EDISON

Cantargia

Company update

‘Post-Novartis’ era has begun

Pharma & biotech

Novartis’s Phase III CANOPY trials with canakinumab have created (until recently) strong tail winds for the class of therapeutics targeting the IL-1 axis, including Cantargia’s lead asset CAN04 (anti-IL1RAP). Two of the CANOPY trials did not meet primary endpoints this year, which was a significant contributor for Cantargia’s share price decline. However, canakinumab’s (anti-IL1β) development has a complicated history and the read-across to Cantargia’s CAN04 (anti-IL1RAP) is not straightforward, which we examine once again in this report. We make no changes to our fundamental assumptions, as we see CAN04 as clearly differentiated from canakinumab. Cantargia has released a solid set of initial efficacy data from its own trials and has expanded its R&D programme, which will provide catalysts over the next two years. Our valuation is virtually unchanged at SEK6.91n or SEK68.9/share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/19	0.0	(110.8)	(1.56)	0.0	N/A	N/A
12/20	0.0	(173.1)	(1.94)	0.0	N/A	N/A
12/21e	0.0	(347.7)	(3.47)	0.0	N/A	N/A
12/22e	0.0	(348.5)	(3.48)	0.0	N/A	N/A

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

CANOPY data negative, but not definitive for CAN04

Negative findings from the CANOPY-2 study in second- and third-line NSCLC were reported earlier this year. On 25 October 2021, Novartis reported that its Phase III CANOPY-1 trial in first-line NSCLC did not meet primary co-endpoints of OS and PFS either. However, Novartis pointed out that the data showed ‘potentially clinically meaningful improvements’ in both co-primary endpoints in pre-specified subgroups of patients based on the baseline inflammatory biomarker. This, it believed, justified the continuation of other CANOPY trials, which are enrolling patients with even earlier-stage disease. In our view, an alternative approach is to achieve a better control of IL-1 signalling, which is what Cantargia’s CAN04 does.

Significantly expanded R&D programme

CAN04 is now being investigated (or about to be) in eight different cancers and different treatments lines and in a variety of combinations. The goal of this expansion of the CAN04 programme beyond the original CANFOUR trial is to accumulate a comprehensive data package, which will position Cantargia well to design the next stage development and enter potential partnership negotiations. The next trial readout from Novartis is not due until 2023, so in the interim period the market will be judging Cantargia’s value based on its own news and data.

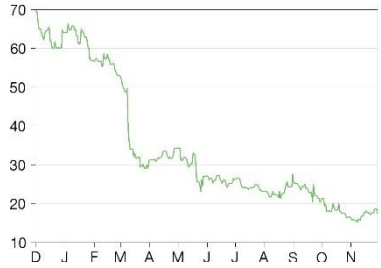
Valuation: SEK6.91n or SEK68.9/share

Our updated valuation of Cantargia is virtually unchanged at SEK6.91bn or SEK68.9/share (rolling our model forward was offset by a lower cash position). Potential use of CAN04 in NSCLC contributes c 38% of our valuation and, while we acknowledge sentiment has been knocked, we view CAN04 as too differentiated to justify a fundamental change to our assumptions.

30 November 2021

Price	**SEK17.5**
Market cap	**SEK1.75bn**
Net cash and short-term investments (SEKm) at end-Q321	647.9
Shares in issue	100.2m
Free float	99%
Code	CANT
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	5.9	(30.4)	(74.6)
Rel (local)	3.5	(30.5)	(80.5)
52-week high/low	SEK69.7	SEK15.2	

Business description

Cantargia is a clinical-stage biotechnology company based in Sweden, established in 2009. It is developing two assets against IL1RAP, CAN04 and CAN10. CAN04 is being studied in several solid tumours with a main focus on NSCLC and pancreatic cancer. The most advanced trial is in Phase II.

