

## Research update

### KANCERA AB

Since its founding in 2010, Kancera has worked with the development of small molecule drug candidates for inflammatory diseases and cancer. The company conducts clinical development in myocardial infarction.

CEO: Thomas Olin

CoB: Erik Nerpin

[www.kancera.com](http://www.kancera.com)

Bloomberg: KAN:SS

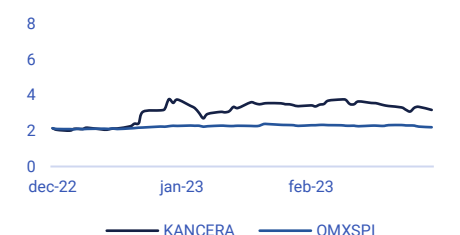
Refinitiv Eikon: KANC.ST

Listing: Nasdaq OMX First North Premier

Last price: SEK 3.2

Market Cap: SEK 252m

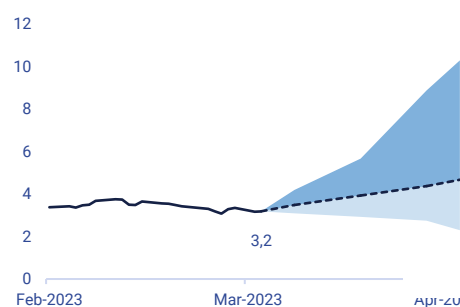
### SHARE DEVELOPMENT



	12M	YTD	6M	1M
Dev. (%)	-54	50	-38	-8

Source: S&P Capital IQ

### VALUATION INTERVAL



	BEAR	BASE	BULL
Share Price (SEK)	2.3	4.7	10.3
Up-/downside (%)	-28%	47%	223%

Source: S&P Capital IQ and Carlsquare estimates

### CARLSQUARE EQUITY RESEARCH

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## Start of cancer trial expected shortly

Carlsquare Equity Research raises the fair value for Kancera since the company has recently achieved two important milestones for the clinical development of the fractalkine project. The heart infarction study is fully recruited with an expected read-out in Q3 2023. A study in advanced ovarian cancer will also start shortly. We expect early effect results already next year.

### On the threshold to start a cancer trial

During the coming six months, Kancera plans to start two new clinical studies: i) a phase Ib/Ila in patients with ovarian cancer treated with KAND567 in combination with carboplatin ii) a phase Ia study with KAND145 in healthy subjects. Recently, the Swedish Medical Products Agency gave its approval to carry out the cancer study. Kancera also submitted applications to the Danish and Norwegian pharmaceutical agencies in January. Although it is a small study, it will provide a first sign of whether Kancera's fractalkine inhibitor can inhibit resistance to platinum-based chemotherapy in patients with advanced ovarian cancer, according to the company's hypothesis. The latter is an indication where treatment alternatives are unfortunately limited at present, but where the commercial potential for new treatments in return is significant.

### Fully recruited heart infarction study raises temperature

The other week, Kancera also announced that the FRACTAL heart attack study has completed recruitment. Thus, the countdown to the presentation of top line results (expected Q3 2023) has begun. It is a binary event where we judge that a positive outcome corresponds to a clear positive trend in clinical effect parameters compared to placebo. In such a scenario (bull case), we assess that the share can multiply in a short time. Conversely, in a negative scenario (bear case) where the outcome does not support further development in myocardial infarction, we see a risk of at least a temporary greater decline (+30 percent). However, a broadened clinical program for cancer makes Kancera less dependent on a single indication, which, all else being equal, should mitigate the risk in the stock.

### Additional capital injection is possible this spring

We raise the risk adjusted fair value in the base scenario by approximately 15 percent to SEK 4.7 (4.1) per share, considering that the fractalkine project received the go-ahead for clinical studies in Sweden in ovarian cancer and as we make somewhat more optimistic sales assumptions. We believe approval in Denmark and Norway should follow shortly. We assess that Kancera has a lower valuation than other companies in the corresponding development stage.

