

# 4SC

## First patient enrolled in pivotal RESMAIN study

4SC has announced the enrolment of the first patient in its RESMAIN study. This is a pivotal study to evaluate resminostat (RES), an epigenetic cancer drug for maintenance treatment (MAIN) in patients with advanced-stage cutaneous T-cell lymphoma (CTCL). We expect early data to be reported in 2019. We increase our rNPV to €120m from €117m as we have raised the probability of the CTCL programme in Europe to 30% (from 20%) following the initiation of the trial.

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	(12.9)	(0.68)	0.0	N/A	N/A
12/17e	4.0	(6.0)	(0.31)	0.0	N/A	N/A

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

## Pivotal RESMAIN study initiated

The pivotal trial of resminostat in advanced-stage CTCL has been initiated with an announcement that the first patient has been enrolled. The study is a 150-patient, double-blind, randomised placebo-controlled study being conducted in 50 centres, across 10 European countries. Patients who are eligible to be part of the study will have achieved disease control with systemic therapy. The patients will be randomised 1:1 to receive either resminostat or a placebo. The primary endpoint will be progression-free survival and the secondary endpoint time to symptom worsening (itching). We forecast cash reach into 2018, at which time 4SC will need to raise further funding to complete the trial.

## Pipeline progression overview

Alongside the CTCL trial, 4SC has a number of other developing parts to its pipeline. It announced potentially positive Phase II results from a more detailed analysis of the HCC Yakult Phase II trial data and has reported that there was a substantial improvement in overall survival in a large subgroup. As a result, 4SC is discussing plans for continued clinical development of resminostat in Japan with its partner Yakult. We expect further data analysis in early 2017. Alongside this, developments during 2016 in its earlier-stage pipeline include a partnership with Link Health in China for its oncology Eg5 inhibitor (4SC-205) and promising preclinical data for its epigenetic HDAC/LSD1 inhibitor (4SC-202), demonstrating preclinical evidence that it could be an effective combination partner for checkpoint inhibitor therapies.

## Valuation: Increased to €120m

We have increased our rNPV-based valuation to €120m or €6.3 per share (vs €6.2), as we have raised our probability of resminostat in the CTCL programme in Europe to 30% (vs 20%) following the initiation of the trial. We now use Q316 reported cash of €12.3m. We have also tweaked R&D and SG&A spend down slightly for FY16 and increased R&D in FY17 following updated guidance at the Q3 results. We have not altered our cash reach, which we continue to forecast to 2018.

Pivotal study initiated

Pharma & biotech

19 December 2016

**Price** €2.32  
**Market cap** €44m

Net cash (€m) at 30 September 2016	12.3
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	(4.1)	7.6	(33.2)
Rel (local)	(10.4)	(3.0)	(38.7)
52-week high/low	€4.2	€2.1	

## Business description

4SC is a Munich-based cancer R&D company. Epigenetic compound resminostat (HDAC inhibitor) is the lead candidate for Cutaneous T-Cell Lymphoma (pivotal study started in Q416), partnered with Yakult Honsha (Japan) and Menarini (Asia ex-Japan). 4SC is partnered with Link Health for a Phase I oncology asset.

## Next events

Further Phase II data analysis in HCC and Phase II NSCLC data Japan (Yakult)	Early 2017
Further patient recruitment into the pivotal resminostat EU trial	2017
FY16 results	March 2017

## Analysts

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**Exhibit 1: 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)	(12,000)	(7,000)	(5,250)
Administrative, distribution and other		(3,779)	(3,908)	(3,163)	(3,957)	(2,369)	(2,440)
Operating profit		(10,592)	(9,437)	(8,915)	(13,867)	(6,969)	(4,440)
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)	(12,795)	(5,897)	(3,368)
Operating profit (before GW and except.)		(8,084)	(8,615)	(8,090)	(13,020)	(6,122)	(3,593)
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)	(12,946)	(5,972)	(3,493)
Profit before tax (FRS 3)		(10,525)	(9,626)	(9,188)	(13,718)	(6,744)	(4,265)
Tax		0	(70)	(40)	0	0	0
Profit after tax (norm)		(8,017)	(8,874)	(8,403)	(12,871)	(5,897)	(3,418)
Profit after tax (FRS 3)		(10,525)	(9,696)	(9,228)	(13,718)	(6,744)	(4,265)
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)	(0.68)	(0.31)	(0.18)
EPS - FRS 3 (€)		(1.04)	(0.96)	(0.64)	(0.72)	(0.36)	(0.22)
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	9,156	12,873	8,693
Stocks		23	25	20	20	20	20
Debtors		346	652	94	94	94	94
Cash		4,899	3,202	21,476	8,419	12,136	7,956
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	15,824	8,678	3,260
<b>CASH FLOW</b>							
Operating cash flow		(7,052)	(8,302)	(8,916)	(11,483)	(5,997)	(3,868)
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	(11,095)	(6,282)	(4,180)
Opening net debt/(cash)		(12,064)	(4,899)	3,246	(19,514)	(8,419)	(2,136)
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)	(8,419)	(2,136)	2,044

Source: 4SC and Edison Investment Research

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