

Cantargia

Q218 company update

Phase IIa set to start in Q418

Cantargia continues to progress its main R&D programme, a Phase I/IIa CANFOUR trial with its lead drug candidate, which was given its official generic name nidanilimab (CAN04 previously) in June. Cantargia reported no concerning side effects from the first 15 patients in the Phase I part of the CANFOUR trial. As the maximum tolerated dose has not been reached, this part will enrol several more patients, although Phase IIa should still start in Q418, as planned. Our valuation is slightly higher at SEK1.79bn or SEK27.1/share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/16	0.0	(47.5)	(2.72)	0.0	N/A	N/A
12/17	0.0	(60.3)	(1.86)	0.0	N/A	N/A
12/18e	0.0	(83.3)	(1.47)	0.0	N/A	N/A
12/19e	0.0	(93.5)	(1.41)	0.0	N/A	N/A

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

Phase IIa likely to start in Q418 as planned

Nidanilimab is a fully humanised, dual-action IgG1 antibody that targets IL1RAP and also has an antibody-dependent cellular cytotoxicity (ADCC) effect. In August 2018, Cantargia reported progress with its lead programme Phase I/IIa CANFOUR trial which tested nidanilimab in patients with various solid cancers (non-small cell lung cancer, pancreatic cancer, colorectal cancer or triple negative breast). The announcement focused on the Phase I part of the trial, which is a typical 3x3 dose escalation used to establish safety and the recommended dose for Phase IIa. In total 15 patients have been enrolled and in general, nidanilimab was well tolerated. As of the announcement date, the maximum tolerated dose has not been reached. Therefore, Cantargia will enrol several more patients before continuing to Phase IIa in Q418, as expected.

CANFOUR results early 2020

In the near term Cantargia will focus on the Phase IIa part of the trial and will look at the efficacy of nidanilimab in NSCLC and pancreatic cancer specifically. It will include three arms which, in total, will recruit around 60-80 patients. Nidanilimab will be tested as a monotherapy or in combination with standard of care therapies for respective cancers (Exhibit 2): in NSCLC with cisplatin/gemcitabine in patients not previously treated with chemotherapy and in pancreatic cancer with gemcitabine/nab-paclitaxel. The recruitment to Phase IIa will take 12 months with results potentially available in early 2020. In the case of a positive data readout, Cantargia is open to various pathways for further development including an out-licensing deal.

Valuation: SEK1.79bn or SEK27.1/share

We value Cantargia at SEK1.79bn (SEK213m in cash) or SEK27.1/share, slightly higher than our previous SEK1.64bn or SEK24.8/share, mainly due to rolling our model forward and a positive forex effect. We make no changes to our assumptions. The near-term catalyst is the final safety results from the Phase I part of the CANFOUR trial in Q418.

Pharma & biotech

13 September 2018

Price **SEK19.05**

Market cap **SEK1261m**

US\$:SEK9.11

Estimated net cash (SEKm) at end Q218 213

Shares in issue 66.2

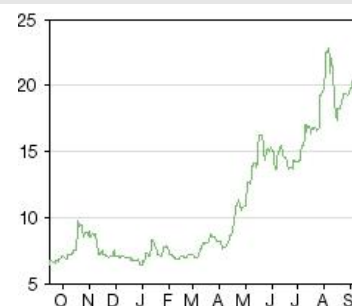
Free float 90%

Code CANT

Primary exchange Nasdaq Stockholm
First North

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (11.4) 23.7 182.0

Rel (local) (11.5) 19.8 166.6

52-week high/low SEK22.8 SEK6.4

Business description

Cantargia is a clinical stage biotechnology company based in Sweden, established in 2009 and listed on Nasdaq Stockholm First North in 2015. It is developing two antibodies against IL1RAP, CAN04 and CANxx. CAN04 is being studied in a Phase I/II CANFOUR in solid tumours focusing on NSCLC and pancreatic cancer.