During the fall of 2022, Kancera carried out a rights issue of SEK 46 million. The financial position can be further strengthened if outstanding warrants, with a subscription period in May and a strike price of SEK 3 per share, are exercised to a large extent.

### Key Ratios (SEKm)

	2020	2021	2022	2023E	2024E	2025E
Net Sales	2,7	0,0	0,0	0,0	0,0	213,0
Revenue	5,4	1,9	0,8	0,1	0,1	213,1
EBITDA	-38,4	-44,9	-51,6	-66,9	-89,0	197,3
EBIT	-40,1	-45,3	-51,9	-66,9	-89,1	197,7
EBT	-40,5	-45,7	-52,5	-66,9	-89,1	197,7
EPS (SEK)	-1,3	-0,9	-0,9	-0,8	-0,9	1,9
EV/Sales	NM	NaN	NaN	NaN	NM	0,8x
EV/EBITDA	NM	NM	NM	NM	NM	0,8x
EV/EBIT	NM	NM	NM	NM	NM	0,8x

Source: Company information and Carlsquare estimates

## Start of cancer trial expected shortly

The fractalkine project has reached important milestones as the myocardial infarction study has been fully recruited and the cancer study has now received the go-ahead from the Swedish authorities. In light of this, we raise our valuation range.

### Timelines clear for clinical development

The Swedish Medical Products Agency has approved the application to conduct the study in patients with ovarian cancer with KAND567 in combination with carboplatin. Kancera is working on the final preparations to start the study (KANDOVA) at two Swedish clinics. In addition, Kancera is also waiting for information from the Danish and Norwegian authorities regarding the application for clinical trials in these countries.

Patients will receive KAND567 orally twice daily for 13 days in conjunction with each carboplatin cycle (typically once every four weeks). Treatment can last up to six cycles or approximately 24 weeks. The study is divided into an initial dose escalation and then a dose expansion (phase IIa). The patients included in the study are second- to fourth-line treatment that have relapsed within six months after previous treatment with platinum-based chemotherapy.

Recently, Kancera announced that 71 patients had been recruited to the ongoing controlled study in myocardial infarction with the fractalkine inhibitor KAND567 and that the FRACTAL study is thus fully recruited. As previously communicated, complete sampling could not be collected from all patients, which is why the study was expanded in September 2022 from an initial 60 patients. The goal is to be able to present top-line results during the third quarter of 2023.

### Cooperation with Nordic network for clinical trials

For the cancer study, Kancera collaborates with the clinical trial unit within the Nordic Society of Gynecological Oncology (NSGO-CTU). The collaboration should facilitate the implementation of the study, for example in terms of recruitment. Kancera has also employed Dr. Hanjing Xie as new CMO (Chief Medical Officer). She is a specialist in, among other things, oncology and has a background from, among others, Oncopeptides and Bayer. She will focus on the KANDOVA study and clinical development of fractalkine inhibitors in oncology.

We assess that the appointment and the upcoming start of studies underline Kancera's increased orientation towards oncology. The former CMO Torbjörn Lundström is a cardiologist, which was a natural choice in light of the FRACTAL study. Dr. Lundström will remain an advisor for the analysis and final report from the heart attack study. As we understand it, Dr. Xie has a broad experience in clinical trials. It should be emphasised that Kancera collaborates with leading external expertise in selected therapeutic areas, including in the form of the aforementioned NSGO-CTU in cancer and, in cardiovascular immunology, a group led by Professor Ioakim Spyridopoulos. The latter is one of the most prominent researchers in the field of fractalkines globally.

The timing of the change may come as a bit of a surprise given that the ongoing FRACTAL study for the company's most advanced project has not yet been completed. However, we see no direct evidence that it is related to safety or efficacy

results from FRACTAL because the study is still blinded and Kancera should therefore have no insight into the outcome.

In addition, a phase Ia in healthy volunteers with KAND145 (a fractalkine inhibitor with improved properties for ovarian cancer) is also expected to start as early as the second quarter of 2023. It is an important piece of the puzzle, not least for the development of the cancer project.