Next events

Phase IIa CANFOUR extension in PDAC data	H122
Phase Ib CIRIFOUR data: combination with check point inhibitor pembrolizumab	H122
CAN04 in PDAC development update	H122

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Edison profile page

Novartis Phase III CANOPY-1 top-line results

Exhibit 1 summarises Novartis's canakinumab in non-small cell lung cancer (NSCLC) programme. There are several trials ongoing that investigate canakinumab in virtually all settings, from the most advanced patients to those with early-stage cancer.

As a reminder, earlier this year Novartis reported that its Phase III CANOPY-2 trial in the most advanced NSCLC patients receiving **second- or third-line** treatment missed the primary endpoint. On 25 October 2021, the large pharma reported that its Phase III CANOPY-1 trial in **first-line** NSCLC did not meet primary co-endpoints of overall survival (OS) and progression-free survival (PFS) either.

However, Novartis pointed out that the CANOPY-1 data showed 'potentially clinically meaningful improvements' in both co-primary endpoints in pre-defined subgroups of patients based on the baseline inflammatory biomarker (high sensitivity C reactive protein, hsCRP), as well as 'other biomarker-defined subgroups' (the latter not defined). So, Novartis is implying that minimal signs of ongoing inflammation in the background could potentially be used as a biomarker to identify a more relevant subgroup of patients. This would make sense given the mechanism of action of canakinumab (anti-IL1β, which diminishes pro-inflammatory IL-1 signalling). If that turns out to be the case, Cantargia would also benefit because it could easily incorporate the biomarker. The CRP test is the most common inflammatory biomarker to evaluate an active infection used in the clinic (the hsCRP test simply measures much smaller amounts of the same protein in seemingly healthy persons; one is used to estimate the risk of heart disease for example).

No further details were released, but Novartis should present data at an upcoming medical meeting, albeit precise timing was not guided. It also confirmed that the other trials are ongoing. The next one in focus now is the ongoing Phase III CANOPY-A, which investigates canakinumab as **an adjuvant therapy in stage II–III NSCLC** after complete resection and adjuvant chemotherapy. The data from this trial are not expected before 2023. A Phase II CANOPY-N trial is investigating canakinumab in the even earlier **neoadjuvant setting** (before surgery).

Exhibit 1: Summary of key lung cancer trials with CAN04 and canakinumab

Pharmacological class/target	Product (generic name)	Current development status of oncology indications	Notes
Anti-IL-1β Mab Novartis	Ilaris (canakinumab)	Phase III in 1L NSCLC (+ pembrolizumab + chemo) (**CANOPY-1**, NCT03631199, n=673)	**Co-primary endpoints** missed, potential improvement in both endpoints in pre-specified subgroup of patients defined by inflammatory biomarkers. Full data to be presented.
		Phase III in 2/3L NSCLC (+ docetaxel) (**CANOPY-2**, NCT03626545, n=245)	**Primary endpoint (OS)** missed.
		Phase III in adjuvant NSCLC (**CANOPY-A**, NCT03447769, n=1,500)	Trial c 40% enrolled in June 2020, expected to be fully enrolled in 2022. Interim analysis expected in 2022 ahead of **final analysis in 2023**.
		Phase II in neoadjuvant NSCLC (+ pembrolizumab) (**CANOPY-N** NCT03968419, n=110)	Trial c 20% enrolled in June 2020.
Anti-IL1RAP Mab Cantargia	CAN04 (nadunollimab)	Phase I/IIa in 1L NSCLC & PDAC (+ SoC chemo) (CANFOUR, NCT03267316, n=100)	Positive interim data reported in Sep/Oct 2020, final efficacy readouts (OS & PFS) expected during 2021.
		Phase Ib in NSCLC, HNSCC, urothelial cancer and melanoma (+ pembrolizumab) (NCT04452214, n=15)	Patient recruitment started in Oct 2020, headline data are expected to be reported in H221

