Cantargia Q3 2022: Focus on Randomised Trials

Cantargia **Research Update** 2022-11-11 07:00 **Updated** 2022-11-11 07:06

Redeye comments on Cantargia's third quarter report and events after the end of the quarter, including the decision to pause three trials.

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CIRIFOUR

In October, Cantargia announced that CIRIFOUR will not be continued. This occurred after a new arm in which nadunolimab would be combined with a checkpoint inhibitor was initiated – it will not continue. The reason is that costs would be much higher than originally planned, as the checkpoint inhibitor would have to be paid for by Cantargia. Other cost-efficient alternatives will be explored instead. We expect further development in this indication, but due to the delay we assume a market launch two years later (2028).

CAPAFOUR, CESTAFOUR

In October, preliminary results from CAPAFOUR (pancreatic cancer with FOLFIRINOX) and CESTAFOUR (in which nadunolimab is combined with various chemotherapy regimens) showed acceptable safety. The only efficacy results communicated were two partial responses (out of four) in non-small cell lung cancer treated with gemcitabine/cisplatin. As the data is not yet mature, Cantargia has refrained from giving any more details. More mature safety and efficacy data from the two trials are planned to be presented in H1 2023. The trials could have been continued with expansion arms, but Cantargia communicated that the trials will not be continued after the phase I parts are completed. Cantargia is going to focus its resources on randomized trials, in pancreatic cancer, lung cancer, and breast cancer.

Other nadunolimab trials

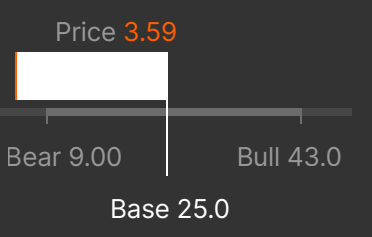
TRIFOUR is Cantargia's phase Ib/II clinical trial in breast cancer and the only ongoing trial which has not yet reported any results. Cantargia expects to report initial data from the trial in Q1 2023; a fully funded randomised expansion arm will follow after this. Recruitment of up to 40 non-squamous NSCLC patients, who will be given carboplatin + pemetrexed and nadunolimab, in CANFOUR started in February 2022. Recruitment will take place over 12-15 months and interim results should be available later in 2023. Recruitment of non-squamous NSCLC patients is expected to continue during H1 2023. This study will provide input for a randomised study. We also expect to hear more about the outcome of the discussions with the FDA and the start of Precision Promise (pancreatic cancer).

SEKm	2020	2021	2022E	2023E	2024E
Revenues	-	-	-	-	866
Revenue Growth	N/A	N/A	N/A	N/A	N/A
EBITDA	(174)	(370)	(370)	(297)	653
EBIT	(171)	(370)	(370)	(297)	653
EBIT Margin	N/A	N/A	N/A	N/A	75.4%
Net Income	(170)	(325)	(359)	(297)	653
EV/Revenue	N/A	N/A	N/A	N/A	(0.2)
EV/EBIT	(26.0)	(2.6)	(0.5)	(1.6)	(0.3)

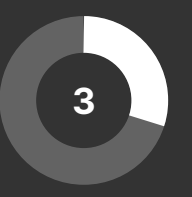
REDEYE

REDEYE QUALITY RATING

FAIR VALUE RANGE



TIMELINESS



KEY STATS

Market Cap	599.8 MSEK
Entprs. Value (EV)	41.0 MSEK
Net Debt	-558.8 MSEK
30 Day Avg Vol	1130 K
Shares Outstanding	100.1 M
EV / Sales	N/A
EV / EBIT	N/A
Price / Earnings	N/A
PEG	0.0
Dividend Yield	N/A

IMPORTANT INFORMATION

All information regarding limitation of liability and potential conflicts of interest can be found at the end of the report.