## Manufacturing patent granted for fractalkine blockers

Recently, Kancera was granted a US patent to protect the company's manufacturing method for fractalkine blockers. The patent has an expiration date of 2039. We see it as an expected, and positive, announcement that confirms the IP protection for the fractalkine portfolio. There are certainly other external fractalkine inhibitors in varying phases of development, but KAND567 is differentiated, among other things, by binding to a different part of the target receptor.

## Q4 report as expected

We do not consider that the report for Q4 2023 deviated significantly from our expectations from a financial perspective. Costs rose sequentially to approximately SEK 14 million but were unchanged compared to the corresponding period in 2021. Cash flow from current operations improved as a result of increased trade payables. Following the rights issue in November 2022, the cash position strengthened to SEK 95 million compared to SEK 68 million at the end of September. We believe that the most important message in the report, as described above, was that the development in the fractalkine project seems to be progressing according to previously communicated plans.

## Investment case

A positive outcome from the first phase II trial in myocardial infarction could lead to a rapid re-rating for Kancera shares in the next year, and vice versa. Expected start of a cancer study can provide supportive news flow before then. The announced rights issue of approximately SEK 90 million lends credibility to the strategy of broadening the clinical program to oncology. We calculate a valuation range of approximately SEK 2 to 10 per share over a period of approximately nine months. Our risk-adjusted valuation in the base case amounts to SEK 4.7 per share after full dilution, which we believe is supported by a relative valuation.

## Important milestone and expansion in sight

Since its founding in 2010, Kancera has worked with the development of small molecule drug candidates for inflammatory diseases and cancer. The company began clinical development with KAND567 in 2017 and since 2020 trials have been ongoing in patients. In 2021, a controlled study was initiated in ST-elevation myocardial infarction in patients undergoing percutaneous coronary intervention (PCI).

- **Significant clinical milestone ahead.** Kancera plans to present top-line results from the randomized phase IIa study in myocardial infarction in Q3, 2023. This constitutes a very significant milestone where we expect the first results regarding clinical effect in this patient group to be presented.
- **Second generation fractalkine inhibitors approach clinic.** KAND567 has in previous studies been generally safe and tolerable but requires high dosage. Kancera has completed the preclinical development of the candidate KAND145, which has improved properties including increased

uptake in tumors. In addition to improved formulation, KAND145 also entails extended patent protection if the patent application is approved, which should facilitate discussions with potential partners.

- **Broadened clinical program strengthens opportunities.** Kancera is on the threshold of starting clinical development with the fractalkine project in cancer. The focus is on ovarian cancer and combination with standard treatment. Given that the authorities approve the arrangement, it means a welcome broadening and acceleration of the clinical program for fractalkine inhibitors.
- **Good scientific and commercial rationale in ovarian cancer.** Preclinical results suggest that Kancera's candidate can counteract tumor resistance to platinum-based chemotherapy by preventing DNA repair. Ovarian cancer is a challenging indication but the success of PARP inhibitors such as Astra Zeneca's multi-blockbuster Lynparza shows that blockade of DNA repair is a viable path. There is currently a lack of adequate treatments for platinum-resistant ovarian cancer, which underlines the potential.
- **Possible additional cash addition already this spring.** In November 2022, Kancera carried out a rights issue of approximately SEK 46 million to finance the announced clinical development of KAND567 and KAND145. The company raised additional capital already in the second quarter via the exercise of warrants TO6. The strike price is SEK 3 per share. Currently, the share is traded above the exercise price, which, all else being equal, provides good conditions for option holders to want to redeem the options. At full utilization, Kancera will receive around SEK 23 million before costs. If the subscription rate becomes high and the financial runway is extended, it should provide support for the share price. The subscription period is May 3 through May 17, 2023. In the event that Kancera does not receive any capital via TO6, a new financing need may arise earlier than planned.

### Intended development plan for Kancera

	Discovery	Preclinical PoC	Preclinical tox	Phase I	Phase II	Phase III	NDA
KAND567							
KAND145				2023			
PFKFB3							
ROR1							

Source: Kancera, Carlsquare.

