

4SC

Steady R&D newsflow

Company update

Pharma & biotech

9 February 2018

Price €6.28

Market cap €192m

Net cash (€m) at end Q317 43.4

Shares in issue 30.6m

Free float 30%

Code VSC

Primary exchange Frankfurt (Xetra)

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 27.5 19.4 126.1

Rel (local) 39.0 30.3 112.8

52-week high/low €7.0 €2.3

Business description

4SC is a Munich-based cancer biopharmaceutical company. Resminostat (HDAC inhibitor) is the lead candidate for cutaneous T-Cell lymphoma (CTCL, pivotal study started in Q416). It has a second compound, 4SC-202 (Phase Ib/II started in Q317) and a preclinical asset, 4SC-208. 4SC also has several partners including Yakult Honsha for resminostat in Japan in various indications.

Next events

Annual report 2017 28 March 2018

Initiation of Phase II trial with resminostat in biliary tract cancer by Yakult H118

4SC-208 preclinical data 2018

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Over the past several months 4SC has reported progress with both its clinical-stage assets – resminostat and 4SC-202. The pivotal trial with resminostat as a maintenance therapy in advanced CTCL passed the first DSMB review and is on track to report data in H119. The Phase Ib/II study with 4SC-202 for melanoma has been initiated, while another Phase II study with 4SC-202 for GI cancer should start in Q118. 4SC-208 completes the core portfolio and is expected to enter the clinic in early 2019. Our valuation is largely unchanged at €347m or €11.3/share (€344m previously).

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/15	3.3	(8.4)	(0.59)	0.0	N/A	N/A
12/16	2.1	(10.9)	(0.54)	0.0	N/A	N/A
12/17e	3.4	(12.8)	(0.49)	0.0	N/A	N/A
12/18e	2.7	(16.3)	(0.51)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles and exceptional items.

Pivotal RESMAIN: First DSMB review passed

On 31 January 2018, 4SC reported that an independent data safety monitoring board (DSMB) had recommended the continuation of the ongoing pivotal RESMAIN study with resminostat, a pan-histone deacetylase (HDAC) inhibitor. 4SC remains blinded to the data and efficacy analysis was not part of the review, therefore the continuation without any changes to the protocol was the best possible outcome. Two additional DSMB reviews are planned until the study is fully enrolled with 150 patients. As a reminder, the trial is designed to uniquely position resminostat as a maintenance therapy to make remissions more durable for patients with advanced cutaneous T-cell lymphoma (CTCL) who have achieved remission with systemic therapy (detailed analysis in our last [outlook report](#)). 4SC reiterated that the study is on track for the data read-out in H119.

First patient in Phase Ib/II SENSITIZE with 4SC-202

In November 2017, the first patient has been recruited into a Phase Ib/II study with 4SC-202 in a combination with Keytruda (anti-PD-1, Merck & Co) for patients with unresectable melanoma. 4SC-202, HDAC Class I specific inhibitor, is the company's second lead asset positioned for the use in combinations with checkpoint inhibitors with the rationale to tackle high non-responder issues. Top line results are expected in H218. In another investigator-led Phase II study 4SC-202 will be tested in combination with the anti-PD-L1 antibody avelumab for treating GI tumours. 4SC's plan is to use the insights from these trials for potential partnering discussions in larger oncological indications, while ultimately the company plans to run its own pivotal trial with 4SC-202 in an orphan indication Merkel-cell carcinoma.

Valuation: Marginally higher at €347m or €11.3/share

Our new rNPV-based valuation is slightly increased to €345m or €11.3/share versus €344m or €11.2/share previously, as a lower cash position was offset by rolling our model forward. We keep all our assumptions for the assets unchanged. Following the €41m gross capital raise in July 2017, 4SC is funded into FY20 on current forecasts and past a number of potential key inflection points (see overleaf).

Valuation and financials

Our updated rNPV-based valuation is marginally higher at €347m or €11.3/share compared to €344m or €11.2/share previously, as a lower cash position (we use our estimate for end-2017) was offset by rolling our model forward. We maintain all our assumptions for the risk-adjusted NPV valuation of the assets unchanged, as summarised in our last [outlook report](#).

Exhibit 1: Risked NPV valuation

Product	Indication	Partner	Launch	Peak sales, €m	NPV (€m)	Probability of success	rNPV (€m)	rNPV/share (€)
Core assets/indications								
Resminostat	Maintenance CTCL		2021	216	532.5	50%	266.3	8.7
4SC-202	r/r MCC		2022	237	219.0	20%	43.8	1.4
4SC-208	Advanced BCC		2023	386	380.3	5%	19.0	0.6
Out-licensed assets/indications								
Resminostat	Biliary tract cancer	Yakult Honsha	2024	149	35.2	20%	15.4	0.5
4SC-205		Link Health			31.9	3%	11.1	0.4
Kv1.3 inhibitors		Maruho			57.5	3%	10.3	0.3
R&D expenses					(46.5)		(46.5)	(1.5)
Admin expenses					(9.3)		(9.3)	(0.3)
Net cash (end-2017)					36.5		36.5	1.2
Total					1,237.2		346.7	11.3

Source: Edison Investment Research

4SC will report its FY17 results on 28 March 2018. In December 2017, 4SC announced that it had received “a single digit million euros” milestone payment from Immunic. The payment relates to a deal signed in September 2016, when 4SC passed the rights for a non-core immunology portfolio of preclinical stage assets to Immunic (deal details not disclosed). While the specific amount received has not been disclosed, we include €1m in our financial estimates in Q417. We make no other changes to our estimates as detailed in the outlook report).

