EDISON

Scandion Oncology

Proof-of-concept data elusive

Clinical trial update

Pharma and biotech

Top-line results from part 2 of the Phase II CORIST trial in metastatic colorectal cancer (mCRC) were disappointing for Scandion, as the SCO-101/FOLFIRI combination failed to reach the 30% tumour reduction threshold. Despite this, SCO-101 did show indications of efficacy and the company intends to begin enrolment for CORIST part 3 in Q322, which will investigate a new dosing regimen in a larger patient population to fully evaluate SCO-101's utility. We continue to estimate a cash runway for the company into FY24; however, as proof-of-concept data have been elusive so far, we expect the company will need to raise capital by end-2023/early FY24 to continue clinical development. Considering CORIST part 2 results, we have reduced our valuation of Scandion Oncology to SEK279.0m or SEK6.9 per share, from SEK609.5m or SEK15.0 per share previously.

Year end	Revenue (DKKm)	PBT* (DKKm)	EPS* (DKK)	DPS (DKK)	P/E (x)	Yield (%)
12/20	1.0	(21.5)	(0.53)	0.0	N/A	N/A
12/21	0.8	(57.2)	(1.61)	0.0	N/A	N/A
12/22e	0.8	(64.9)	(1.66)	0.0	N/A	N/A
12/23e	0.8	(82.4)	(1.89)	0.0	N/A	N/A

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

SCO-101 development continues

While clinical proof-of-concept has not yet been demonstrated for SCO-101, management is continuing with its planned clinical development programme. CORIST part 3 will investigate an optimised dosing protocol, which, in our view, may have potential for increased efficacy (to be assessed in part 4). Additionally, we see the continued demonstration of SCO-101's safety and tolerability as encouraging support for higher dosing regimens.

Funding sufficient for part 3, PANTAX

Our estimates for FY22 and FY23 and cash runway to FY24 are unchanged. Our estimated runway will see the company past key readouts from the PANTAX and CORIST (part 3) trials. However, we now expect final CORIST results in mid- to late FY24. We estimate a licensing deal will be found for SCO-101 in 2026 (previously 2024), assuming future clinical results are positive. We estimate the company will need to raise funds (c DKK200m, SEK288m) by end-FY23/early-FY24 to fund development to FY26.

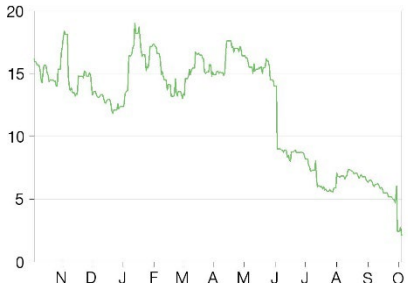
Valuation: SEK279.0m or SEK6.9 per share

We value Scandion Oncology at SEK279.0m or SEK6.9 per share (previously SEK609.5m or SEK15.0 per share). The reduction in our valuation comes as we reduce the probability of success for SCO-101 in mCRC to 10% from 20% and in pancreatic cancer (PC) to 10% from 15%, following CORIST part 2 data. Furthermore, we have adjusted our timeline assumptions and our mCRC patient population estimates to include mutant RAS patients, which is offset by a decreased peak penetration estimate.

5 October 2022

Price	**SEK2.08**
Market cap	**SEK85m**
	SEK11.1:US$; SEK1.46:DKK
Net cash (DKKm) at end-Q222 (pre-July rights issue)	72.7
Shares in issue	40.7m
Free float	74%
Code	SCOL
Primary exchange	Nasdaq First North Growth Market
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(67.9)	(72.9)	(87.3)
Rel (local)	(66.8)	(72.8)	(84.1)
52-week high/low	SEK19.0		SEK2.1

Business description

Scandion Oncology is a biotechnology company focused on the development of add-on therapies to reverse chemotherapy resistance in oncology. The company's lead asset, SCO-101, is in Phase II trials for mCRC and Phase Ib trials for pancreatic cancer.

