

Cantargia

Company update

Great equity story underpins large share issue

In February 2020, Cantargia raised SEK410m gross. This is an impressive amount of capital for a pure-play European biotech with assets in early- to mid-stage development, and is underpinned by the successful progression of its R&D pipeline. In recent months, the company reported positive interim data from the ongoing Phase IIa trial with lead asset CAN04, an anti-IL1RAP antibody, announced the first clinical trial in the US (IND accepted) and introduced CAN10, a preclinical project in inflammation (Phase I study start likely in 2022). Tailwinds in the industry include Novartis initiating [multiple](#) Phase I–III trials with its canakinumab (anti-IL-1beta) in oncology after a [surprising discovery](#) in a large cardiovascular outcomes study and deals involving assets targeting the IL-1 pathway (in cancer and inflammation). Our valuation post the share issue is SEK3.48bn or SEK38.2 per share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/18	0.0	(91.2)	(1.38)	0.0	N/A	N/A
12/19	0.0	(110.8)	(1.56)	0.0	N/A	N/A
12/20e	0.0	(138.0)	(1.69)	0.0	N/A	N/A
12/21e	0.0	(138.5)	(1.52)	0.0	N/A	N/A

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

Update on COVID-19 impact

In April 2020, Cantargia provided an update on the potential impact of the COVID-19 pandemic. The key Phase I/IIa CANFOUR clinical trial with CAN04 in non-small cell lung cancer (NSCLC) and pancreatic ductal adenocarcinoma (PDAC) has been progressing as expected as of the update (7 April 2020). The dose escalation part has been completed in both indications. Recruitment of the remaining patients is ongoing. Due to COVID-19, future timelines are difficult to estimate, but assuming the situation will normalise by the end of Q220, Cantargia expects that the last patient in each arm will be recruited in Q320 (PDAC) and Q420 (NSCLC), later by one quarter – not a major delay given the circumstances.

IND approved for the US study with CAN04 plus CPI

In 2019, Cantargia announced a major expansion of its clinical programme, with plans to initiate a Phase Ib study in the US. The company filed an investigational new drug (IND) application in April 2020, which was approved in May and the trial could start in Q320 (depending on progression of the COVID-19 outbreak). The goal is to explore the potential of CAN04 in combination with checkpoint inhibitors (CPIs) in four indications (NSCLC, head and neck cancer and urothelial cancer or malignant melanoma).

Valuation: SEK3.48bn or SEK38.2 per share

Our updated valuation of Cantargia is higher at SEK3.48bn vs SEK2.94bn previously due to a higher cash position after the private placement and rolling the model forward. On a per share basis, the valuation is lower at SEK38.2 per share vs SEK40.4 per share due to dilution. We keep our R&D assumptions unchanged.

Pharma & biotech

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Price **SEK16.54**
Market cap **SEK1.51bn**

Net cash (SEKm) at end-Q419 plus share issue in Q120 539.5

Shares in issue 91.0m

Free float 90%

Code CANT

Primary exchange Nasdaq Stockholm

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 6.7 (25.0) (4.3)

Rel (local) (3.3) (9.1) 1.2

52-week high/low SEK25.0 SEK12.8

Business description

Cantargia is a clinical-stage biotechnology company based in Sweden, established in 2009 and listed on the Nasdaq Stockholm main market. It is developing two assets against IL1RAP, CAN04 and CAN10. CAN04 is being studied in a Phase IIa clinical trial, CANFOUR, in solid tumours focusing on NSCLC and pancreatic cancer. Cantargia is preparing to file an IND and initiate a trial in the US next year.

Next events

Initiate new US study with CAN04 in combination with CPIs Mid-2020

Phase IIa CANFOUR updates 2020

CAN10 preclinical development updates 2020

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Successful large share issue will help weather the storm of COVID-19

In February 2020, Cantargia completed a private placement, raising SEK410m gross (the cash position was SEK150m as of end-FY19). This was one of the largest share issues we have seen in the Nordic healthcare sector over the last few years. The ongoing positive [equity story](#), steady R&D progress and upcoming catalysts (listed in the Valuation section) were the key factors in attracting such a significant amount of new capital, in our view. Existing and new institutional investors participated in the share issue, with Swedbank Robur and HBM being the key new investors. The uses of the proceeds include:

- preparation of the lead asset for Phase III development (currently Phase IIa);
- development of the CANxx/CAN10 preclinical programme into early clinical development; and
- validation of the production process and general corporate purposes.