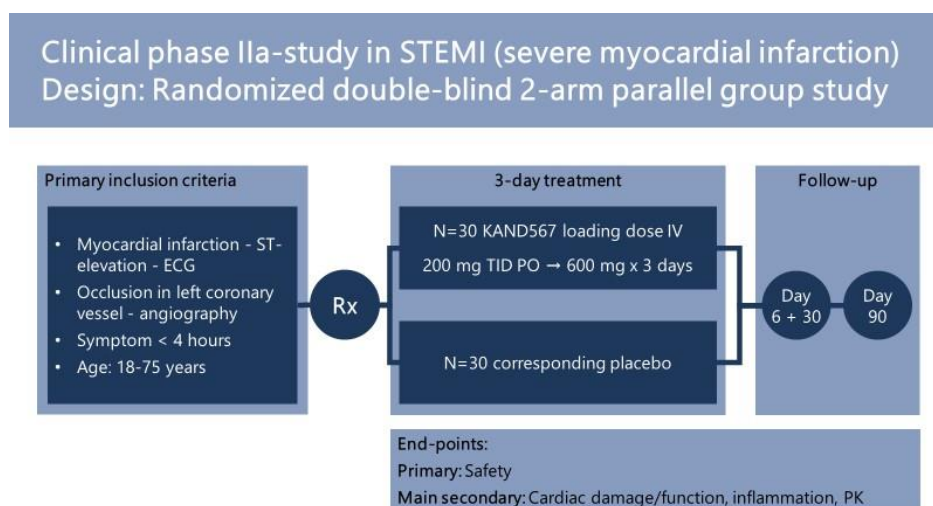
- **Great potential but also high risk in heart study.** We assess that Kancera is valued somewhat lower than similar companies. We expect that upcoming top-line results in myocardial infarction will have great significance for the outlook for the shares and the company. In a positive scenario, we estimate that the shares can rise multi-fold from today's levels. We believe today's valuation reflects low expectations about the chance of success, which in turn is largely explained by the fact that the indication has historically been challenging for clinical development. Only roughly 20 percent of all phase II studies are successful in the indication cardiovascular diseases. In a negative scenario where development in cardiovascular disease is shut down, we see, on the other hand, a further fall, tentatively to just over two SEK per share.

## Clinical development is ongoing in myocardial infarction

Currently, the phase IIa study FRACTAL is ongoing with a total of 71 patients who have suffered a myocardial infarction in the anterior wall of the heart muscle (STEMI). It was recently reported that the study was fully recruited. Topline data will be presented in the third quarter. We assess that the study followed the expected schedule and that the recruitment rate has been good. A certain question mark was that complete sampling had not been able to be collected for all patients, which meant that the study was expanded from the planned 60 to around 70 patients.

The study is placebo-controlled (1:1). The aim of the study is primarily the safety and tolerability of intravenous treatment with a bolus dose of 134 mg over six hours followed by oral treatment (a 200 mg tablet every eight hours for three days).

### Study design myocardial infarction



Source: Kancera

## Previous studies suggest that the primary objective will be met

For reference, a phase Ib study in 17 people showed that intravenous KAND567 for six hours was well tolerated. With longer infusions, inflammation in the blood vessels has been observed.

Oral administration has also been generally well tolerated. In 2020 to 2021, a study was conducted in Covid patients of which 15 received KAND567 250 mg twice a day for seven days. According to top-line results, this dose was well tolerated, and no treatment-related safety signals could be identified. In a phase I multi-dose study, treatment was well tolerated at doses up to 1000 mg per day (2 x 500 mg). At higher doses, dose-limiting toxicity occurred in the form of clinically relevant, but transient, effects on liver values.

Overall, KAND567 must be administered in relatively high doses but for a short time. Since similar dosage and treatment time have already been investigated, it suggests that even the ongoing study will show at least acceptable tolerability. However, the combination of intravenous and oral treatment has not yet been investigated in humans and, as in all drug development, it is not certain that all safety problems will be discovered already during the initial studies in humans. Fraktalkin bidrar till ökad överlevnad för makrofager. Fractalkine contributes to increased survival of macrophages. Inhibition of the fractalkine system should therefore theoretically lead to a certain impairment of the immune system. So far,



however, there are no reports of severe side effects in clinical trials. One caveat is that we do not know the background to the fact that a collaboration between Ablynx and Boehringer Ingelheim concerning fractalkine receptor blockers was apparently abandoned after a phase I study.