Next events

PANTAX top-line data	Q123
CORIST part 3 top-line data	Q323

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CORIST part 2 results

As a reminder, CORIST part 2 was a Phase II trial investigating the efficacy of the SCO-101 in combination with FOLFIRI in mCRC patients harbouring wild-type RAS. The primary endpoint for the study was objective response rate (ORR), defined as complete response and partial response using RECIST v 1.1. Secondary endpoints included progression free survival (PFS), duration-of-response, overall survival (OS) and biomarker analysis. While management has reported that results from part 2 confirmed the safety and tolerability of the SCO-101/FOLFIRI combination in mCRC patients, the trial failed to reach the +30% tumour reduction threshold defined as its primary endpoint. The combination did, however, show evidence of tumour reduction, with prolonged PFS and stable disease.

With the CORIST part 2 results announced, the company will continue with its development timeline for SCO-101 in mCRC. Part 3 of the CORIST study will investigate the safety and tolerability of new, optimised dosing regimens and will inform Part 4, which will investigate the efficacy of the chosen dose. While the results of CORIST part 2 are disappointing for Scandion, we note that patients have continued treatment past the eight-week endpoint and longer-term results will be important in definitively assessing efficacy.

Part 3 to optimised dosing, part 4 to follow

Following top-line date from CORIST part 2, Scandion intends to begin enrolment for CORIST part 3, which will investigate use of the SCO-101/FOLFIRI combination in both mutant and wild-type RAS mCRC patients. As discussed in a brief company update, the trial will enrol up to 36 patients and aims to identify a new dosing schedule (based on pharmacokinetic and pharmacodynamic data from CORIST part 1 and 2), using a dose-escalation [3+3] design. SCO-101 in combination with FOLFIRI will be administered once daily on days one to six and FOLFIRI administered on days two to four of each treatment cycle. The company expects this protocol could be more efficacious than previous regimens. We expect top-line results from part 3 to be reported in Q323. However, this may vary as patient enrolment depends on the observed safety profiles of the new dosing protocols. CORIST part 4, which we expect could begin as soon as Q323 (subject to part 3 enrolment), will then assess the efficacy of the optimised SCO-101/FOLFIRI dosing protocol (n=24) identified in part 3. We expect part 4 will use a similar trial design to that used in part 2 and will run for six months, bringing the earliest potential top-line readout to Q224. Management will provide an update on clinical timelines in Q123.

As evidence of efficacy was observed in CORIST part 2, exploring new dosing regimens of SCO-101/FOLFIRI is an attractive strategy for Scandion, in our view. Additionally, the drug has consistently demonstrated a good safety profile, suggesting higher doses and potentially better efficacy may be tolerated. However, we note that higher doses do not always correlate with increased efficacy and may result in undesirable side effects.

Next catalyst: PANTAX top-line data

We see Phase Ib PANTAX data in PC (expected in H123) as the next key catalyst for Scandion. If the SCO-101/gemcitabine/paclitaxel combination being studied can show signs of efficacy in the PANTAX trial, we expect this will increase confidence in management's development plans in mCRC. We note, however, that as SCO-101's proposed mechanism of action in mCRC and PC are the same, there could be potential read-across between the two indications. The trial will primarily assess the safety and tolerability of the SCO-101/gemcitabine/paclitaxel combination; however, secondary endpoints, including ORR, PFS, OS and pharmacokinetic profile, will be a crucial focus, in our view, following the CORIST part 2 data.

Preclinical platform to bolster clinical pipeline

In addition to its clinical development programme, Scandion is conducting preclinical studies for the use of SCO-101 in double combination with chemotherapy and immunotherapy. In a setting (oncology) where many higher lines of treatment are dominated by immune checkpoint inhibitors, we see this as a natural progression for the company. In addition, a second oral efflux pump inhibitor, known as SCO-201, is being evaluated in preclinical studies for the treatment of solid tumours. We anticipate the company will continue to progress assets towards clinical development, thus demonstrating its ability to create value from its drug discovery platform.

