EDISON

Cantargia

Q219 update

CANFOUR study on track, US trial preparations

Pharma & biotech

On 23 August, Cantargia announced fresh preclinical *in vivo* data on CAN04 in bladder cancer, which suggests an opportunity to explore this indication. The company also recently announced that the CAN04 monotherapy arm is now fully enrolled (n=20) and these patients are receiving doses of 10mg/kg. Due to the fast enrolment, Cantargia has decided to enrol an additional monotherapy cohort to test a higher dose of 15mg/kg (n=12). Efficacy and biomarker data from the first 20 patients are expected in Q419. Preparations for its US study are underway – specific timelines were not provided, but we expect more news in this regard this year. Our valuation is virtually unchanged at SEK2.65bn or SEK36.4/share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
12/17	0.0	(60.3)	(1.86)	0.0	N/A	N/A
12/18	0.0	(91.2)	(1.38)	0.0	N/A	N/A
12/19e	0.0	(94.6)	(1.36)	0.0	N/A	N/A
12/20e	0.0	(117.8)	(1.62)	0.0	N/A	N/A

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

Fresh preclinical data: Opportunity in bladder cancer

This is the first preclinical data Cantargia has released on bladder cancer, and the first time the company is discussing it as a potential indication for CAN04 development. Results from immunohistochemistry carried out on tumour samples from 15 patients demonstrated that around 80% of the tumour samples contained IL1RAP positive cells (vs 85% NSCLC, 86% pancreatic cancer, 87% melanoma in a previous study). It was also able to demonstrate single agent activity in an *in vivo* mouse model with a functioning immune system, where the tumour cells overexpress IL1RAP. Cantargia also recently extended its collaboration with BioWa for its technology POTELLIGENT, which is important for Cantargia's antibodies since it enhances antibody dependent cellular cytotoxicity (ADCC).

Financials: Q219 results, long cash runway to H121

With its Q219 results, Cantargia reported an operating loss of SEK25.2m vs SEK28.6m in Q218. R&D costs in Q219 were SEK20.8m vs SEK22.1m in Q218. In March 2019, Cantargia raised SEK106m (gross) in a directed share issue, primarily by long-term institutional investors. This extended the cash runway to H121 (in line with management guidance). The current net cash position is SEK219.2m (including short-term investments) vs SEK251.2m at end-Q119.

Valuation: SEK2.65bn or SEK36.4/share

We value Cantargia at SEK2.65bn or SEK36.4/share vs SEK2.62bn or SEK36.0/share previously (Exhibit 2). The slight increase in total NPV is due to rolling our model forward, which was offset by the lower net cash position. We make no changes to the assumptions described in previous reports and in detail in our initiation report. The next key catalyst for the share price will be the Phase IIa CANFOUR data in early 2020.

27 August 2019

Price	**SEK16.82**
Market cap	**SEK1,225m**
	US$:SEK9.05
Net cash (SEKm) at end Q219 (cash and cash equivalents + short term investments)	219.2
Shares in issue	72.8m
Free float	90%
Code	CANT
Primary exchange	Nasdaq Stockholm
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	0.7	(7.0)	(11.9)
Rel (local)	5.8	(6.1)	(9.0)
52-week high/low	SEK23.3		SEK13.7

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 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

Initiate new US study	H219
CANFOUR monotherapy cohort data	Q419
Preclinical data supporting combination with platinum-based chemotherapy	2019
Phase IIa CANFOUR data	Early 2020

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Data from monotherapy cohort expected Q419

Cantargia recently announced that the CAN04 monotherapy arm is now fully enrolled (n=20) and these patients are receiving doses of 10mg/kg. According to management, enrolment has been faster than expected. So far, the drug has a good safety profile, as in the Phase I part of the study. Around 12 additional patients are expected to be enrolled due to the fast enrolment into the monotherapy arm which will receive 15mg/kg. 60 further patients in total are due to be enrolled in the combination arms. Efficacy and biomarker data from the first 20 patients are expected in Q419.

Update on IL-1 competitive landscape

Exhibit 1 shows a summary of all ongoing studies with agents targeting the IL-1 pathway in cancer indications. Novartis now has two IL-1 beta antibodies, canakinumab and gevokizumab, which are being studied in a total of 10 clinical trials. Canakinumab is the most advanced asset and is being studied in three Phase III studies in NSCLC in different patient populations. Completion of these trials is estimated in 2021–22.

