EDISON

Cantargia

FY22 results

Next phase of clinical development in sight

Pharma and biotech

Following a period of increased clinical activity, Q422, as we noted previously, saw Cantargia narrow its development focus to its three most promising/advanced programmes. In our opinion, this was driven by a combination of financing considerations (given the bearish biotech sentiment) and early efficacy signals. The clinical focus in FY23 will be on progressing it lead asset, nadunolimab (CAN04), in controlled, randomised trials in pancreatic cancer (PDAC), non-small cell lung cancer (NSCLC) and triple negative breast cancer (TNBC), although the first two trials are likely to start about six months later than our prior estimates. The FY22 operating loss of SEK381.5m (SEK370.3m in FY21) was largely due to R&D expenses of SEK364.7m (up 3% y-o-y). End-FY22 net cash (SEK426.7m, including short-term investments) provides a runway to mid-2024, per our projections. We have rolled forward our model and adjusted our estimates, resulting in a valuation of SEK6.6bn or SEK39.6/share (SEK7.5bn or SEK44.9/share previously).

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/21	0.0	(366.5)	(3.66)	0.0	N/A	N/A
12/22	0.0	(371.8)	(2.90)	0.0	N/A	N/A
12/23e	0.0	(306.6)	(1.84)	0.0	N/A	N/A
12/24e	0.0	(292.6)	(1.75)	0.0	N/A	N/A

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

Randomised trials in focus for FY23

Cantargia's October 2022 decision to focus its clinical efforts on the three most advanced indications – PDAC (as one of the trial arms in PanCAN's ongoing Phase II/III adaptive study, Precision Promise), NSCLC (randomised study following the Phase I/IIa CANFOUR study) and TNBC (randomised Phase II part of the Phase Ib/II TRIFOUR study) – allows the company to maximise the pipeline's potential while preserving cash. We view the initiation of randomised studies for each of these indications as potential inflection points with interim readouts, if positive, opening the door for potential partnering/licensing opportunities.

TNBC data encouraging

The swift advancement of the TRIFOUR trial to the randomised stage (n=98) is another significant development for Cantargia, particularly given the early efficacy signals – of the 12 evaluable patients, there was one complete response, five partial responses and four patients with stable disease. Additional data from the study will be presented in H223 but we expect the focus will be on the interim futility analysis in Q423, which will likely map the course for subsequent trial progression.

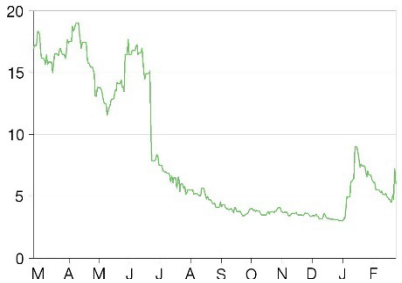
Valuation: SEK6.6bn or SEK39.6 per share

We have rolled forward our model and revised our forecasts for the FY22 results and our updated clinical timeline estimates. Our revised valuation is SEK6.6bn or SEK39.6/share (previously SEK7.5bn or SEK44.9/share) and includes the updated net cash position of SEK426.7m at end-FY22. Based on our projected cash burn rates, we estimate the balance to be sufficient to fund operations to mid-2024.

27 February 2023

Price	**SEK6.81**
Market cap	**SEK1bn**
	SEK10.4/US$
Net cash and short-term investments (SEKm) at 31 December 2022	426.7
Shares in issue	166.99m
Free float	99%
Code	CANTA
Primary exchange	Nasdaq Nordic
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(2.3)	85.7	(51.7)
Rel (local)	(1.1)	79.0	(51.5)
52-week high/low	SEK15.81	SEK3.01	