### Outcomes will be scrutinized for trends in effect

Secondary objectives in the myocardial infarction study are biological and clinical outcome measures such as activated T cells, inflammation markers such as CRP and outcome measures assessed based on image diagnostics such as infarct size and heart function. We judge that the study, as it is relatively small, probably has too little statistical power for the differences between the groups to be statistically significant. However, we believe overall that the result will be interpreted positively if we see a clear positive and relevant trend in clinical efficacy measures, and vice versa. Achieving a reduction in infarct size is of utmost importance as there is a clear link to mortality.

In the Covid-19 study, the primary objective was to investigate the effect on oxygen restoration (ROX index) and respiration in patients with SARS-Cov-2 infection. According to top-line results, there was no difference in terms of the degree of lung damage, measured by CT scan, or oxygen absorption capacity. No results regarding the effect on inflammatory markers such as CRP or cytokines have been communicated. The study was small and there was an imbalance between the study arms in terms of inflammation status to the detriment of KAND567. However, according to Kancera, an effect was measured in the form of a significantly reduced activation of immune cells that carried the marker CD163. No detailed results have yet been published, which in combination with the limited sample overall makes it difficult for us to draw any conclusions for, for example, the chance of success in myocardial infarction.

## New drugs could change the treatment of advanced ovarian cancer

### Antibody conjugate under review after accelerated approval

Since our initiation analysis, the FDA has granted accelerated approval for Elahere (mirvetuximab soravtansine), an antibody conjugate targeting the folate receptor alpha (FR $\alpha$ ) molecule that is frequently expressed in ovarian cancer. The decision was based on results from a relatively small (n=106), non-randomized trial as monotherapy in patients who had received up to three lines of treatment and were platinum resistant. The primary objective was objective response and in the study 32 percent was achieved. Treatment is indicated for FR $\alpha$ -positive patients according to a diagnostic test. However, regulators have labelled Elahere with a so-called "Black Box Warning" for eye toxicity. Results of a confirmatory study are expected to be presented shortly, with the aim of reaching full approval based on progression-free survival as the primary objective. It will be a decisive event for the outlook for Elahere and could have a major impact on the competitive landscape in ovarian cancer.

### Combination possibilities key to greater success

In parallel, progress has been made with Elahere as a combination therapy. According to NCCN guidelines, Elahere can already be given as combination therapy with bevacizumab in platinum-resistant patients, although formal approval for the combination is not yet in place. The background is promising results in a small study where mirvetuximab was combined with precisely bevacizumab in FR $\alpha$ -positive, platinum-resistant patients in the second line.

Despite the fact that there are still some question marks surrounding Elahere (apart from eye toxicity, for example, the effect on overall survival is not clear), sales should be able to benefit from a promising tumor effect and a lack of approved treatment alternatives. According to a compilation by Global Data, sales of 377 million USD in 2026 are expected for Elahere. Given that full approval is

obtained and that the indication can subsequently be broadened, this assessment appears to be within reach. That against the backdrop of a very high list price of the equivalent of \$29,000 per month.

Another FRα-targeted antibody conjugate, luveltamab tazevibulin, is in development. Early results appear to be in line with, or slightly better than, Elahere. We assess that FRα-targeted treatments are likely to gain good penetration and that competition should increase in the longer term, especially in the second line. However, it can open up possibilities in later-line treatment.

### More innovative projects, including immunotherapy, in late clinical phase

At the same time, the growth of PARP inhibitors has hit a snag after studies failed to confirm any benefit in late-line patients. As a result, manufacturers have withdrawn treatments in these indications. As previously described, the PARP inhibitors are maintenance treatments and therefore we do not consider them to be direct competitors with Kancera's fraktalkine inhibitor if it reaches the market.