Following the €41m gross (estimated €40m net) capital raise in July 2017, 4SC is well-funded (into FY20 on current forecasts), which should enable it to execute on progressing its pipeline. A number of potential key inflection points over the next three to four years are expected, including:

2018

- initiation of the next trial with **resminostat** in biliary tract cancer by Yakult;
- data read-out from Phase Ib/II study with **4SC-202** in melanoma in H218 (first patient in Q417);

2019

- CTCL pivotal RESMAIN study with **resminostat** data read-out in H119;
- starting Phase II study with **4SC-202** in Q118 in GI cancer (investigator-led), data readout in H219;

2020

- **4SC-208** entering the clinic in Q119, data read-out in 2020;

2021

- pivotal study with **4SC-202** following on from melanoma and GI cancer studies in MCC in Q119, data readout 2021.

Exhibit 2: Financial summary

	€'000s	2015	2016	2017e	2018e
Year end 31 December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		3,266	2,060	3,369	2,724
Cost of sales		(1,763)	(76)	(202)	(163)
Gross profit		1,503	1,984	3,167	2,561
R&D expenditure		(7,255)	(10,601)	(14,000)	(16,800)
Administrative, distribution and other		(3,163)	(3,175)	(3,022)	(3,113)
Operating profit		(8,915)	(11,792)	(13,855)	(17,352)
Intangible amortisation		(827)	(892)	(892)	(892)
Exceptionals (impairment / restructuring costs)		0	0	0	0
Share-based payments		2	0	(20)	(20)
EBITDA		(7,914)	(10,900)	(12,718)	(16,215)
Operating profit (before amort and except.)		(8,090)	(10,900)	(12,943)	(16,440)
Net interest		(331)	(14)	150	100
Other (profit/loss from associates)		58	711	711	711
Profit before tax (norm)		(8,421)	(10,914)	(12,793)	(16,340)
Profit before tax (FRS 3)		(9,188)	(11,095)	(12,994)	(16,541)
Tax		(40)	(71)	0	0
Profit after tax (norm)		(8,403)	(10,274)	(12,082)	(15,629)
Profit after tax (FRS 3)		(9,228)	(11,166)	(12,994)	(16,541)
Average number of shares outstanding (m)		14.3	19.0	24.8	30.6
EPS - normalised (€)		(0.59)	(0.54)	(0.49)	(0.51)
EPS - FRS 3 (€)		(0.64)	(0.59)	(0.52)	(0.54)
Dividend per share (€)		0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed assets		11,077	7,096	6,214	5,357
Intangible assets		9,123	6,499	5,667	4,835
Tangible assets		357	222	172	147
Investments and other		1,597	375	375	375
Current assets		22,415	11,959	38,449	22,299
Stocks		20	0	0	0
Debtors		94	95	95	95
Cash		21,476	10,048	36,538	20,388
Other current assets		817	1,816	1,816	1,816
Current liabilities		(5,593)	(3,257)	(3,511)	(3,188)
Creditors		(688)	(834)	(834)	(834)
Short-term borrowings		(1,962)	0	0	0
Deferred revenue (short term)		(1,779)	(1,431)	(1,685)	(1,362)
Other current liabilities		(1,164)	(992)	(992)	(992)
Long-term liabilities		(1,471)	(525)	(32)	(32)
Long-term borrowings		0	0	0	0
Deferred revenue (long term)		(1,433)	(493)	0	0
Other long-term liabilities		(38)	(32)	(32)	(32)
Net assets		26,428	15,273	41,120	24,435
CASH FLOW					
Operating cash flow		(8,916)	(12,320)	(12,479)	(15,893)
Net interest		(2)	(531)	4	3
Tax		(40)	(71)	0	0
Capex		(109)	(404)	(175)	(200)
Expenditure on intangibles		(114)	(60)	(60)	(60)
Acquisitions/disposals		0	2,808	0	0
Financing		27,608	0	39,200	0
Other		4,333	650	0	0
Net cash flow		22,760	(9,928)	26,490	(16,150)
Opening net debt/(cash)		3,246	(19,514)	(10,048)	(36,538)
HP finance leases initiated		0	0	0	0
Other		0	462	(0)	0
Closing net debt/(cash)		(19,514)	(10,048)	(36,538)	(20,388)

Source: Edison Investment Research, 4SC accounts

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