Business description

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

Next events

PanCAN PDAC Phase II/III trial begins	2023
NSCLC Phase II/III trial begins	2023

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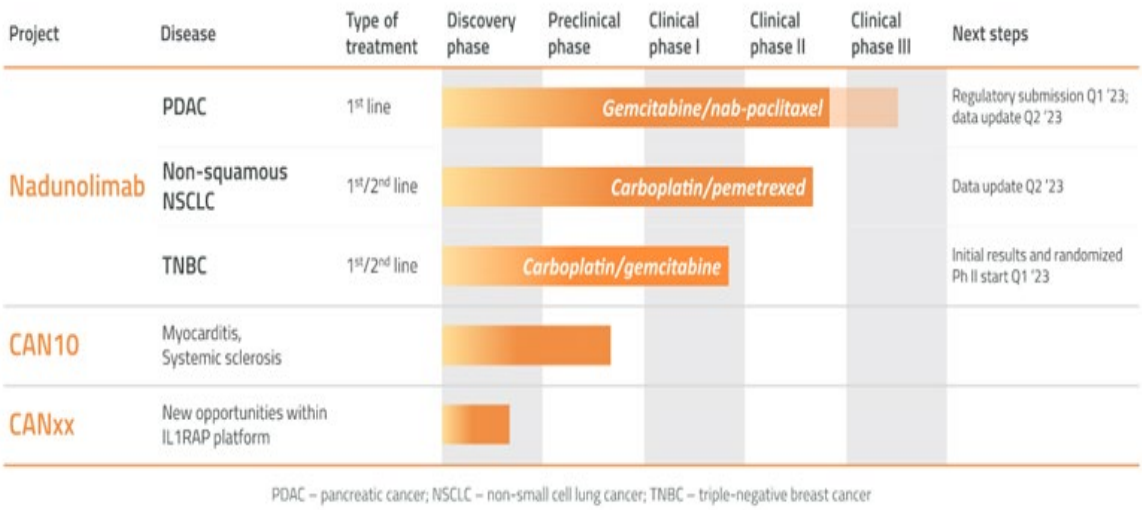
Randomised studies on the horizon in FY23

2023 is set to be a busy year for Cantargia as it continues to progress the clinical development of its lead IL1RAP-targeting antibody candidate, nadunolimab (CAN04). CAN04 is currently being investigated in combinational treatment regimens across a range of solid tumours; however, management intends to focus strategically on three key indications: PDAC, NSCLC and TNBC, Exhibit 1.

Exhibit 1: Cantargia's strategic priorities



Source: Cantargia corporate website

More specifically, Cantargia intends to prioritise bringing CAN04 into randomised clinical studies in 2023 across these three tumour indications. This includes a potentially significant Phase II/III study (Precision Promise) in PDAC in collaboration with the Pancreatic Cancer Action Network (PanCAN), the Phase I/II TRIFOUR study in TNBC supported by Spanish breast cancer group GEICAM, and a planned follow-on randomised study in NSCLC. Cantargia intends to use the funding from its mid-2022 rights issue (c SEK250m raised) to finance these clinical activities. Given the encouraging clinical data reported from the CANFOUR study in PDAC and NSCLC patients, we view management's decision to prioritise these indications within its portfolio as sensible, particularly in light of the ongoing capital market tightness.

CANFOUR data pave the way in PDAC and NSCLC

The most significant clinical news for Cantargia in FY22 came in the form of positive interim data presented at the American Society of Clinical Oncology from the CANFOUR study, consisting of a Phase IIa arm in NSCLC and a Phase I/IIa arm in PDAC.

In first- or second-line NSCLC, CAN04, in combination with gemcitabine and cisplatin, reported an overall response rate (ORR) of 53% (30 evaluable patients), a significant improvement over the ORRs of 22–28% historically seen with chemotherapy only. This was supported by an 83% disease control rate (ORR + stable disease), median progression-free survival (mPFS) of 6.8 months and overall survival (OS) of 13.7 months. The results were even more pronounced in the 16 patients with non-squamous NSCLC (the largest NSCLC sub-group, accounting for 75–80% of all NSCLC cases) with an ORR of 56% and mPFS of 7.3 months. While the data are still maturing, we see this as an encouraging sign for the CAN04-chemotherapy combination, given historical response rates. The study was expanded in February 2022 to include another open-label arm, specifically targeting