In 2023, top line results are expected from a randomized phase III study with combination treatment with **batiraxcept** plus paclitaxel in platinum-resistant ovarian cancer patients. Batiraxcept is a fusion protein that blocks a signaling pathway, AXL, which is thought to have a role in driving both tumor drug resistance and their spread. There were promising efficacy signals in a phase Ib study but the half-life is short and high doses are required to reach effective concentrations.

Immunotherapy has had difficulty achieving clinical success in ovarian cancer. For example, adding atezolizumab to standard treatment did not provide any benefit in the first-line treatment of advanced cancer. However, there are other immunotherapy combinations that are under development. An example is **nemvaleukin alpha** in combination with pembrolizumab, a project run by Alkermes. Nemvaleukin alpha is a modified version of the cytokine IL-2 to produce a more specific variant of IL-2 (which is otherwise associated with severe side effects). Early results in platinum-resistant ovarian cancer were relatively promising (about 30 percent objective response), and a phase III study is ongoing.

Swedish Vivesto has developed **Apalea**, which is a new formulation of paclitaxel. The treatment is approved in the EU in platinum-resistant ovarian cancer (at first relapse) in combination with carboplatin. That makes Apalea an interesting benchmark for Kancera. In clinical studies, progression-free survival was 10.7 months. However, it should be emphasized that the majority of patients were "first relapse", that is, relatively "healthy" and probably with better prospects than an average patient who will be part of the KANDOVA study. Examples of other Swedish companies that conduct or plan clinical development in ovarian cancer are Bioinvent (immuno-oncology) and Spago Nanomedical (radionuclide).

Overall, the prospect of accelerated approval in platinum-resistant cancer is tantalizing. At best, a non-randomized phase II study (in severely ill patients in later-line treatment) with tumor response as the primary objective would be sufficient. In order to reach full approval for second-line treatment, however, we see it as likely that authorities can set stricter criteria and requirements for controlled confirmatory studies.

### Around 30 percent tumor response is a reasonable benchmark

The upcoming KANDOVA study is an exciting development step for the fraktalkine project. The study is open to accepting patients already in the second line, which we see as a positive and explained by the fact that carboplatin is already indicated for this patient group. The earlier the line of treatment, the greater the chance of response. It is likely, however, that a large proportion will be made up of patients with more advanced disease. Below we report results from external

clinical studies in corresponding patient groups such as KANDOVA. It should be emphasized that, unlike KANDOVA, the compilation below deals with reasonably large phase III studies.

### Treatments for advanced platinum-resistant ovarian cancer

Treatment/Phase	Indication	N (patients)	ORR %	PFS, m	OS, m
Chemotherapy (non platinum) (FORWARD I)	PROC 2-4L, FRα+	109	10%	4.4	12.0
Chemotherapy (non platinum) (AURELIA)	PROC 2-3L	182	13%	3.4	13.3
BEV + Chemotherapy (non platinum) (AURELIA)	PROC 2-3L	179	31%	6.7	16.6
mirvetuximab (SORAYA)	PROC 2-4L, FRα+	106	32%	4.3	13.8

Source: Carlsquare. PROC: Platinum-resistant ovarian cancer. FRα+: Tumors with high expression of folate receptor alpha. ORR: Objective response rate. PFS: Progression Free Survival (median). OS: Total Survival (median)

A standard of care is bevacizumab plus chemotherapy, which is therefore normally used relatively early. We assess that in the absence of a control arm, around 30 percent tumor response should be seen as competitive, although it is always difficult to compare results between studies.

## Assumptions and forecasts

In the last few years Kancera has become leaner in terms of overhead costs, directing more resources toward clinical development. We see the biggest chance of a revenue-generating partnership in the fractalkine project. Relatively limited competition indicates possibilities for high market share should the drug candidates reach approval. We see the biggest potential for revenues in the oncology indication, of which around USD 600 million in ovarian cancer.

## Revenue and profitability forecasts

### Extended clinical program

The current company focus centers around completing the phase IIa “FRACTAL”-study within myocardial infarction and the start of the first study on cancer patients, including the application for approval.