Next events

Final results from Phase I of CANFOUR Q418

Start of Phase IIa CANFOUR Q418

Q318 results 15 November 2018

Preclinical data H218

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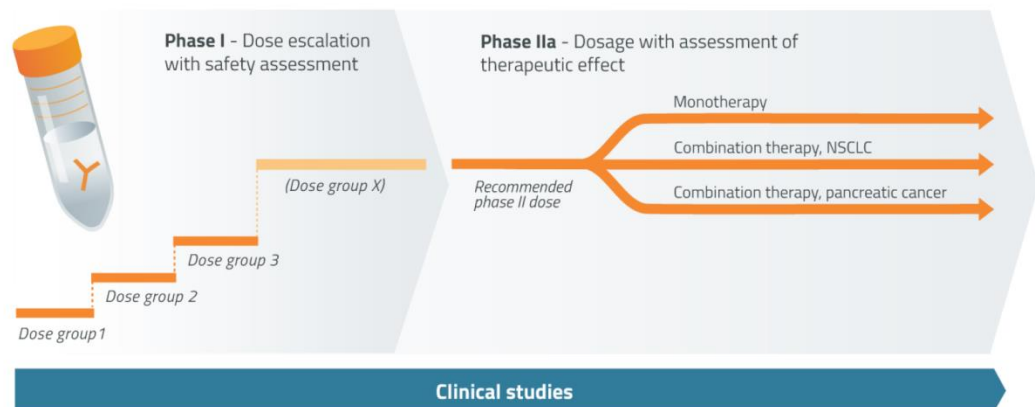
Phase I/IIa CANFOUR design

Exhibit 1: Phase I/IIa CANFOUR design, total n=65

Trial	Stage	Trial status, design and upcoming events
CANFOUR	Phase I	<ul style="list-style-type: none"> Study ongoing (started September 2017) Patients with relapsed or refractory NSCLC, pancreatic cancer, breast cancer or colorectal cancer Design – open label, non-randomised, dose escalation followed by dose expansion, safety and tolerability study. Dose escalation: patients receiving intravenous nidanilimab once weekly in cohorts of three Well tolerated by the first 15 patients; final safety findings in Q418
	Phase IIa	<ul style="list-style-type: none"> Patients with advanced NSCLC or pancreatic cancer Design – open label, non-randomised, three treatment arms: monotherapy; combinations in NSCLC and pancreatic cancer Results early 2020 Primary endpoint – treatment related AEs (safety and tolerability) Secondary endpoints – pharmacokinetic parameters, preliminary signs of efficacy as assessed by tumour response Study sites in EU

Source: Edison Investment Research, Cantargia, clinicaltrials.gov. Note: AEs = adverse events; MTD = maximum tolerated dose.

Exhibit 2: Phase I/IIa



Source: [Cantargia year-end report 2017](#)

Novartis's canakinumab in three Phase III trials

The patients in the Phase IIa CANFOUR trial will be relapsed or refractory, so presenting with an advanced disease. When it comes to clinical setting, it is premature to envision the precise positioning, but due to its differentiated mode of action from other therapies in oncology, nidanilimab has the potential to be used in various combinations and across different stages of the disease (as long as IL-1RAP is [sufficiently expressed](#)). This is supported by Cantargia's newly released [findings](#) (June 2018) that provided a preclinical proof-of-concept for the combination with cisplatin. In an animal model, nidanilimab and cisplatin led to a stronger antitumor effect than a monotherapy using either of the drugs. In addition, the side effects in the combination group were less pronounced than the cisplatin-alone group.

A guide on how wide nidanilimab's application could be recently came from Novartis. As we described in detail in [our initiation report](#), Novartis conducted a large, six-year Phase III trial [CANTOS](#) (n=10,062) with canakinumab to establish the role of IL-1 β inhibition in atherosclerosis in patients who had a history of myocardial infarction. While this is an unrelated area for nidanilimab,

additional analysis by Novartis revealed that IL-1 β inhibition had an effect on cancer incidence in these patients. Compared with the placebo arm, canakinumab **reduced** lung cancer mortality by 77% and reduced lung cancer incidence by 67%. Since canakinumab targets IL-1 β , it acts upstream to nidanilimab and does not affect IL-1 α . Therefore it does not completely abolish IL-1 pathway signalling like nidanilimab does. Theoretically, nidanilimab could have a more robust effect.

Following these findings, Novartis initiated three new Phase III trials. The most recent updates on clinicaltrials.gov show that Novartis will focus on NSCLC patients starting as early as a neo-adjuvant therapy (NCT03447769, n=1,500), to combination with first-line (NCT03631199, n=627) and second-line treatments (NCT03626545, n=240). This shows Novartis's confidence in immediately going for as broad label as possible, in our view. The completion of these trials is estimated in 2021-22.

Financials and valuation

Cantargia's results were largely in line with our expectations. The company reported an operating loss of SEK43.8m in H218, compared to SEK34.3m in H117. The increase was mainly due to higher R&D activities as the CANFOUR trial accelerates, but also due to higher other external expenses (SEK8.6m vs SEK3.2m a year ago). The latter was a consequence of the uplisting process (in July Cantargia was approved to uplist to Nasdaq Stockholm First North Premier). We already expected increasing R&D costs as the trial progresses to Phase IIa, therefore we make no changes to our R&D estimate and we treat the uplisting costs as a one off. Our operating loss estimates for 2018 and 2019 are SEK85.9m (vs SEK80.9m) and SEK93.8m (unchanged) respectively. Cantargia had cash and short-term investments of SEK213m at the end of Q218. According to the company, the operations are now financed until 2020, which is in line with our model.