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Case

Cantargia is approaching a stage when finding a partner is logical

Cantargia is sponsoring several trials in various cancer indications to pinpoint the optimal indications to target and to document the breadth of nadunolimab. If the company can demonstrate good results across these indications, it will reinforce its standing when negotiating a large licensing deal. Upcoming trial results set the company up for a potential large licensing deal in 2024. Cantargia may also choose to continue developing nadunolimab by itself, as two planned placebo-controlled phase II trials in PDAC (Precision Promise) and NSCLC will bring it closer towards the market. After the rights issue in mid-2022 that raised net SEK 225m, Cantargia has a respectable cash position that should last at least until mid-2024.

Evidence

Cantargia has demonstrated excellent results in CANFOUR in pancreatic and lung cancer

Patients with non-small cell lung cancer (N=30) showed a response of 53 per cent, resulting in a median progression-free survival of 6.8 months and median OS of 13.7 months. In patients with pancreatic cancer (N=73), long-term responses or pseudoprogression have been observed, resulting in a median progression-free survival of 7.2 months and a median survival of 12.7 months. These are impressive results.

Supportive Analysis

Three phase II trials are already planned: • A pivotal phase II/III trial in PDAC in the US with up to 175 patients (plus a control group of comparable size) should be initiated in early 2023, due to conclude in 2027 at the latest. • A phase II trial with a control arm is planned in non-squamous NSCLC in 2023 (the details of which have not yet been communicated). • A randomised trial in triple negative breast cancer (TRIFOUR), which is fully funded, is scheduled to start in Q1 2023.

Challenge

The main risks for Cantargia are negative clinical outcomes...

...which we believe are somewhat unlikely in the short run thanks to the especially robust results already reported in PDAC and NSCLC. However, Cantargia has not conducted clinical trials with a placebo group. Patient conditions can vary substantially between the various trials, leading to widely differing outcomes. There is still a risk that the strong results obtained so far will prove less favorable in placebo-controlled conditions.

Challenge

Additional funding may be needed

Cantargia's planned phase IIb trial in lung cancer might need additional funding, depending on its size etc. Otherwise, the company should be funded to mid-2024. We believe that Cantargia will wait for results from several clinical trials to mature in 2023. Assuming outstanding results, negotiations with a partner might start in H2 2023 and lead to a deal in H1 2024. Otherwise, additional funds will be needed at this time.

Valuation

Nadunolimab constitutes most of the value

The share price has collapsed following the rights issue of SEK 250m, even though it was fully subscribed, potentially catalyzed by Canakinumab's failure in lung cancer. At the same time, the world economy appears to approach a recession, with a deteriorating capital market. This may put a lid on a potential price recuperation. Still, the valuation is disconnected from fundamentals.

You more or less pay for the cash position and get the company for free (though the cash will obviously be spent, eventually). Our Base Case of SEK 24 assumes a deal with nadunolimab in 2024, with an upfront of USD 150m, milestones of USD 850m and royalties of 17.5 percent.

Translational preclinical results for nadunolimab

Two preclinical results that may help explain nadunolimab's mode of action were recently published.

At AACR in 2022, Cantargia presented new data. In a preclinical pancreatic cancer (PDAC) model, nadunolimab reduced the migration of monocytes to the tumour. Monocytes are believed to be a source of tumor-associated myeloid cells (TAMs), which aid the cancer in suppressing and evading the immune system. This shows that nadunolimab has an immunologic effect in vitro. When the same type of cells were inoculated in mice, treatment with nadunolimab reduced tumour growth, demonstrating the concept in vivo.

At SITC 2022, Cantargia presented new preclinical results with nadunolimab compared to an anti-IL-1β antibody, as well as biomarker data from CANFOUR. Both IL-1α and IL-1β cause a release of CXCL1, CXCL5 and additional related markers by blood cells and cancer-associated cells. Blockade of IL1RAP reduces this release. The cancer-associated cells also release CXCL1, CXCL5 and related markers in the presence of pancreatic cancer cells. Blockade of IL1RAP also reduces the release of these markers, but an anti-IL-1β antibody did not. When analysing biomarkers from patients with both lung and pancreatic cancer in CANFOUR, patients with higher levels of CXCL1 and CXCL5 had a poorer prognosis. General levels were also reduced when compared to samples taken before the trial. This suggests that nadunolimab may have reduced the levels of CXCL1 and CXCL5 in patients who responded to treatment.

