

Cantargia

Nidanilimab transitioning to Phase IIa

Phase I data update

Pharma & biotech

3 January 2019

Price **SEK14.30**

Market cap **SEK947m**

US\$:SEK9.05

Net cash (SEKm) at end Q318 190.7

Shares in issue 66.2m

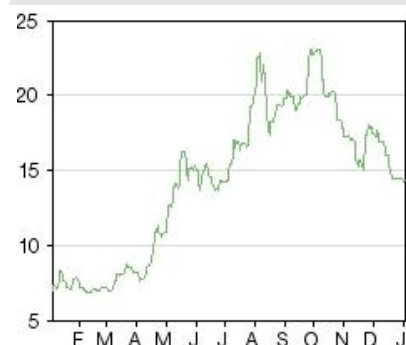
Free float 90%

Code CANT

Primary exchange Nasdaq Stockholm

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (16.9) (37.6) 112.2

Rel (local) (10.9) (27.0) 131.0

52-week high/low SEK23.3 SEK6.6

Business description

Cantargia is a clinical-stage biotechnology company based in Sweden, established in 2009 and listed on Nasdaq Stockholm main market. It is developing two antibodies against IL1RAP, nidanilimab (CAN04) and CANxx. Nidanilimab is being studied in a Phase I/II clinical trial CANFOUR in solid tumours focusing on NSCLC and pancreatic cancer.

Next events

Presentation of the complete Phase I data H119

IND discussions with US FDA H119

Phase IIa CANFOUR data Early 2020

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On 7 December 2018 Cantargia reached an important milestone – the completion of the Phase I part of its Phase I/IIa CANFOUR study with nidanilimab in solid tumours. Patients are now being screened for the Phase IIa part of the study and we expect the first patient to be recruited in the coming weeks, with top-line data expected in early 2020. Cantargia also recently presented fresh pre-clinical data at an antibody conference that support the rationale for developing nidanilimab in combination with chemotherapy. Our valuation has increased to SEK2.28bn or SEK34.5/share reflecting the increased probability of success for nidanilimab.

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	(86.0)	(1.52)	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.

Nidanilimab shown to be safe in all 22 patients

The final dose cohort (10mg/kg) was evaluated for safety and tolerability and Cantargia reported that nidanilimab was safe and well tolerated in all patients. There were no dose-limiting toxicities and the most common side effects were infusion-related reactions. Patients are still being assessed for efficacy and biomarker studies and the complete Phase I data will be presented at a scientific conference in H119. Phase IIa screening has started, with the first patient expected to be recruited in the coming weeks. The Phase IIa will test nidanilimab in a larger number of patients, as monotherapy and in combination with chemotherapy (cisplatin/gemcitabine in non-small cell lung cancer (NSCLC), gemcitabine/nab-paclitaxel in pancreatic cancer). Efficacy and safety will also be assessed. Data are expected in early 2020.

Fresh preclinical data support combination approach

Cantargia recently presented some new pre-clinical data at Antibody Engineering and Therapeutics in San Diego in December 2018. Findings from a syngeneic colorectal cancer mouse model (MC38) support the rationale to study nidanilimab in combination with chemotherapy in its Phase IIa trial, especially because this mouse model has a competent immune system.

Valuation: SEK2.28bn or SEK34.5/share

We value Cantargia at SEK2.28bn or SEK34.5/share compared to our previous valuation of SEK1.80bn or SEK27.2/share due to an increased probability of success for nidanilimab and rolling our model forward. Now that the recommended dose has been established, we have increased the probability of success for nidanilimab from 10% to 15%. We leave all other model assumptions unchanged, as described in our [initiation report](#). Cash and short-term investments were SEK190.7m at the end of Q318, which is expected to cover costs up to 2020.

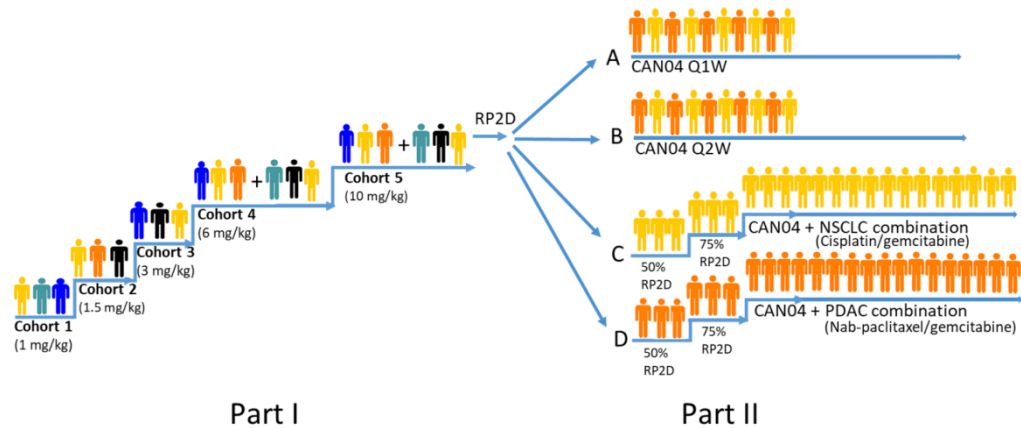
Phase I results: Safety, tolerability, recommended dose