We value Cantargia based on a risk-adjusted NPV using a 12.5% discount rate, including net cash at end-Q218, which results in a value of SEK1.79bn or SEK27.1/share, slightly higher compared to SEK1.64bn or SEK24.8/share previously, mainly due to rolling our model forward and positive forex effect. We make no changes to our assumptions, which were described in detail in our recent initiation report.

Exhibit 3: Sum-of-the-parts Cantargia valuation							
Product	Launch	Peak sales (\$m)	Unrisked NPV (SEKm)	Unrisked NPV/share (SEK)	Technology probability (%)	rNPV (SEKm)	rNPV/share (SEK)
CAN04 - NSCLC	2026	3,144	5,689.1	86.0	10%	647.4	9.8
CAN04 - pancreatic cancer	2024	2,132	5,753.5	86.9	10%	930.5	14.1
Net cash at end-Q218			212.8	3.2	100%	212.8	3.2
Valuation			11,655.4	176.1		1,790.7	27.1

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations.

Exhibit 4: Financial summary

	SEK'000s	2016	2017	2018e	2019e
December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		0	0	0	0
Cost of Sales		0	0	0	0
Gross Profit		0	0	0	0
Research and development		(35,493)	(44,819)	(65,219)	(77,699)
EBITDA		(47,557)	(60,010)	(85,845)	(93,815)
Operating Profit (before amort. and except.)		(47,557)	(60,010)	(85,845)	(93,815)
Intangible Amortisation		0	0	0	0
Exceptionals		0	0	0	0
Other		0	0	0	0
Operating Profit		(47,557)	(60,010)	(85,845)	(93,815)
Net Interest		67	(243)	2,500	360
Profit Before Tax (norm)		(47,490)	(60,253)	(83,345)	(93,455)
Profit Before Tax (reported)		(47,490)	(60,253)	(83,345)	(93,455)
Tax		0	0	0	0
Profit After Tax (norm)		(47,490)	(60,253)	(83,345)	(93,455)
Profit After Tax (reported)		(47,490)	(60,253)	(83,345)	(93,455)
Average Number of Shares Outstanding (m)		17.5	32.4	56.6	66.2
EPS - normalised (SEK)		(2.72)	(1.86)	(1.47)	(1.41)
EPS - normalised fully diluted (SEK)		(2.72)	(1.86)	(1.47)	(1.41)
EPS - reported (SEK)		(2.72)	(1.86)	(1.47)	(1.41)
Dividend per share (SEK)		0.0	0.0	0.0	0.0
Gross Margin (%)		N/A	N/A	N/A	N/A
EBITDA Margin (%)		N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets		2,662	2,957	2,957	2,957
Intangible Assets		0	0	0	0
Tangible Assets		0	0	0	0
Investments		2,662	2,957	2,957	2,957
Current Assets		35,636	271,126	173,196	79,741
Stocks		0	0	0	0
Debtors		0	0	0	0
Cash		25,904	149,781	61,496	78,041
Other		9,732	121,345*	111,700*	1,700
Current Liabilities		(9,494)	(27,957)	(14,600)	(14,600)
Creditors		(9,494)	(27,957)	(14,600)	(14,600)
Short term borrowings		0	0	0	0
Long Term Liabilities		0	0	0	0
Long term borrowings		0	0	0	0
Other long term liabilities		0	0	0	0
Net Assets		28,804	246,126	161,553	68,098
CASH FLOW					
Operating Cash Flow		(42,405)	(40,860)	(100,787)	(93,815)
Net Interest		67	(243)	2,500	360
Tax		0	0	0	0
Capex		0	0	0	0
Acquisitions/disposals		0	0	0	0
Financing		56,225	304,479	0	0
Other		2,376	(139,499)	10,002	110,000
Dividends		0	0	0	0
Net Cash Flow		16,263	123,877	(88,285)	16,545
Opening net debt/(cash)		(9,641)	(25,904)	(149,781)	(61,496)
HP finance leases initiated		0	0	0	0
Other		0	0	0	(0)
Closing net debt/(cash)		(25,904)	(149,781)	(61,496)	(78,041)

Source: Cantargia's accounts, Edison Investment Research. Note: *Mainly short-term investments.

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