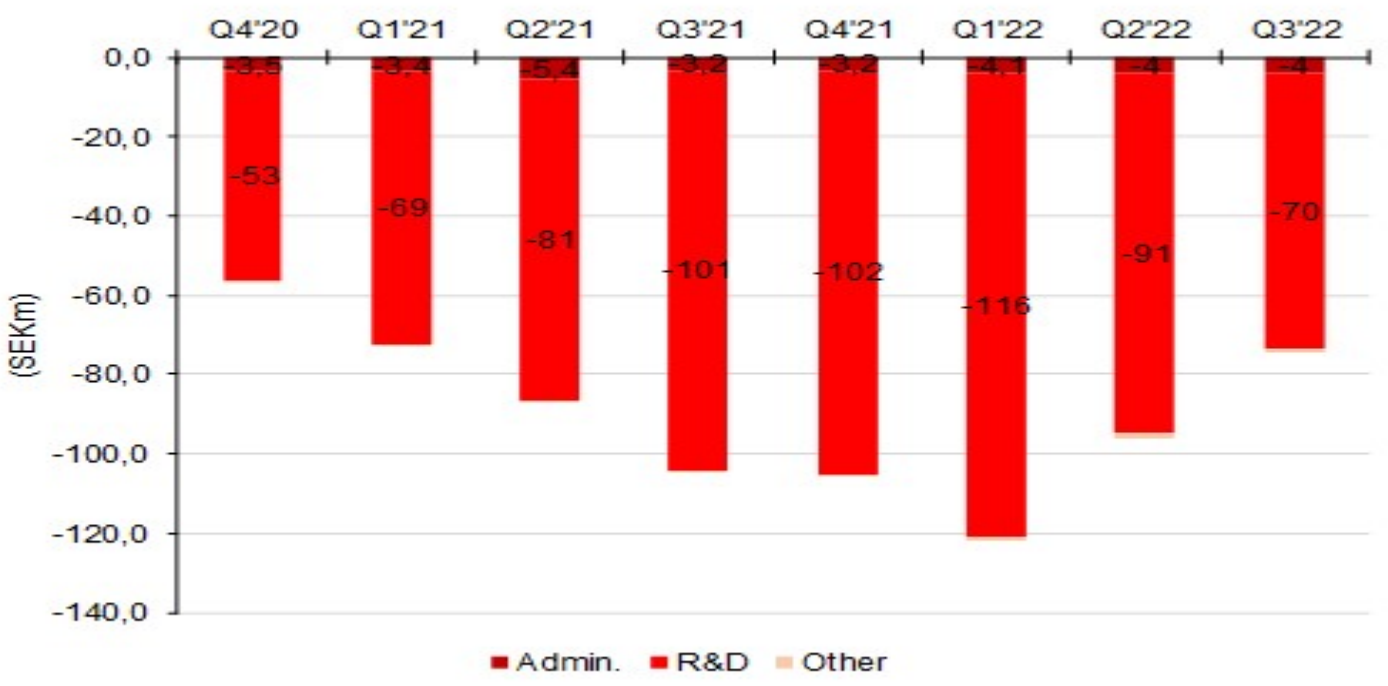
CAN10

CAN10 is being developed in systemic sclerosis and heart inflammation, but it also has potential in atherosclerosis (plaques in the blood vessels) prevention, which is a mass indication. A phase I trial with healthy volunteers will be initiated in H1 2023. Positive results in a preclinical model for myocarditis (inflammation of the heart) were published in July at BCVS 2022 - a surrogate CAN10 antibody decreased inflammation and disease burden. Additional preclinical data in systemic sclerosis will be presented at the ACR Convention in November. An abstract has already been published that summarizes the experiment. Firstly, skin samples from systemic sclerosis patients showed upregulation of the IL1RAP pathway compared to healthy controls. In a mouse model, mouse CAN10 reduced skin thickening, hydroxyproline content (which is a major skin component) and skin wound healing cell (myofibroblast) counts compared to controls; the lungs were also in better shape in the mCAN10-treated mice. In the skin bleomycin mouse model, mCAN10 treatment strongly reduced skin thickness and skin wound healing cell (myofibroblast) counts. RNA sequencing also demonstrated decreased expression of inflammatory proteins. These results support further development in systemic sclerosis.

Financials

Operating expenses have continued to decline and were SEK74m in the third quarter, down from SEK96m in the second quarter. This already begins to reflect Cantargia's previously communicated strategy to focus on a few promising indications and not continue all projects of the previously broad pipeline. In the conference call, management mentioned that costs should decrease more in 2023 after some additional production runs with nadunolimab have been completed.

Cantargia: Operating Expenses



Source: Redeye Research

Due to positive financial income, the result for the period was SEK-70m. Cash flow from operating activities was SEK-81m; the difference from operating costs is largely due to negative effects from changes in working capital. Cash and short-term investments amounted to SEK497m. It should last until at least mid-2024.