In total, Cantargia issued 18.2m new shares, which represents 25% of the previous number of outstanding shares. The subscription price was SEK22.5 per share, which equalled the volume weighted average price of the last 20 trading days and only a 6% discount to the closing price on the day before the issue. Cantargia's cash burn (defined as cash flow from operating activities) was SEK105m and SEK112m in 2018 and 2019, respectively.

R&D progress update and COVID-19 impact

Lead asset CAN10: Dose escalation part complete

As of the latest update from Cantargia (7 April 2020), the Phase IIa CANFOUR trial is progressing according to plan (Exhibit 1). So far, in the combination therapy arms, 17 patients with PDAC and seven patients with NSCLC have started therapy. The dose escalation part was completed and the 5mg/kg dose was selected in both indications where CAN10 is administered in combination with standard-of-care (SoC) chemotherapies. The interim data reported in December 2019 (described in detail in our [previous report](#)) were derived using the same dose. This dose level was deemed sufficient for IL1RAP targeting and no new safety/tolerability issues were reported.

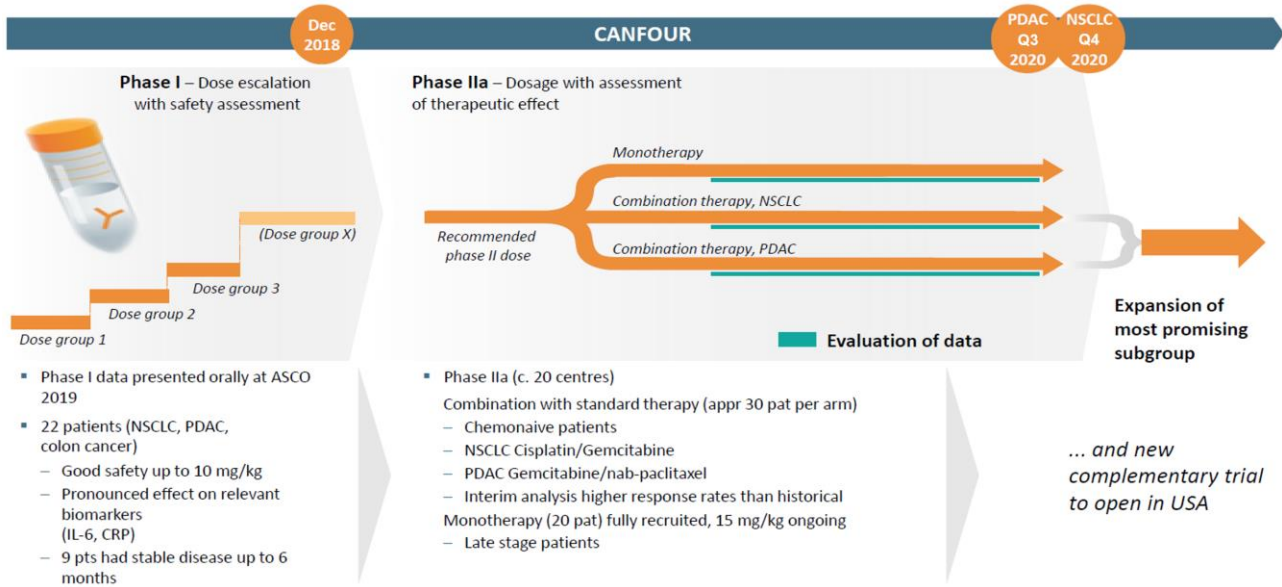
With regards to the impact of COVID-19 on the CANFOUR trial, Cantargia highlighted that despite restrictive measures in place, all recruited patients are continuing the treatment. Recruitment of new patients is also ongoing, although the number of active sites has decreased, causing temporary restrictions on new patient recruitment. Timelines are difficult to estimate, but assuming that the situation normalises in Q220, Cantargia expects that the last patient in each arm will be recruited in Q320 (PDAC) and Q420 (NSCLC). Previously, guidance was for Q220 and Q320, so this is certainly not a major delay given the circumstances, in our view. Cantargia also planned to release biomarker data from this trial, which will likely be delayed by several months. The supply of CAN10 has not been interrupted so far, and planning and preparations for subsequent studies remains on track.

