EDISON

4SC

FY17 results

Yakult joined the pivotal RESMAIN study

Pharma & biotech

Together with its Q417 results announced last week, 4SC also reported progress with its R&D activities. All three lead assets – resminostat, 4SC-202 and 4SC-208 – remain on course to be developed for specialty dermato-oncological indications. New details include an update on the 4SC-202 development plan and the news that 4SC's Japanese partner, Yakult Honsha, joined 4SC's pivotal resminostat study and will enrol patients in Japan. Our valuation is largely unchanged at €349m or €11.4/share (€11.3/share previously).

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	2.1	(10.9)	(0.54)	0.0	N/A	N/A
12/17	4.2	(10.0)	(0.41)	0.0	N/A	N/A
12/18e	4.7	(17.6)	(0.57)	0.0	N/A	N/A
12/19e	3.1	(19.2)	(0.63)	0.0	N/A	N/A

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

Resminostat on track for pivotal data readout in H119

A recent major development was the news from 4SC's partner Yakult that it had joined the pivotal RESMAIN study. By enrolling additional patients in Japan, Yakult will be able to submit resminostat for approval, assuming the data are positive. In our view, this indicates an external validation of 4SC's R&D strategy. Resminostat (a broad-spectrum histone deacetylase [HDAC] inhibitor) is uniquely positioned 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. Timelines remain unchanged for the study to report data in H119. Yakult is also committed to initiate the next Phase II trial with resminostat in biliary tract cancer patients in Japan after it reported positive data from a Phase I trial.

Broad development plan for 4SC-202

4SC has a broad development plan for its second lead product 4SC-202 (HDAC Class I specific inhibitor) positioned to be used in combination with checkpoint inhibitors with the rationale to tackle the high non-responder issue. 4SC is running a Phase Ib/II trial SENSITIZE in unresectable melanoma in combination with Keytruda. Final results are expected in H119, but the company plans several interim readouts starting this year. Another investigator-led Phase II study will test 4SC-202 in combination with the anti-PD-L1 antibody avelumab for treating GI tumours. Beyond SENSITIZE and EMERGE, the company sees potential for 4SC-202 in other solid tumours and plans to explore this in several other Phase II trials in combination with checkpoint inhibitors. 4SC will use the insights from these trials for potential partnering discussions, while ultimately the company plans to run its own pivotal trial with 4SC-202 in an orphan indication Merkel-cell carcinoma.

Valuation: Marginally upped to €349m or €11.4/share

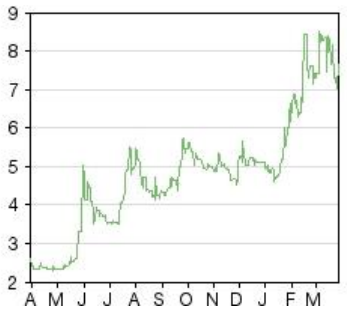
We have updated our rNPV-based valuation which is now €349m or €11.4/share versus €345m or €11.3/share previously, due to rolling our model forward. We keep all our assumptions for the assets unchanged. First interim data from both SENSITIZE and EMERGE studies are expected later this year.

28 March 2018

Price	**€7.47**
Market cap	**€229m**

Net cash (€m) at 31 December 2017	41.3
Shares in issue	30.7m
Free float	30%
Code	VSC
Primary exchange	Frankfurt (Xetra)
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	3.0	54.2	187.6
Rel (local)	7.4	68.4	188.2
52-week high/low		€8.5	€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

Initiation Phase II trial with resminostat in biliary tract cancer by Yakult	H118
Initiation of EMERGE study	H118
Top-line data from SENSITIZE study	H218
Safety data from EMERGE study	H218

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Financials and valuation

Total FY17 revenues of €4.2m were ahead of our estimate of €3.4m and included income from services, changes in deferred income accounting and smaller milestone payments, including "a single digit million euros" milestone from Immunic as announced in December 2017. Total operating expenses of €14.6m were better than our expected €17.0m mainly due to lower R&D spend of €11.5m (our estimate €14.0m). 4SC guided a monthly cash burn of €1.2-1.4m for 2017, but due to the deferral of clinical expenses from 2017 into 2018, this measure was better than expected at €723k.

Following the postponed clinical costs we have revised our estimates and now forecast FY18 R&D spend of €19.6m compared with €16.8m previously, while our FY18 G&A estimate is little changed at €3.2m. The cash position at the year-end was €41.3m. After fine-tuning the estimates, our model is in line with 4SC's updated guidance of monthly cash burn of €1.8-2.0m for FY18.

4SC received a milestone payment from Yakult after it had joined the RESMAIN study. While the specific amount has not been not disclosed, we include €2m in our financial estimates in H118. The existing cash should be sufficient to fund operations until FY20.

