82	2022	810	tiered up to 15%
4SC-205	Haematological/solid tumours	WW	Phase I	-			20	1.05			
R&D expenses							(18.5)	(0.98)	2016-18 expenses (risk-adjusted)		
Admin expenses							(6.6)	(0.35)	2016-18 expenses (risk-adjusted)		
Net cash (Q116)							17.1	0.90	Includes €1.3m long-term financial asset		
Total							104	5.50			

Source: Edison Investment Research

**Exhibit 2: Financial summary**

	€000s	2013	2014	2015	2016e	2017e	2018e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>							
Revenue		4,904	7,055	3,266	3,800	4,000	5,000
Cost of sales		(1,474)	(4,080)	(1,763)	(1,710)	(1,600)	(1,750)
Gross profit		3,430	2,975	1,503	2,090	2,400	3,250
R&D expenditure		(10,243)	(8,504)	(7,255)	(11,000)	(10,000)	(7,500)
Administrative, distribution and other		(3,779)	(3,908)	(3,163)	(3,447)	(3,551)	(3,657)
Operating profit		(10,592)	(9,437)	(8,915)	(12,357)	(11,151)	(7,907)
Intangible amortisation		(1,593)	(819)	(827)	(827)	(827)	(827)
Exceptionals (impairment / restructuring costs)		(862)	0	0	0	0	0
Share-based payments		(53)	(3)	2	(20)	(20)	(20)
EBITDA		(7,804)	(8,339)	(7,914)	(11,285)	(10,079)	(6,835)
Operating profit (before GW and except.)		(8,084)	(8,615)	(8,090)	(11,510)	(10,304)	(7,060)
Net interest		48	(228)	(331)	75	150	100
Other (profit/loss from associates)		19	39	58	75	75	75
Profit before tax (norm)		(8,036)	(8,843)	(8,421)	(11,436)	(10,154)	(6,960)
Profit before tax (FRS 3)		(10,525)	(9,626)	(9,188)	(12,208)	(10,926)	(7,732)
Tax		0	(70)	(40)	0	0	0
Profit after tax (norm)		(8,017)	(8,874)	(8,403)	(11,361)	(10,079)	(6,885)
Profit after tax (FRS 3)		(10,525)	(9,696)	(9,228)	(12,208)	(10,926)	(7,732)
Average number of shares outstanding (m)		10.1	10.1	14.3	19.0	19.0	19.0
EPS - normalised (€)		(0.80)	(0.88)	(0.59)	(0.60)	(0.53)	(0.36)
EPS - FRS 3 (€)		(1.04)	(0.96)	(0.64)	(0.64)	(0.58)	(0.41)
Dividend per share (€)		0.0	0.0	0.0	0.0	0.0	0.0
<b>BALANCE SHEET</b>							
Fixed assets		11,591	10,639	11,077	10,043	9,280	8,542
Intangible assets		10,651	9,836	9,123	8,164	7,451	6,738
Tangible assets		602	425	357	282	232	207
Investments and other		338	378	1,597	1,597	1,597	1,597
Current assets		6,114	4,295	22,415	10,665	10,201	2,555
Stocks		23	25	20	20	20	20
Debtors		346	652	94	94	94	94
Cash		4,899	3,202	21,476	9,928	9,464	1,818
Other current assets		846	393	817	623	623	623
Current liabilities		(3,587)	(4,842)	(5,593)	(3,187)	(3,437)	(3,937)
Creditors		(675)	(993)	(688)	(688)	(688)	(688)
Short-term borrowings		0	(317)	(1,962)	0	0	0
Deferred revenue (short term)		(1,589)	(2,638)	(1,779)	(1,750)	(2,000)	(2,500)
Other current liabilities		(1,323)	(894)	(1,164)	(749)	(749)	(749)
Long-term liabilities		(2,836)	(8,042)	(1,471)	(188)	(10,038)	(10,038)
Long-term borrowings		0	(6,131)	0	0	(10,000)	(10,000)
Deferred revenue (long term)		(2,682)	(1,788)	(1,433)	(150)	0	0
Other long-term liabilities		(154)	(123)	(38)	(38)	(38)	(38)
Net assets		11,282	2,050	26,428	17,333	6,006	(2,878)
<b>CASH FLOW</b>							
Operating cash flow		(7,052)	(8,302)	(8,916)	(9,973)	(10,179)	(7,335)
Net interest		66	0	(2)	2	4	3
Tax		0	(70)	(40)	0	0	0
Capex		(99)	(100)	(109)	(150)	(175)	(200)
Expenditure on intangibles		(21)	(3)	(114)	(114)	(114)	(114)
Acquisitions/disposals		10	0	0	650	0	0
Financing		0	477	27,608	0	0	0
Other		0	0	4,333	0	0	0
Net cash flow		(7,096)	(7,998)	22,760	(9,586)	(10,464)	(7,647)
Opening net debt/(cash)		(12,064)	(4,899)	3,246	(19,514)	(9,928)	536
HP finance leases initiated		0	0	0	0	0	0
Other		(69)	(147)	0	0	0	0
Closing net debt/(cash)		(4,899)	3,246	(19,514)	(9,928)	536	8,182

Source: 4SC accounts, Edison Investment Research

Edison, the investment intelligence firm, is the future of investor interaction with corporates. Our team of over 100 analysts and investment professionals work with leading companies, fund managers and investment banks worldwide to support their capital markets activity. We provide services to more than 400 retained corporate and investor clients from our offices in London, New York, Frankfurt, Sydney and Wellington. 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 Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison and is not regulated by the Australian Securities and Investment Commission. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. [www.edisongroup.com](http://www.edisongroup.com)

#### DISCLAIMER

Copyright 2016 Edison Investment Research Limited. All rights reserved. This report has been commissioned by 4SC 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 Aus and any access to it, is intended only for "wholesale clients" within the meaning of the Australian Corporations Act. 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 2016. "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.