As a reminder, the CANFOUR study is an open-label, three-arm [Phase I/IIa trial](#) with CAN04 in NSCLC and PDAC as monotherapy and in combination with first-line chemotherapy regimens. The trial consists of two parts – Phase I and Phase IIa. Full Phase I data were presented at ASCO on 2 June 2019, which showed that CAN04 was generally safe and well tolerated, and inflammatory biomarkers were reduced, in line with the proposed mechanism of action. The ongoing Phase IIa study includes initial efficacy endpoints, among others. The first results from the combination with chemotherapy arm were reported in December 2019 (see our [last published report](#) for a detailed

review). These results support the hypothesis that CAN04 is synergistic with the SoC chemotherapy.

The key readouts (progression-free survival and overall survival) from the combination arms are likely to be available in 2021 (depending on the impact of the COVID-19 outbreak).

Exhibit 1: Phase IIa CANFOUR trial design



Source: Cantargia

Next step with CAN04: Combination with CPI study

Cantargia filed an IND application in April 2020, which was approved in May 2020, and plans to initiate a Phase Ib clinical trial in the US. This is a major R&D expansion as the combination will involve CPIs. The rationale is based on several observations:

- Myeloid suppressive cells, such as tumour-associated macrophages or myeloid-derived suppressor cells, express IL1RAP and play a substantial role in PD-1 resistance.
- IL-1 upregulates PD-L1 on macrophages and induces downstream factors, such as IL-6, which add to immunosuppression in the tumour microenvironment.
- IL-1beta blockade has been shown to reverse tolerance to anti-PD-1 in an in vivo setting.

The indications (NSCLC, head and neck cancer and urothelial cancer or malignant melanoma) were selected because the tumours express IL1RAP and are relatively immunogenic, therefore suitable for treatment with CPIs. In addition, the checkpoint inhibitor, Keytruda, is a standard therapy in these indications. The patients in the trial will be eligible if they have progressed on prior PD1/PDL-1 antibody therapy (second-line positioning). The trial plans to include up to 18 patients. Endpoints will include typical safety evaluation, as well as exploratory biomarkers and initial efficacy. The trial could start in Q320 (depending on the progression of the COVID-19 outbreak).

CAN10: Parts of preclinical programme on hold, but in vivo efficacy studies ongoing

Cantargia disclosed its second drug candidate last year. This antibody is in preclinical development for systemic sclerosis and myocarditis. Animal studies in inflammatory disease are ongoing. Other parts of the programme (biochemistry, production) are affected since they are performed with suppliers in the US that have been forced to temporarily close their facilities. The start of the clinical trial is now expected in 2022 (we previously expected it in 2021). Since this asset is still in

preclinical development, we believe most of Cantargia's value is in CAN04. We therefore do not include it in our valuation.

Financials and valuation

With its Q419 results, Cantargia reported an operating loss of SEK36.4m versus SEK28.1m in Q418. R&D costs in Q419 were SEK32.8m versus SEK24.7m in Q418, an increase due to the Phase IIa CANFOUR study advancing, higher spending on CAN04 production development (CMC) and the maturing preclinical pipeline (CAN10 and CANxx).

FY19 R&D costs were SEK97.5m compared to SEK77.0m the year before, while FY19 operating loss was SEK111.6m vs SEK93.3m in FY18 (with the same reasons for the increase as above). Cantargia will continue its Phase IIa study in 2020, but also plans to initiate the combination with CPIs study (Phase IIb) in the US later this year (depending on the progression of the COVID-19 outbreak) and preclinical development is also accelerating. We have therefore increased our R&D cost estimates for 2020 and 2021 by a similar amount as in 2019 vs 2018, ie up 27% to SEK123.5m from SEK99.6m. This led to operating loss increase to SEK139m from SEK114m in 2020 and 2021. We note that until the outcome of the COVID-19 pandemic is known, spending visibility is decreased due to multiple possible effects. For example, if the combination study in the US is delayed, associated costs could also be delayed. The reported cash position at end Q419 was SEK150m (including short-term investments) plus the share issue of SEK410m gross in Q120.