Our updated rNPV-based valuation is marginally higher at €349m or €11.4/share compared to €345m or €11.3/share previously. All our assumptions for the risk-adjusted NPV valuation of the assets are 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	548.5	50%	274.2	8.9
4SC-202	r/r MCC		2022	237	222.4	20%	44.5	1.5
4SC-208	Advanced BCC		2023	386	386.2	5%	19.3	0.6
Out-licensed assets/indications								
Resminostat	Biliary tract cancer	Yakult Honsha	2024	149	36.2	20%	15.9	0.5
4SC-205		Link Health			32.4	3%	11.3	0.4
Kv1.3 inhibitors		Maruho			58.4	3%	10.5	0.3
R&D expenses					(54.0)		(54.0)	(1.8)
Admin expenses					(10.0)		(10.0)	(0.3)
Net cash (as of 20 March 2018)					37.0		37.0	1.2
Total					**1,257.2**		**348.7**	**11.4**

Source: Edison Investment Research

Upcoming newsflow, within cash reach

2018

- First data read-out from Phase Ib/II SENSITIZE study in melanoma (**4SC-202** with pembrolizumab) in H218 (first patient in Q417)
- Completion of recruitment to **resminostat** pivotal RESMAIN CTCL study
- Initiation of the next Phase II trial with **resminostat** in biliary tract cancer by Yakult in H118
- Initiation of Phase II EMERGE study (**4SC-202** with avelumab) in H118, and safety data expected H218
- Data from preclinical studies with **4SC-202** in combination with checkpoint inhibitors published at oncological conferences in 2018

- Expected initiation of additional **4SC-202** checkpoint combination studies, including the first triple combination therapy study in collaboration with a new partner
- At least one new non-core asset licensing/partnering deal

2019

- CTCL pivotal RESMAIN study with **resminostat** data read-out in H119
- Final data read-out from Phase Ib/II SENSITIZE study
- Interim data from Phase II EMERGE study

2020

- **4SC-208** entering the clinic in Q119, data read-out in Q419/Q120

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	2017	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	3,266	2,060	4,197	4,724	3,133
Cost of sales	(1,763)	(76)	(574)	(574)	(574)
Gross profit	1,503	1,984	3,623	4,150	2,559
R&D expenditure	(7,255)	(10,601)	(11,475)	(19,555)	(19,461)
Administrative, distribution and other	(3,163)	(3,175)	(3,084)	(3,195)	(3,289)
Operating profit	(8,915)	(11,792)	(10,936)	(18,600)	(20,191)
Intangible amortisation	(827)	(892)	(892)	(892)	(892)
Exceptionals (impairment / restructuring costs)		0	0	0	0
Share-based payments	2	0	0	(20)	(20)
EBITDA	(7,914)	(10,900)	(9,819)	(17,463)	(19,054)
Operating profit (before amort and except.)		(8,090)	(10,900)	(10,044)	(17,688)
Net interest	(331)	(14)	9	100	100
Other (profit/loss from associates)	58	711	0	0	0
Profit before tax (norm)	(8,421)	(10,914)	(10,035)	(17,588)	(19,179)
Profit before tax (FRS 3)	(9,188)	(11,095)	(10,927)	(18,500)	(20,091)
Tax	(40)	(71)	(33)	0	0
Profit after tax (norm)	(8,403)	(10,274)	(10,068)	(17,588)	(19,179)
Profit after tax (FRS 3)	(9,228)	(11,166)	(10,960)	(18,500)	(20,091)
Average number of shares outstanding (m)		14.3	19.0	24.8	30.6
EPS - normalised (€)	(0.59)	(0.54)	(0.41)	(0.57)	(0.63)
EPS - FRS 3 (€)	(0.64)	(0.59)	(0.44)	(0.60)	(0.66)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed assets	11,077	7,096	6,365	5,452	4,539
Intangible assets	9,123	6,499	5,694	4,806	3,918
Tangible assets	357	497	570	545	520
Investments and other	1,597	100	101	101	101
Current assets	22,415	11,959	41,548	22,957	4,522
Stocks	20	0	0	0	0
Debtors	94	95	30	30	30
Cash	21,476	10,048	41,327	22,736	4,301
Other current assets	817	1,816	191	191	191
Current liabilities	(5,593)	(3,257)	(2,759)	(3,636)	(2,840)
Creditors	(688)	(834)	(1,175)	(1,175)	(1,175)
Short-term borrowings	(1,962)	0	0	0	0
Deferred revenue (short term)	(1,779)	(1,431)	(1,485)	(2,362)	(1,566)
Other current liabilities	(1,164)	(992)	(99)	(99)	(99)
Long-term liabilities	(1,471)	(525)	(461)	(511)	(486)
Long-term borrowings	0	0	0	0	0
Deferred revenue (long term)	(1,433)	(493)	(394)	(444)	(419)
Other long-term liabilities	(38)	(32)	(67)	(67)	(67)
Net assets	26,428	15,273	44,693	24,263	5,735
CASH FLOW					
Operating cash flow	(8,916)	(12,320)	(8,508)	(18,390)	(18,234)
Net interest	(2)	(531)	0	3	3
Tax	(40)	(71)	(33)	0	0
Capex	(109)	(404)	(168)	(200)	(200)
Expenditure on intangibles	(114)	(60)	(4)	(4)	(4)
Acquisitions/disposals	0	2,808	39	0	0
Financing	27,608	0	39,953	0	0
Other	4,333	650	0	0	0
Net cash flow	22,760	(9,928)	31,279	(18,591)	(18,435)
Opening net debt/(cash)	3,246	(19,514)	(10,048)	(41,327)	(22,736)
HP finance leases initiated	0	0	0	0	0
Other	0	462	0	0	0
Closing net debt/(cash)	(19,514)	(10,048)	(41,327)	(22,736)	(4,301)

Source: Company accounts, Edison Investment Research

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