Source: EvaluatePharma, company websites, clinicaltrials.gov

Reiterating: Cantargia's CAN04 is different from Novartis's canakinumab

The Novartis CANOPY programme with its multiple trials originates from observations from the Phase III CANTOS trial (historical details are discussed in our initiation report), which also

investigated canakinumab, but in an unrelated cardiovascular indication, to establish the role of IL-1β inhibition in atherosclerosis. The unexpected finding that canakinumab reduced lung cancer incidence ultimately led Novartis to initiate the CANOPY programme. By design, all participants in that trial had to be free of previously diagnosed cancer, but that does not mean they were actually cancer-free on inclusion. Chances are, and this was c 10,000-patient trial, some of the patients already had a malignant process underway, but demonstrated no symptoms. Canakinumab then either reduced the development of cancer or reduced the rate of progression. Either way this was happening very early in the disease.

Earlier this year Novartis reported negative data from its Phase III CANOPY-2 trial, which had investigated canakinumab in the most advanced NSCLC (Exhibit 1). This setting and the patients in the original Phase III CANTOS study are on the opposite ends of the course of this disease. The more recent announcement is from the CANOPY-1 trial, which investigated canakinumab as a front-line treatment after surgery, but still in an advanced stage of lung cancer. And while the trial technically failed, knowing the historical perspective it makes sense that some efficacy has potentially been observed in a subset of patients, specifically in those with measurable chronic inflammation. The totality of Novartis data now points to even earlier settings, which is the reason behind the company's determination to proceed with CANOPY-A and CANOPY-N trials, or **the need for better control of IL-1 signalling**, which is what Cantargia's CAN04 provides.

IL-1 is a proinflammatory cytokine that exists in two forms: IL-1α and IL-1β. IL-1α and IL-1β are both ligands for IL-1R and through this receptor initiate the same signalling processes inside the cell. Canakinumab is an IL-1β monoclonal antibody and acts more upstream of Cantargia's target IL1RAP. So, canakinumab blocks only one of two cytokines that activate the IL-1 receptor, while Cantargia's CAN04 completely abrogates IL-1 signalling pathway. In addition, CAN04's mechanism of action is not only inflammation modulation via IL1RAP, but also the antibody-dependent cellular cytotoxicity (ADCC), which directly causes cancer cell death.

Cantargia has recently released new preclinical data that clearly demonstrate the different effects of an anti-IL1RAP approach (CAN04) versus an anti-IL1β (canakinumab). The model used was mice with established subcutaneous MC38 tumours (colorectal cancer model), which were treated with docetaxel in combination with CAN04 or an anti-IL1β antibody. Data showed that CAN04 increased the effect of the chemotherapy docetaxel in tumour-bearing mice, which was not achieved by IL-1β blockade alone. Looking at cytokine level (in vitro data), it is known that some chemotherapeutic agents induce the malignant cells to produce IL-1α, which leads to tumour-promoting inflammation and may induce resistance to chemotherapy. CAN04, an IL-1RAP inhibitor, counteracts this defensive mechanism against chemotherapy, which is in sharp contrast to canakinumab's more limited mechanism of action (anti-IL1β, so anti-IL1α remains intact).

Our view

Novartis started publishing trial data on patients starting with the most advanced setting and moving to earlier stages of the disease. So, there has been a period of negative sentiment weighing on Cantargia's share price since early 2021 (admittedly, the share price more than doubled in late 2020 in the run-up period ahead of the Novartis CANOPY-2 readout). Because of the complicated history of canakinumab, we believe, the read-across to Cantargia's CAN04 was misinterpreted by many. Novartis's CANOPY studies will provide valuable information of how to position CAN04, but do not invalidate the IL-1 axis theory in cancer, in our view. The next update from Novartis is not due until 2023, so in the interim period the market will be judging Cantargia's value based on its own news flow and data. Most recent updates in this regard are promising (details below) and the company is taking steps at the moment to significantly expand the data sets with more indications and more settings. This will provide definitive answers about CAN04's potential.