Our updated valuation of Cantargia is higher at SEK3.48bn vs SEK2.94bn previously due to a higher cash position after the private placement and rolling the model forward. On a per share basis, the valuation is lower at SEK38.2 per share vs SEK40.4 per share due to dilution. We keep our R&D assumptions uncaged. Potential catalysts for Cantargia's share price in the near term include:

- initiation of the US trial with CAN04 in combination with checkpoint inhibitors (2020, depending on the progression of the COVID-19 outbreak);
- Phase IIa CANFOUR trial combination results in PDAC and NSCLC:
 - further response, biomarker and safety data in 2020;
 - progression-free survival and overall survival in 2021;
- Phase IIa CANFOUR trial monotherapy biomarker/biopsy results (2020); and
- CAN10 preclinical development update.

Exhibit 2: 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	3,100	6,830.2	75.1	18.0%	1,260.7	13.9
CAN04 – pancreatic cancer	2024	2,100	6,930.7	76.2	18.0%	1,679.9	18.5
Net cash (FY19) plus share issue (Q120)			539.5	5.9	100%	539.5	5.9
Valuation			14,300.4	157.1		3,480.0	38.2

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

Exhibit 3: Financial summary

	SEK'000s	2018	2019	2020e	2021e
		IFRS	IFRS	IFRS	IFRS
December					
PROFIT & LOSS					
Revenue		0	0	0	0
Cost of Sales		0	0	0	0
Gross Profit		0	0	0	0
Research and development		(76,951)	(97,477)	(123,478)	(123,478)
EBITDA		(93,306)	(111,590)	(138,015)	(138,451)
Operating Profit (before amort. and except.)		(93,306)	(111,590)	(138,015)	(138,451)
Intangible Amortisation		0	0	0	0
Exceptionals		0	0	0	0
Other		0	0	0	0
Operating Profit		(93,306)	(111,590)	(138,015)	(138,451)
Net Interest		2,145	780	0	0
Profit Before Tax (nom)		(91,161)	(110,810)	(138,015)	(138,451)
Profit Before Tax (reported)		(91,161)	(110,810)	(138,015)	(138,451)
Tax		0	0	0	0
Profit After Tax (norm)		(91,161)	(110,810)	(138,015)	(138,451)
Profit After Tax (reported)		(91,161)	(110,810)	(138,015)	(138,451)
Average Number of Shares Outstanding (m)		66.2	71.1	81.9	91.0
EPS - normalised (ore)		(137.73)	(155.74)	(168.51)	(152.13)
Dividend per share (ore)		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		2,957	6,868	6,868	6,868
Intangible Assets		0	6,868	6,868	6,868
Tangible Assets		0	0	0	0
Investments		2,957	0	0	0
Current Assets		168,486	159,189	411,686	274,698
Stocks		0	0	0	0
Debtors		0	0	0	0
Cash		76,528	39,870	292,367	155,379
Other*		91,958	119,319	119,319	119,319
Current Liabilities		(16,398)	(23,785)	(23,785)	(23,785)
Creditors		(16,398)	(23,785)	(23,785)	(23,785)
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		155,045	142,272	394,769	257,781
CASH FLOW					
Operating Cash Flow		(105,165)	(111,853)	(138,015)	(138,451)
Net Interest		478	597	1,463	1,463
Tax		0	0	0	0
Capex		0	(6,880)	0	0
Acquisitions/disposals		0	0	0	0
Financing		0	98,037	389,048	0
Other		31,434	(16,559)	0	0
Dividends		0	0	0	0
Net Cash Flow		(73,253)	(36,658)	252,497	(136,988)
Opening net debt/(cash)		(149,781)	(76,528)	(39,870)	(292,367)
HP finance leases initiated		0	0	0	0
Other		0	0	0	0
Closing net debt/(cash)		(76,528)	(39,870)	(292,367)	(155,379)

Source: Cantargia accounts, Edison Investment Research

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