Following the interim data from the Phase I part of the study presented at ESMO conference in October 2018 ([see our last note](#)), Cantargia announced on 7 December that the Phase I part of the study was complete (in terms of the safety and tolerability). A total of 22 patients received weekly infusions of between 1mg/kg and 10mg/kg. The results were in line with the interim results in 16 patients in that nidanilimab appears to be well tolerated at the highest dose (10mg/kg), there were no dose-limiting toxicities at the highest dose and the most common treatment-related adverse event was an infusion-related reaction. Infusion-related [reactions are common](#) with antibody therapies and accepted as part of the treatment as long as they are manageable. Biomarker and efficacy analyses are ongoing and results will be presented with the other data at a conference in H119.

Next steps

With positive safety and tolerability data and the recommended dose, Cantargia can move to the Phase IIa part of the trial. The first patient is expected to be recruited in the coming weeks. The Phase IIa part of the CANFOUR trial will evaluate nidanilimab as monotherapy and in combination with chemotherapy (cisplatin/gemcitabine in NSCLC, gemcitabine/nab-paclitaxel in pancreatic cancer). The dose from Phase I will be used (10mg/kg). The Phase II will test for efficacy signals and further safety. The results are expected 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. Cantargia previously decided to focus on NSCLC and a pancreatic cancer as lead indications based on high IL1RAP expression (pancreatic cancer 86%, NSCLC 85%) and commercial potential.

Exhibit 1: Phase I/IIa



Source: [Cantargia](#). Note: RP2D – recommended dose for Phase II; PDAC - pancreatic ductal adenocarcinoma.

Fresh pre-clinical data support combination approach

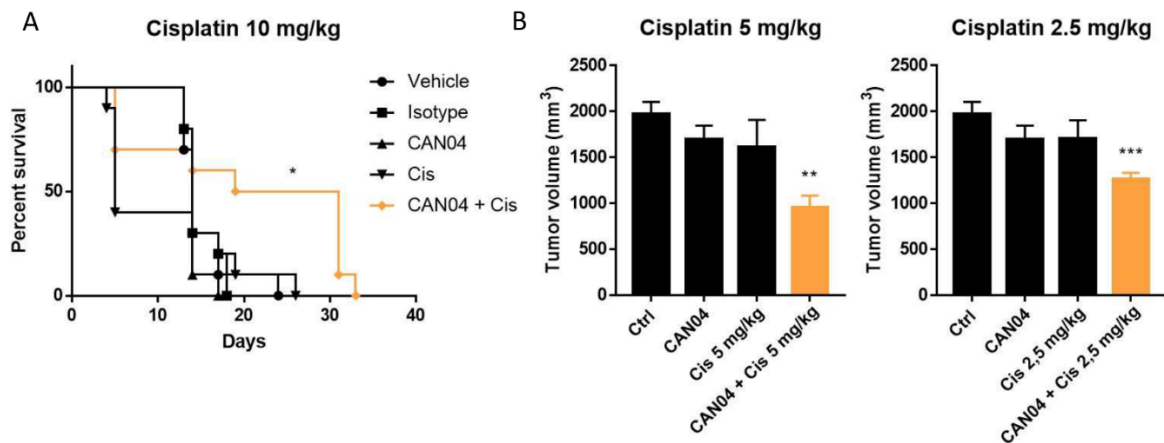
Cantargia presented a poster at Antibody Engineering and Therapeutics in San Diego in December 2018. The poster contained results from pre-clinical studies testing CAN04/CAN04 surrogate antibody 3A9 in combination with cisplatin in two different mouse models. Cisplatin is one of three chemotherapeutic agents that will be tested in combination with nidanilimab in the Phase IIa CANFOUR study (others are gemcitabine and nab-paclitaxel). Cantargia is collecting pre-clinical

data that support the scientific rationale for studying nidanilimab in these particular combinations. These agents are commonly used in the treatment of NSCLC and pancreatic cancer.

Lung cancer PDX mouse model

CAN04 was studied in a patient-derived xenograft model, results of which were [previously announced](#), and now published. Cantargia found that treatment with CAN04 + cisplatin resulted in an increased survival and reduced lung tumour growth vs treatment with cisplatin or CAN04 alone (Exhibit 2).

Exhibit 2: CAN04 monotherapy vs CAN04 + cisplatin combination in a LU2503 PDX mouse model: A) survival curves; B) tumour volume