Broadening CAN04 development

The Phase IIa CANFOUR trial

The PDAC arm: Extension phase fully recruited

Cantargia is completing its Phase IIa CANFOUR trial, which investigates CAN04 plus chemotherapy in first-line NSCLC and CAN04 plus chemotherapy in metastatic pancreatic cancer (PDAC) (Exhibit 2; more details on trial design in our previous report). The final data from the PDAC arm (n=36, of which 33 were evaluable) were released in May 2021. This was the first-line treatment setting with patients receiving a standard of care chemotherapy gemcitabine/nab-paclitaxel (around 50% of all PDAC patients receive it). Interim response data have been published previously and compared very well with historical control data. So, the positive outcome of this particular arm of the CANFOUR trial has already been mostly discounted. Still, the new efficacy details reported in May 2021 are promising. Median PFS in the PDAC arm was 7.8 months and the median OS at that time was 12.6 months. These data compare well with historical control data: PFS 5.5 months and median OS of 8.5 month (Von Hoff et al, 2013), although the normal cross-trial comparison caveats apply. No major new side effects were reported. The extension phase (n=40) is now ongoing, which is designed to check the effects of lower doses of CAN04 and expand the safety profile before progressing into Phase III trial. The recruitment is already complete and the data from this part are **expected in H122**. Cantargia is currently planning the next step, which could be a pivotal trial and is in discussions with regulatory authorities.

The NSCLC arm: Focus on non-squamous histology

The latest interim results from the NSCLC arm were presented recently at the ESMO Congress in September 2021. Like with PDAC, interim results have been presented previously, so the positive update this time has already been discounted in the share price. The updated results showed that overall response rate (ORR) was 48%, while median PFS was 7.2 months. Putting this into context, historical control data show 22–28% ORRs for first-line intervention with gemcitabine/pemetrexed chemotherapy in NSCLC with median PFS of 5.1 months (Schiller et al, 2002; Scagliotti et al, 2008).

The new and unexpected finding was that a subset of patients who had non-squamous NSCLC showed a more pronounced benefit compared to those with squamous histology. The ORR in this subpopulation was 53%. Furthermore, an interesting finding was that the subgroup of eight patients previously treated with pembrolizumab monotherapy showed an ORR of 75%. Based on this insight Cantargia decided to focus on further development in non-squamous NSCLC, which is the largest subgroup of NSCLC and constitutes about 70–80% of all NSCLC cases. The most frequently used first-line platinum-based chemotherapy for this patient group is carboplatin/pemetrexed (so far CAN04 was being used in combination with gemcitabine/cisplatin in the NSCLC arm of the CANFOUR trial). As the CANFOUR trial is approaching its completion and seeing this benefit in a more specific subgroup of patients, Cantargia quickly initiated a new trial within the CANFOUR programme, which will enrol patients with non-squamous NSCLC for front-line treatment with CAN04 in combination with carboplatin/pemetrexed. In total, 40 new patients are planned to be recruited.

Broadening the scope with a set of new trials

Throughout the course of this year Cantargia has substantially expanded its development programme of CAN04 (Exhibit 2):

- In March 2021, Cantargia announced it will initiate another Phase I/II CAPAFOUR trial (n=30) with CAN04 in combination with the FOLFIRINOX chemotherapy regimen as a first-line

treatment for PDAC. This is in addition to the PDAC arm in the same indication in the CANFOUR trial, but with a different combination (gemcitabine plus nab-paclitaxel chemotherapy). The two chemotherapies (FOLFIRINOX and gemcitabine/nab-paclitaxel) are standard of care and would cover most of the patients in this setting, so this new trial significantly expands the target patient population. Recruitment is ongoing with **data due some time in 2023**.