patients with non-squamous NSCLC. The arm is expected to recruit up to 40 patients (across seven countries) and management has indicated that patient recruitment will continue at least into Q123, following which the company will decide the next steps. Cantargia had earlier expected to complete patient enrolment by end H123, with plans to commence randomised trials in NSCLC thereafter. We see this recent communication as being more cautious in terms of committing to a timeline for the randomised study. On the premise that the randomised trial will now start in H124 versus our previous expectation of H223, we now estimate commercial launch in H127 versus 2026 previously.

Another area of focus for Cantargia is PDAC, for which the company had reported promising interim results from the Phase I/IIa arm of the CANFOUR trial in first-line PDAC. This extended interim analysis brings the number of patients assessed to 73. The combination of CAN04 with gemcitabine and nab-paclitaxel demonstrated an OS of 12.7 months and an mPFS of 7.2 months. Against historical averages for first-line gemcitabine and nab-paclitaxel treatment in PDAC (OS: 8.5 months; mPFS: 5.5 months), we see this as a positive result. Additional long-term data from both the PDAC and NSCLC arms are expected in Q223, along with new biomarker data.

In January 2022, Cantargia announced its decision to take part in PanCAN's Precision Promise adaptive clinical Phase II/III trial and one of Cantargia's key priorities for FY23 is to initiate the randomised study. Being part of the adaptive study comes with funding advantages (as the study will primarily be funded by PanCAN) and the benefit of access to a diverse patient pool across centres, which could result in more robust data sets, although the offset is that Cantargia is likely to have little control over the clinical process and timelines. We note that initiation of the CAN04 study arm has been delayed, with the company still in discussions with the FDA on details for the study protocol, and we expect more clarity on this in the coming months. At the time of the initial announcement in January 2022, Cantargia expected the trial results to become available in 2027, but given the ongoing discussions with the FDA we now estimate a launch in the PDAC indication in 2028.

TRIFOUR study underway

Cantargia is also developing CAN04 (in combination with chemotherapy) for the treatment of TNBC, which is being investigated in the Phase I/II TRIFOUR trial. This study is divided into two phases: Phase Ib, which is single arm, and Phase II, which will be randomised. The main goal of the Phase Ib portion was to ensure that the combination of CAN04 plus chemotherapy (gemcitabine plus carboplatin) was safe and to determine the maximum tolerated dose of CAN04. With the announcement of the FY22 results, Cantargia reported a favourable safety profile for the treatment. Importantly, the company also announced encouraging early signs of efficacy following an initial analysis of the Phase Ib part of the trial. Of the 12 evaluable patients (n=15), one showed confirmed complete response and five showed confirmed partial response, corresponding to a preliminary response rate of 50%. This compares favourably to the historical response rate of approximately 30% reported for gemcitabine and carboplatin. Among the other six evaluated patients, four showed stable disease and two showed progressive disease. Cantargia now plans to expand the trial to a randomised Phase II, which will assess the efficacy of CAN04 combined with gemcitabine and carboplatin chemotherapy compared to gemcitabine plus carboplatin only. The study plans to recruit up to an additional 98 patients (n=49 in each arm) and an interim futility analysis planned for Q423 will determine if the study will be continued.

CAN10 progressing towards the clinic

Cantargia's potential second clinical asset is CAN10, a IL1RAP-binding antibody for the treatment of systemic sclerosis (SS). SS (also known as scleroderma) is a rare autoimmune disease that affects 1.4/100,000 people per year and is characterised by fibrosis (scar-like tissue formation) in the skin and visceral organs. To date, there are no curative treatments for SS and existing therapies

only control the symptoms of the disease, for example anti-hypertensives, immunosuppressants and pain relief. We therefore see an opportunity for Cantargia to differentiate with CAN10 in the SS treatment market, if it can demonstrate efficacy or a disease-modifying effect.