Valuation

Due to the pausing of three ongoing trials, we have extended the timelines of the respective projects. We have extended the launch year of the CESTAFOUR indication by two years to 2029, the CIRIFOUR indication by two years to 2028, and those of CAPAFOUR by one year each (2029). We also make some changes to the CAN10 forecasts. We assume a slightly lower total market share of 5.6% (7%), we raise development and launch costs and assume a one-year-later market entry (in 2030); however, we assume lower sales and administrative costs of 30% of sales (previously 40%), as it is a niche indication with potentially high margins. These changes lead to an increase in the value of the project of around SEK 100m. We raise the WACC by 0.5% to 13.5% and raise the USD/SEK exchange rate. As the most valuable project in our model is Precision Promise (PDAC), these changes combined do not have a major impact on our Base Case, which is SEK24 (25).

Cantargia sum-of-the-parts valuation

Project	Clinical Trial	Combination	Indication	LOA	Phase	Royalty	Peak sales (USDm)	Launch	NPV	NPV / share
CAN04/	Precision Promise	Gemcitabin/nab-paclitaxel	Pancreas	36%	II	17,5%	1 500	2027		
Nadunolimab	CAPAFOUR	FOLFIRINOX	Pancreas	15%	I	17,5%	600	2028		
	CANFOUR	Pemetrexed carboplatin/CS	NSCLC	16%	II	17,5%	600	2026		
	CIRIFOUR	PD-1 inhibitors	NSCLC	14%	II	17,5%	1 800	2028		
	TRIFOUR	Carboplatin/gemcitabin	TNBC	8%	I	17,5%	400	2027		
	CESTAFOUR	Chemotherapy basket	NSCLC, Colon, Biliary	8%	I	17,5%	700	2029		
									4318	26
CAN10		Monotherapy	Systemic sclerosis	11%	Precl.		600	2030	472	3
Overhead (incl. taxes) (SEKm)									-1 213	-7,3
EV (SEKm)									3 577	
Net cash (SEKm)									497	3,0
Total value (SEKm)									**4 073**	**24**

Near-term catalysts for nadunolimab

Below we summarize the upcoming catalysts for nadunolimab.

- CANFOUR: new updates with more details from the PDAC and NSCLC arms presented at ASCO, expected in Q1.
- CIRIFOUR: more complete results from the phase I trial in combination with pembrolizumab presented at ASCO, also expected around Q1.