Exhibit 1: IL-1 pathway inhibitor landscape cancer indications

Pharmacological class / target	Product (generic name)	Company	Current development status of oncology indications	Notes
Anti-IL-1 beta Mab	Ilaris (canakinumab)	Novartis	Phase III NSCLC CANOPY-A, recruiting (NCT03447769, n=1,500) Phase III NSCLC CANOPY-1, recruiting (NCT03631199, n=627) Phase III NSCLC CANOPY-2, recruiting (NCT03626545, n=240) Phase II NSCLC CANOPY-N, not yet recruiting (NCT03968419, n=110) Phase II melanoma, recruiting (NCT03484923, n=230) Phase I renal cell carcinoma, recruiting (NCT04028245, n=14) Phase Ib triple negative breast cancer, recruiting (NCT03742349, n=220) Phase I, Colorectal Cancer, Triple Negative Breast Cancer, NSCLC - Adenocarcinoma (NCT02900664, n=432) Phase I NSCLC, active not recruiting (NCT03064854, n=114)	Already marketed in immune indications: CIAS1 associated periodic syndromes, gout, juvenile idiopathic arthritis, adult-onset Still's disease, familial Mediterranean fever, hyper-IgD syndrome. Filed in myocardial infarction prophylaxis and stroke prophylaxis. Lung cancer data published from CANTOS (NCT01327846).
	Gevokizumab	Novartis	Phase I metastatic colorectal, gastroesophageal and renal cancers (NCT03798626, n=172)	Novartis licensed gevokizumab from Xoma in 2017 with the rest of Xoma's IL-1 beta IP portfolio. Prior to this, Xoma and Servier were developing the antibody for several immune indications, but these were not successful.
Anti-IL-1 alpha Mab	Xilonix	XBiotech	Two Phase III trials in colorectal cancer, status unclear (NCT01767857, NCT02138422); Phase I pancreatic cancer patients with cachexia (NCT03207724) Phase I NSCLC (XBiotech)	The first Phase III trial (European) trial was positive for the symptomatic progression of the cancer. The second Phase IIII trial (XCITE) was terminated due to lack of efficacy. Current development status in this indication unclear.
Anti-IL1RAP Mab	CAN04	Cantargia	Phase I/II NSCLC, pancreatic cancer (NCT03267316, n=100)	No other indications in the Phase IIa part of the trials.
	CSC012	Cellerant Therapeutics	Preclinical acute myeloid leukaemia	No other indications found.
Anti-IRAK 4 small molecule	CA-4948	Curis	Phase I non-Hodgkin lymphoma (NCT03328078, n=110) Preclinical acute myeloid leukaemia	Also in preclinical testing for arthritis and myelodysplastic syndrome.

Source: EvaluatePharma, company websites, clinicaltrials.gov. Notes: Ordered by most pharmacological target and most advanced asset.

More recently, Novartis disclosed new trials in its Q219 results and R&D day presentations, where canakinumab is being studied alongside other agents in triple negative breast cancer, melanoma and RCC. Gevokizumab is being studied in metastatic colorectal, gastroesophageal and renal cancers. In terms of the possible rationale for Novartis choosing these particular cancers, IL-1 is associated with tumour invasiveness and angiogenesis in RCC and breast cancers. XBiotech appears to have restarted Xilonix activity in cancer indications, since it recently announced that it has received funding from the Medical Research Council to conduct a Phase II study in advanced lung, pancreatic and ovarian cancers. We have described previous trials with Xilonix in our initiation report on Cantargia.

For the moment we do not include bladder cancer in our valuation, since it is still pre-clinical but will revise our valuation once we have more visibility on clinical development timelines.

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	3,091	6,279.1	86.2	15%	1,019.5	14.0
CAN04 - pancreatic cancer	2024	2,100	6,371.9	87.5	15%	1,413.2	19.4
Net cash at end-Q119			219.2	3.0	100%	219.2	3.0
Valuation			**12,870.2**	**176.8**		**2,652.0**	**36.4**

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

Exhibit 3: Financial summary

SEK'000s	2017	2018	2019e	2020e
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	(52,419)	(76,951)	(86,951)	(109,602)
EBITDA	(60,010)	(93,306)	(94,924)	(117,815)
Operating Profit (before amort. and except.)	(60,010)	(93,306)	(94,924)	(117,815)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(60,010)	(93,306)	(94,924)	(117,815)
Net Interest	(243)	2,145	360	0
Profit Before Tax (norm)	(60,253)	(91,161)	(94,565)	(117,815)
Profit Before Tax (reported)	(60,253)	(91,161)	(94,565)	(117,815)
Tax	0	0	0	0
Profit After Tax (norm)	(60,253)	(91,161)	(94,565)	(117,815)
Profit After Tax (reported)	(60,253)	(91,161)	(94,565)	(117,815)
Average Number of Shares Outstanding (m)	32.4	66.2	69.5	72.8
EPS - normalised (SEK)	(1.86)	(1.38)	(1.36)	(1.62)
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	2,957	2,957	2,957	2,957
Intangible Assets	0	0	0	0
Tangible Assets	0	0	0	0
Investments	2,957	2,957	2,957	2,957
Current Assets	271,496	168,486	174,623	56,808
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	149,781	76,528	172,984	55,169
Other*	121,715	91,958	1,639	1,639
Current Liabilities	(28,334)	(16,398)	(16,398)	(16,398)
Creditors	(28,334)	(16,398)	(16,398)	(16,398)
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	246,119	155,045	161,182	43,367
CASH FLOW				
Operating Cash Flow	(40,860)	(105,165)	(94,924)	(117,815)
Net Interest	(243)	478	360	0
Tax	0	0	0	0
Capex	0	0	0	0
Acquisitions/disposals	0	0	0	0
Financing	304,479	0	100,700	0
Other	(139,499)	31,434	90,320	0
Dividends	0	0	0	0
Net Cash Flow	123,877	(73,253)	96,456	(117,815)
Opening net debt/(cash)	(25,904)	(149,781)	(76,528)	(172,984)
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)	(149,781)	(76,528)	(172,984)	(55,169)

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

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