In November 2022 Cantargia reported encouraging preclinical data in which CAN10 was found to elicit a reduction in fibrosis and inflammation in skin and lung tissues in three different in vivo models of SS, while also reducing IL1RAP-stimulated inflammatory biomarkers. To further support CAN10's progression into clinical development, the company announced in January 2023 the results of a Good Laboratory Practice toxicity study in which CAN10 was found to be well tolerated when administered over six weeks. Management has communicated that it intends to use the preclinical data packages to support the initiation of Phase I studies in SS and myocarditis in H123 (filing expected in Q123). While we acknowledge that preclinical results may not necessarily translate into clinical utility, the encouraging preclinical data are, in our view, supportive of the company's strategy to pursue the treatment of SS with CAN10 and add to previous evidence gathered by the company on IL1RAP's potential utility in inflammatory and fibrotic diseases.

Valuation

We value Cantargia using a risk-adjusted NPV approach for its lead clinical asset CAN04 across two indications – NSCLC and PDAC. Following the recent management announcements and improved visibility on development timelines, we have pushed out our launch assumptions for both indications by a year: to 2027 (from 2026) for NSCLC and to 2028 (from 2027) for PDAC. Our model also assumes a lower probability of success for NSCLC versus PDAC (25% vs 40% respectively; unchanged from previously) given the highly competitive lung cancer space with multiple novel therapeutics vying for market share. Furthermore, we continue to leave out the TNBC indication from our valuation for now; we may include it following data from the interim futility analysis in Q423, which offers the potential for upside. Our estimates also do not include consideration for other clinical/preclinical assets and programmes, which may offer incremental upside on successful clinical progress. Our valuation benefits from rolling forward our model by a year but is offset by the revised timelines for the expected launches of CAN04 in NSCLC and PDAC and a lower net cash position (SEK426.7m, including short-term investments, versus SEK496.5m previously). Overall, our valuation resets to SEK6.6bn or SEK39.6/share, from SEK7.5bn or SEK44.9/share. Of this, 54% of the valuation is attributable to the PDAC indication (rNPV SEK3.55bn or SEK21.3/share) and 40% is attributable to NSCLC (rNPV SEK2.64bn or SEK15.8/share). Our key assumptions are summarised in Exhibit 2.

Exhibit 2: Cantargia valuation breakdown

Product	Launch	Peak sales ($m)	NPV (SEKm)	NPV/share (SEK)	Probability	rNPV (SEKm)	rNPV/share (SEK)
CAN04 – NSCLC	2027	3,000	10,400.4	62.3	25.0%	2,641.7	15.8
CAN04 – PDAC	2028	2,000	7,890.5	47.3	40.0%	3,550.7	21.3
Net cash at end FY22 (including short-term investments)			426.7	2.6	100%	426.7	2.6
Valuation			**18,717.5**	**112.1**		**6,619.1**	**39.6**

Source: Edison Investment Research

Financials

FY22 total operating expenses of SEK381.5m represented 3% y-o-y growth versus the FY21 figure of SEK370.3m and were higher than our expectation of SEK333.8m. With multiple trials ongoing, R&D-related expenses made up the bulk of the operating expenses (>95%). FY22 R&D costs were SEK364.7m, up 3.5% y-o-y, although the Q422 figure of SEK88m was marginally lower than the

quarterly run-rate in FY22. We attribute this to management's decision to focus its R&D on three core programmes for CAN04 in October 2022 and we anticipate R&D costs to decrease in FY23 as a result. Cash flows from operations were SEK358.9m in FY22, 3.6% higher than the FY21 figure of SEK346.6m, again reflecting the higher R&D spend. We have updated our FY23 estimates for R&D and other operating expenses based on the Q422 trend and current visibility on clinical programmes and we introduce FY24 estimates. We estimate R&D expenses of SEK291.7m and SEK277.2m respectively in FY23 and FY24 (previously SEK282.3m for FY23). The company ended the year with a cash balance of SEK189.6m (supported by c SEK223.9m in net proceeds from the July 2022 rights issue), which along with an additional SEK237.1m in short-term investments should be sufficient to fund operations into Q224, based on our projected cash burn rates. We anticipate the need to raise another SEK300m in H224 if a partnership/licensing deal is not signed by then. Assuming this fund-raise is effected through an equity issue at the 23 February 2023 closing price (SEK6.03/share), the company will have to issue an additional 49.8m shares, resulting in our per share valuation reducing to SEK30.5/share from SEK39.6/share currently.