Valuation

Considering recent events, we have reduced our valuation of Scandion Oncology to SEK279.0m or SEK6.9 per share from SEK609.5m or SEK15.0 per share. Our valuation is based on a risk-adjusted NPV calculation for SCO-101 in mCRC and PC (applying a 12.5% discount rate) and reflects an estimated net cash position of DKK114m at 30 June 2022 (including estimated net proceeds of the July 2022 SEK75m gross rights issue). The company's value is reduced as we lower the probability of success for SCO-101 in mCRC to 10% (previously 20%) and in PC to 10% (previously 15%). We believe the failure to reach proof-of-concept in CORIST part 2 could have read-across to potential efficacy readouts in the PANTAX trial, hence our lower probability of success in both indications. Scandion will continue developing SCO-101 in CORIST part 3 and 4, bringing the earliest potential end of the CORIST programme (and Phase II development) to Q224. Therefore, we have delayed our estimated potential launch date for SCO-101 in mCRC to 2028, from 2026 previously. We now assume a potential full licensing deal for SCO-101 is signed in 2026 (previously 2024).

As part 3 and 4 will investigate SCO-101 in both mutant and wild-type RAS patients, we have incorporated this new patient population into our model (previously we only included wild-type patients). However, considering this large increase in patient population (c 50% of mCRC patients harbour mutant RAS) and in light of the recent CORIST part 2 data, we have lowered our peak penetration estimate for SCO-101 to 10% (20% previously) in mCRC and to 10% from 15% in PC. Our remaining valuation assumptions are detailed in our initiation report. A breakdown of our valuation is shown in Exhibit 1.

Exhibit 1: Scandion Oncology valuation

Product	Indication	Launch	Peak	Peak sales ($m)	Value (SEKm)	Probability	rNPV (SEKm)	rNPV/ share (SEK)
SCO-101	mCRC	2028	2032	297.3	1,114.8	10%	51.3	1.3
SCO-101	PC	2029	2033	456.7	1,113.3	10%	60.5	1.5
Pro-forma net cash at 30 June 2022 (estimated after July 2022 raise)					167.1	100%	167.1	4.1
Valuation					**2,395.2**		**279.0**	**6.9**

Source: Edison Investment Research

Financials

As management's near-term clinical development plan for SCO-101 is largely unchanged by the recent CORIST part 2 data, our FY22 and FY23 financial estimates are unchanged and we continue to estimate that Scandion is sufficiently funded into FY24. As described in our prior note, Scandion had an H122 net cash position of DKK72.7m and in July 2022 it completed a rights issue, raising gross proceeds of c SEK75m. Based on estimated transaction costs of SEK17m (DKK12m), we estimate it resulted in a net cash injection of c SEK58m (DKK41m).

However, we now assume a licensing deal for SCO-101 will be delayed to 2026 (previously 2024), as we expect the company will still need to generate positive randomised data in a Phase II/III trial before a licensing deal is viable. We now estimate the company will need to raise capital by end-2023/early-2024 to fund the longer-term development of SCO-101. Our model suggests c DKK200m (SEK288m) would be sufficient to fund the company's operations to into FY26 where we anticipate a licensing deal for SCO-101 is agreed.

Our cash runway estimate will see the company past key top-line data readouts from the Phase Ib PANTAX trial (expected H123) and the newly initiated Phase II CORIST part 3. If enrolment for Part 3 is started quickly, then current funds may see the company past part 4. However, if part 3 enrolment is delayed, our estimates indicate Scandion will need additional funds to complete part 4 of the CORIST study and SCO-101's Phase II development. If timelines are delayed, or clinical data prove positive, this may lead us to revise our cash runway estimate. Our model assumes illustrative debt funding of c DKK200m in early FY24.