- It is worth noting that recently Novartis also initiated a Phase Ib study in PDAC before receiving an orphan drug designation in pancreatic cancer from the FDA in March 2021 (Cantargia also has this designation in the United States and Europe). These developments demonstrate a strong interest in this indication, in our view. The new trial will evaluate canakinumab in combination with nab-paclitaxel/gemcitabine (the same chemotherapy as in CANFOUR trial), but also spartalizumab, an anti-PD-1 antibody owned by Novartis. Cantargia has been exploring the idea of combining the IL-1 axis inhibition with checkpoint inhibitors for a while now and already has a US-based Phase Ib CIRIFOUR trial up and running. It is primarily a safety and tolerability study that investigates CAN04 in combination with pembrolizumab in several solid tumours, with initial data **expected in Q421**. These should provide the first insights of how CAN04 combines with a checkpoint inhibitor (CPI) in a range of solid tumours (Exhibit 2). Note, that one of the cancer types being investigated in this study is non-squamous NSCLC, so the data from this arm (which will include a CAN4 combination with a CPI plus chemotherapy) will complement the newly initiated non-squamous NSCLC study in the original CANFOUR trial (CAN04 plus chemotherapy).
- Two other trials are also running that investigate CAN04 with various chemotherapy regimens in a range of cancers. One is a Phase Ib/II TRIFOUR trial in first- or second-line triple negative breast cancer (n=120). This trial has a Phase II component, meaning that the data will be randomised and will have a control arm. The trial is starting to enrol patients and the data from the Phase Ib part is **expected sometime in 2022**. Another basket Phase I/II CESTAFROUR trial (n=165) is investigating CAN04 in combinations with various chemotherapy regimens in several solid tumours and in different settings (from first-line to second- and third-line). The **final data is expected in 2023**, but there will be interim readouts before that.

Exhibit 2: R&D pipeline

Study	Disease	Combination therapy	Status	ClinicalTrials.gov ID
CANFOUR	NSCLC	Cisplatin/gemcitabine	Recruitment completed	NCT03267316
	Non-squamous NSCLC	Carboplatin/pemetrexed	Recruitment expected to start in Q4 2021	
	PDAC	Gemcitabine/nab-paclitaxel	Recruitment for extension part completed	
CIRIFOUR	NSCLC, bladder cancer, HNSCC, melanoma	Pembrolizumab	Recruitment completed	NCT04452214
	Non-squamous NSCLC	Pembrolizumab/ carboplatin/pemetrexed	Recruitment expected to start in Q4 2021	
CAPAFOUR	PDAC	FOLFIRINOX	Recruitment ongoing	NCT04990037
CESTAFOUR	NSCLC	Docetaxel	Recruitment ongoing	NCT05116891
	Biliary tract cancer	Cisplatin/gemcitabine		
	Colon cancer	FOLFOX		
TRIFOUR	TNBC	Carboplatin/gemcitabine	Recruitment expected to start in November 2021	-

Abbreviations: NSCLC – non-small cell lung cancer; PDAC – pancreatic cancer; HNSCC – head and neck cancer; TNBC – triple negative breast cancer

Source: Cantargia

Financials and valuation

During the first nine months of 2021 (9M21), Cantargia reported an increased operating loss of SEK265m (9M20: SEK118m), driven by the growing R&D costs. We had already anticipated growing R&D costs. Following the latest results, we have revised our operating loss estimates somewhat further up, to SEK348m from SEK276m previously, and keep the spending similar in 2022. Cantargia is well capitalised and the existing cash and short-term investments (SEK648m at end-Q321) are still sufficient until 2023. This means that many of the catalysts listed above are within cash reach.

Our updated valuation of Cantargia is virtually unchanged at SEK6.91bn or SEK68.9 per share, versus SEK6.86bn or SEK68.5 per share previously, as rolling our model forward was offset by a lower cash position. We make no changes to our other assumptions.

Potential use of CAN04 in NSCLC contributes c 38% of our valuation and, while we acknowledge sentiment has been knocked and the share price declined significantly after the Novartis Phase III trial data, because of the differences described above we do not feel this currently necessitates a fundamental change to our assumptions. The expanded R&D programmes will provide many catalysts in the near term:

- Phase IIa CANFOUR extension phase in PDAC data in H122,
- Phase Ib CIRIFOUR data in H122,
- CAN04 in PDAC development update in H122, when Cantargia could provide more details about the pivotal trial, and
- major results readouts from several trials are expected later in 2022 and in 2023.