- CAPAFOUR: more detailed readout with 15 patients in the phase I part in PDAC with FOLFIRINOX in H1 2023.
- CESTAFOUR: more detailed readout with 15 patients in three phase I studies in H1 2023 —in NSCLC with docetaxel; in biliary tract cancer in combination with cisplatin/gemcitabine; and in colon cancer in combination with FOLFOX.
- TRIFOUR: first readout from the phase I part in triple-negative breast cancer in combination with carboplatin/gemcitabine in Q1, and the decision on whether to expand into a randomized phase II trial.
- Precision Promise: first patient treated in H1 2023
- New preclinical and translational results.

People: 3

Cantargia is led by an experienced and close-knit team. CEO Göran Forsberg has been involved in licensing agreements, providing critically important experience that will benefit Cantargia's future partner negotiations. Furthermore, three new members of the management team were recruited in 2020-2021 to support the expanded clinical development. We believe the board is solidly composed and includes members with different and complementary experience.

Business: 3

Pharmaceutical is a high-margin industry in which there is clear product protection via patents for companies' projects. It is generally a non-cyclical industry. For research companies like Cantargia the situation is different, with risks associated not just with clinical development but also with the (cyclical) stock market, where capital requirements are large and often handled via new issues.

Financials: 1

Cantargia has a solid cash position that should last until mid-2024. No revenue is expected before a potential exit, such a license deal.

Income Statement

SEKm	2020	2021	2022E	2023E	2024E
Revenues	-	-	-	-	48
Cost of Revenue	-	-	-	-	-
Operating Expenses	29	52	51	27	90
Exchange Rate Differences	-	-	-	-	-
EBITDA	(29)	(52)	(51)	(27)	(42)
Depreciation	-	2	2	0	0
Amortizations	2	-	-	0.01	0.01
EBIT	(31)	(54)	(53)	(27)	(42)
Shares in Associates	-	-	-	-	-
Interest Expenses	-	-	-	-	-
Net Financial Items	-	-	(1)	-	-
Non Recurring Income Expense	-	-	-	-	-
EBT	(31)	(54)	(53)	(27)	(42)
Income Tax Expenses	-	-	-	-	-
Net Income	(31)	(54)	(53)	(27)	(42)

Balance Sheet

SEKm	2020	2021	2022E	2023E	2024E
Accounts Receivable	3	5	2	-	69
Average Inventories	-	-	-	-	-
Other Current Assets	7	27	38	-	17
Total Current Assets	913	591	450	134	908
Property, Plant and Equipment (Net)	5	3	3	3	3

SEKm	2020	2021	2022E	2023E	2024E
Invested Capital	(8)	(25)	(12)	(34)	(68)
Goodwill	-	-	-	-	-
Right-of-Use Assets	-	-	-	-	-
Other Long Term Assets	-	-	-	-	-
Total Non-Current Assets	13	10	10	10	10
Total Assets	925	600	459	144	918
Short Term Debt	-	1	1	1	1
Accounts Payable	11	35	17	-	104
Other Current Liabilities	20	32	44	43	61
Total Current Liabilities	30	67	62	44	165
Long Term Debt	3	-	-	-	-
Other Long Term Lease Liabilities	-	1	(2)	(2)	(2)
Shareholder's Equity	892	533	399	102	755
Non Controlling Interest	-	-	-	-	-
Total Liabilities and Equity	926	600	459	144	918
Cash Equivalents	903	559	409	134	822

Cash Flow

SEKm	2020	2021	2022E	2023E	2024E
Change in Working Capital	7	14	(13)	22	35
Operating Cash Flow	(156)	(346)	(375)	(275)	688
Capital Expenditures	(1)	(0)	-	-	-
Investing Cash Flow	(9)	(0)	-	-	-
Financing Cash Flow	919	-	225	-	-
Free Cash Flow	(165)	(347)	(375)	(275)	688

Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive longterm earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.
The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don’t understand the competitive environment and don’t have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won’t succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.
The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company’s financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.
The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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