Exhibit 2: Financial summary

Accounts: IFRS, year-end: 31 December, DKK'000s	2020	2021	2022e	2023e
PROFIT & LOSS				
Total revenues	1,003	797	797	797
Cost of sales	0	0	0	0
Gross profit	1,003	797	797	797
Total operating expenses	(24,758)	(56,164)	(65,160)	(83,165)
Research and development expenses	(21,672)	(47,711)	(52,480)	(70,485)
SG&A	(3,086)	(8,453)	(12,680)	(12,680)
EBITDA (normalized)	(23,474)	(54,763)	(63,980)	(82,098)
Operating income (reported)	(23,755)	(55,367)	(64,363)	(82,368)
Operating margin %	N/A	N/A	N/A	N/A
Finance income/(expense)	2,233	(1,846)	(576)	0
Exceptionals and adjustments	0	0	0	0
Profit before tax (reported)	(21,522)	(57,213)	(64,939)	(82,368)
Profit before tax (normalised)	(21,522)	(57,213)	(64,939)	(82,368)
Income tax expense (includes exceptionals)	4,384	5,508	5,500	5,500
Net income (reported)	(17,138)	(51,705)	(59,439)	(76,868)
Net income (normalised)	(17,138)	(51,705)	(59,439)	(76,868)
Basic average number of shares, m	32.1	32.1	35.9	40.7
Basic EPS (DKK)	(0.53)	(1.61)	(1.66)	(1.89)
Adjusted EPS (DKK)	(0.53)	(1.61)	(1.66)	(1.89)
Dividend per share (DKK)	0.00	0.00	0.00	0.00
BALANCE SHEET				
Tangible assets	136	386	338	418
Intangible assets	0	0	0	0
Right-of-use assets	312	1,215	789	789
Other non-current assets	148	314	290	290
Non-current tax receivables	0	0	5,500	5,500
Total non-current assets	596	1,915	6,917	6,997
Cash and equivalents	5,814	105,710	81,529	3,095
Current tax receivables	4,384	5,500	5,500	5,500
Trade and other receivables	1,414	2,018	1,748	1,748
Other current assets	174,513	1,076	787	787
Total current assets	186,125	114,304	89,564	11,130
Non-current loans and borrowings	8	0	0	0
Non-current lease liabilities	0	500	500	500
Other non-current liabilities	504	84	1,390	1,390
Total non-current liabilities	512	584	1,890	1,890
Accounts payable	26,064	4,580	10,954	10,954
Illustrative debt	0	0	0	0
Current lease obligations	316	723	305	305
Other current liabilities	3,962	5,791	6,810	6,810
Total current liabilities	30,342	11,094	18,069	18,069
Equity attributable to company	155,867	104,541	76,522	(1,831)
CASH FLOW STATEMENT				
Operating income	(23,755)	(55,367)	(64,363)	(82,368)
Depreciation and amortisation	281	604	382	270
Share based payments	0	0	0	0
Other adjustments	4,223	2,899	5,303	4,015
Movements in working capital	2,024	2,066	(5,815)	0
Cash from operations (CFO)	(17,227)	(49,798)	(64,492)	(78,083)
Capex	(46)	(318)	(334)	(351)
Acquisitions & disposals net	0	(167)	25	0
Other investing activities	0	0	0	0
Cash used in investing activities (CFIA)	(46)	(485)	(309)	(351)
Capital changes	7,892	150,690	41,000	0
Debt Changes	0	0	0	0
Other financing activities	(226)	(511)	(380)	0
Cash from financing activities (CFF)	7,666	150,179	40,620	0
Cash and equivalents at beginning of period	15,421	5,814	105,710	81,529
Increase/(decrease) in cash and equivalents	(9,607)	99,896	(24,181)	(78,434)
Effect of FX on cash and equivalents	0	0	0	0
Cash and equivalents at end of period	5,814	105,710	81,529	3,095
Net (debt)/cash	5,806	105,710	81,529	3,095

Source: Scandion Oncology, Edison Investment Research

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