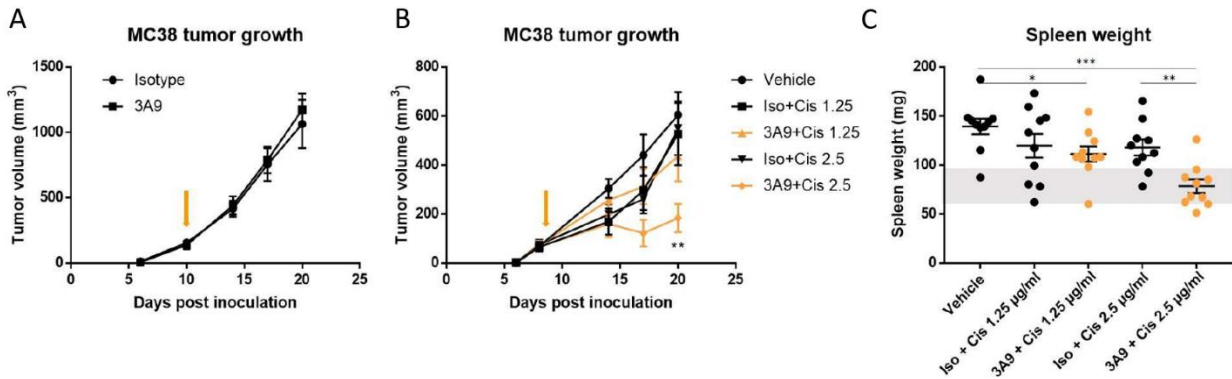


Source: [Cantargia poster presentation December 2018](#)

Syngeneic mouse model

Cantargia also tested a CAN04 surrogate antibody 3A9 in combination with cisplatin in a syngeneic mouse model (MC38 colorectal cancer). Syngeneic models are [more useful](#) for the development of immunotherapies because they allow testing of immunotherapies in a model where the tumour cells can interact with an intact immune system. Cantargia found that the combination of a nidanilimab mouse surrogate antibody 3A9 + cisplatin was much more effective than 3A9 monotherapy at reducing tumour volume and spleen weight (Exhibit 3). This effect was clearly seen with the highest dose of cisplatin, where at 20 days post-inoculation the mice treated with 3A9 + cisplatin 2.5mg/kg had a much lower tumour volume and spleen weight than mice treated with 3A9 + cisplatin 1.25/kg and controls. These pre-clinical data support the rationale to study nidanilimab in combination with chemotherapy in its Phase IIa clinical study, especially because this mouse model has a fully functioning immune system. We believe this model complements the previous xenograft (PDX) mouse model in lung cancer, which is one of the key indications Cantargia is targeting.

Exhibit 3: Studying CAN04 mouse surrogate antibody (3A9) in a MC38 mouse model. A) 3A9 monotherapy B, C) 3A9 + cisplatin combination therapy



Source: [Cantargia poster presentation December 2018](#)

Valuation

We value Cantargia based on a risk-adjusted NPV using a 12.5% discount rate and including net cash at end-Q318, which results in a value of SEK2.28bn or SEK34.5/share vs SEK1.80bn or SEK27.2/share previously. This increase is due to an increased success probability for nidanilimab now that the safety and tolerability part of the Phase I study is concluded (10% to 15%) and rolling our model forward, partially offset by a lower net cash position. We make no other changes to our assumptions, described in detail in our [initiation report](#).

Exhibit 4: 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	3,091	5,785.4	87.4	15%	885.6	13.4
CAN04 - pancreatic cancer	2024	2,100	5,871.1	88.7	15%	1,204.9	18.2
Net cash at end-Q318			190.7	2.9	100%	190.7	2.9
Valuation			11,847.2	179.0		2,281.3	34.5

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

We make no changes to our financial estimates, except a small increase to our 2018 estimate for other external expenses related to the relisting. Cantargia had cash and short-term investments of SEK190.7m at the end of Q318. According to the company, the operations are now financed until 2020, which is in line with our model.

Exhibit 5: 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)	(88,514)	(93,815)
Operating Profit (before amort. and except.)		(47,557)	(60,010)	(88,514)	(93,815)
Intangible Amortisation		0	0	0	0
Exceptionals		0	0	0	0
Other		0	0	0	0
Operating Profit		(47,557)	(60,010)	(88,514)	(93,815)
Net Interest		67	(243)	2,500	360
Profit Before Tax (norm)		(47,490)	(60,253)	(86,014)	(93,455)
Profit Before Tax (reported)		(47,490)	(60,253)	(86,014)	(93,455)
Tax		0	0	0	0
Profit After Tax (norm)		(47,490)	(60,253)	(86,014)	(93,455)
Profit After Tax (reported)		(47,490)	(60,253)	(86,014)	(93,455)
Average Number of Shares Outstanding (m)		17.5	32.4	56.6	66.2
EPS - normalised (SEK)		(2.72)	(1.86)	(1.52)	(1.41)
EPS - normalised fully diluted (SEK)		(2.72)	(1.86)	(1.52)	(1.41)
EPS - reported (SEK)		(2.72)	(1.86)	(1.52)	(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	170,527	77,072
Stocks		0	0	0	0
Debtors		0	0	0	0
Cash		25,904	149,781	58,827	75,372
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	158,884	65,429
CASH FLOW					
Operating Cash Flow		(42,405)	(40,860)	(103,456)	(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	(90,954)	16,545
Opening net debt/(cash)		(9,641)	(25,904)	(149,781)	(58,827)
HP finance leases initiated		0	0	0	0
Other		0	0	0	0
Closing net debt/(cash)		(25,904)	(149,781)	(58,827)	(75,372)

Source: Company data, Edison Investment Research. Note: *Mainly short-term investments.

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