Exhibit 3: SOTP Cantargia valuation

Product	Launch	Peak sales ($m)	NPV (SEKm)	NPV/share (SEK)	Probability	rNPV (SEKm)	rNPV/share (SEK)
CAN04 – NSCLC	2026	3,100	8,925.0	89.1	25.0%	2,642.6	26.4
CAN04 – PDAC	2024	2,124	9,310.5	92.9	25.0%	3,614.7	36.1
Net cash* (last reported)			647.9	6.5	100%	647.9	6.5
Valuation			**18,883.5**	**188.5**		**6,905.3**	**68.9**

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations. *Including short-term investments.

Exhibit 4: Financial summary

SEK'000s	2018	2019	2020	2021e	2022e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	0	0	0	0	0
Cost of Sales	0	0	0	0	0
Gross Profit	0	0	0	0	0
Research and development	(76,951)	(97,477)	(158,396)	(330,000)	(330,000)
EBITDA	(93,306)	(111,577)	(170,697)	(347,702)	(348,547)
Operating Profit (before amort. and except.)	(93,306)	(111,589)	(173,945)	(347,702)	(348,547)
Intangible Amortisation	0	0	0	0	0
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit	(93,306)	(111,589)	(173,945)	(347,702)	(348,547)
Net Interest	2,145	780	860	0	0
Profit Before Tax (norm)	(91,161)	(110,809)	(173,085)	(347,702)	(348,547)
Profit Before Tax (reported)	(91,161)	(110,809)	(173,085)	(347,702)	(348,547)
Tax	0	0	0	0	0
Profit After Tax (norm)	(91,161)	(110,809)	(173,085)	(347,702)	(348,547)
Profit After Tax (reported)	(91,161)	(110,809)	(173,085)	(347,702)	(348,547)
Average Number of Shares Outstanding (m)	66.2	71.1	89.4	100.2	100.2
EPS - normalised (SEK)	(1.38)	(1.56)	(1.94)	(3.47)	(3.48)
Dividend per share (SEK)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets	2,957	6,868	12,622	12,622	12,622
Intangible Assets	0	0	7,360	7,360	7,360
Tangible Assets	0	6,868	5,262	5,262	5,262
Investments	2,957	0	0	0	0
Current Assets	168,486	159,189	912,892	573,395	233,052
Stocks	0	0	0	0	0
Debtors	0	0	0	0	0
Cash	76,528	39,870	693,354	353,857	13,514
Other*	91,958	119,319	219,538	219,538	219,538
Current Liabilities	(16,398)	(23,785)	(30,469)	(30,469)	(30,469)
Creditors	(16,398)	(23,785)	(30,469)	(30,469)	(30,469)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	0	0	(3,111)	(3,111)	(3,111)
Long term borrowings	0	0	0	0	0
Other long term liabilities	0	0	(3,111)	(3,111)	(3,111)
Net Assets	155,045	142,272	891,934	552,437	212,094
CASH FLOW					
Operating Cash Flow	(105,165)	(111,852)	(156,887)	(340,358)	(341,203)
Net Interest	478	597	500	860	860
Tax	0	0	0	0	0
Capex	0	(6,880)	(890)	0	0
Acquisitions/disposals	0	0	0	0	0
Financing	0	98,037	917,545	0	0
Other	31,434	(16,560)	(106,784)	1	0
Dividends	0	0	0	0	0
Net Cash Flow	(73,253)	(36,658)	653,484	(339,497)	(340,343)
Opening net debt/(cash)	(149,781)	(76,528)	(39,870)	(693,354)	(353,857)
HP finance leases initiated	0	0	0	0	0
Other	0	0	0	0	0
Closing net debt/(cash)	(76,528)	(39,870)	(693,354)	(353,857)	(13,514)

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

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