Exhibit 3: Financial summary

SEK'000s	2020	2021	2022	2023e	2024e
Year end 31 December					
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	(158,396)	(352,709)	(364,686)	(291,749)	(277,161)
General and administrative	(14,919)	(15,309)	(14,964)	(13,468)	(13,872)
Other operating expenses	(630)	(2,249)	(1,899)	(1,709)	(1,760)
EBITDA	(170,697)	(366,821)	(377,857)	(302,149)	(286,878)
Operating Profit (before amort. and excepts.)	(173,945)	(370,267)	(381,549)	(306,926)	(292,793)
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit	(173,945)	(370,267)	(381,549)	(306,926)	(292,793)
Net interest	501	924	483	374	235
FX income/(expense)	359	2,839	9,252	0	0
Profit Before Tax (norm)	(173,085)	(366,504)	(371,814)	(306,552)	(292,558)
Profit Before Tax (reported)	(173,085)	(366,504)	(371,814)	(306,552)	(292,558)
Tax	0	0	0	0	0
Profit After Tax (norm)	(173,085)	(366,504)	(371,814)	(306,552)	(292,558)
Profit After Tax (reported)	(173,085)	(366,504)	(371,814)	(306,552)	(292,558)
Average Number of Shares Outstanding (m)	89.4	100.2	128.0	167.0	167.0
EPS - normalised (ore)	(193.65)	(365.80)	(290.43)	(183.58)	(175.20)
Dividend per share (ore)	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	12,622	9,556	12,954	10,177	7,262
Intangible Assets	7,360	6,459	5,559	5,559	5,559
Tangible Assets	5,262	3,097	7,395	4,618	1,703
Investments	0	0	0	0	0
Current Assets	912,893	590,687	461,844	154,605	167,510
Stocks	0	0	0	0	`
Debtors	0	0	0	0	0
Cash	693,354	247,322	189,573	119,429	132,334
Short-term investments	210,019	312,064	237,095	0	0
Other including short-term investments	9,520	31,301	35,176	35,176	35,176
Current Liabilities	(30,469)	(66,607)	(85,090)	(77,676)	(76,271)
Creditors	(30,469)	(66,607)	(85,090)	(77,676)	(76,271)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(3,111)	(892)	(24)	(24)	(300,024)
Long term borrowings	0	0	0	0	(300,000)
Other long term liabilities	(3,111)	(892)	(24)	(24)	(24)
Net Assets	891,935	532,744	389,684	87,083	(201,524)
CASH FLOW					
Operating Cash Flow	(156,387)	(346,446)	(358,915)	(305,239)	(284,096)
Purchase of intangibles	(8,112)	0	0	0	0
Capex	(890)	(383)	(7,089)	(2,000)	(3,000)
Proceeds from sale of PPE	0	0	0	0	0
Capital Financing	917,545	0	223,934	0	0
Others	969	0	0	0	0
Effect of FX on cash	359	2,839	9,352	0	0
Net Cash Flow	753,484	(343,990)	(132,718)	(307,239)	(287,096)
Opening net debt/(cash)*	(149,890)	(903,373)	(559,386)	(426,668)	(119,429)
HP finance leases initiated	0	0	0	0	0
Other	0	0	0	0	0
Closing net debt/(cash)*	(903,373)	(559,386)	(426,668)	(119,429)	167,666

Source: Company accounts, Edison Investment Research. Note: *Includes short-term investments.

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