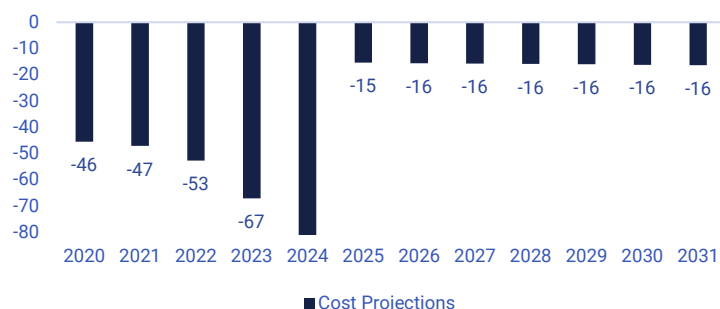
In our forecasts we have assumed that Kancera, provided a convincing conclusion to the FRACTAL-study, will begin a phase IIb study in myocardial infarction in-house. This will aid in evaluating efficacy, using the phase IIa for signal finding.

Compared to our previous estimate of 7 per cent we have increased the probability for a launch in oncology to 9 per cent on the back of the approval gained in February by the Swedish medical products agency for a phase Ib/IIa-study in patients with ovarian cancer. This sequentially improves the value of the project in oncology, balanced by an increase in the risk-adjusted cost projections.

Predicated on a positive outcome in one of the currently planned clinical studies, we see a chance for a licensing deal in a few years' time. In our base case scenario we account for this happening in the year 2025. Thereafter, we assume a partner will shoulder the costs associated with further development and commercialization.



## Forecast of costs (SEKm) risk-adjusted



Source: Company information and Carlsquare estimates

## Project assumptions

### Fractalkine inhibitors in myocardial infarction

According to statistics from the American Heart Association, approximately 635,000 heart attacks are diagnosed annually in the United States. Statistics from the European Society of Cardiology indicate an incidence of over 900,000 in the EU and Great Britain. Assuming that ST-elevated myocardial infarction makes up 30 percent (Source: Swedeheart Annual Report 2021), this means around 460,000 cases in total for these geographical areas.

We further assume that on average 80 percent receive PCI treatment. The proportion varies however and is lower for patients over 80 but higher among younger patients. In the FRACTAL study, patients with infarction in the anterior descending branch of the left coronary artery (LAD) are included and we assume that this will be the indication even after market approval. We estimate that this is 50 percent of the population. With these assumptions, a fractalkine inhibitor would address a population corresponding to 12 percent of all heart attack cases.

An assumption about penetration or market share at this early stage is fraught with great uncertainty. FDY-5301 is a competitor that has a head start in clinical development and, it seems, easier administration with a single dose. In the absence of comparable data, we assume a "duopoly" and a 50 percent penetration in the US, EU, and UK.

Kancera has commissioned analysis using a pricing point between \$2,000 and \$9,000 per three-day treatment. Since there is no approved drug treatment for damage caused by heart attack, there is uncertainty as to how KAND567 could be priced. A number of anti-inflammatory treatments that are approved in other indications have also been tested in heart attack patients, for example anakinra and tocilizumab. In clinical studies, anakinra has been administered with high doses, which indirectly speaks for a very high cost/pricing, while in return relatively low doses have been used for, for example, tocilizumab, which in turn speaks for a significantly lower pricing point. After completed coronary artery dilation, patients are treated with blood-thinning treatments such as ticagrelor (a so-called P2Y12 receptor antagonist) for up to 12 months. Based on list prices in the USA, the cost of an annual treatment is approximately USD 5,500. Given a smaller target population, we use Kancera's market research as a benchmark for KAND567 and assume a net income of USD 8,000 in the US and USD 4,000 in Europe.

### Assumptions regarding peak sales for myocardial infarctions

2038P	USA	Europe	Total
Myocardial infarction	690000	910000	1600000
STEMI-myocardial infarctions	30%	30%	
Treated	85%	85%	
PCI-intervention	80%	80%	
LAD-localization	50%	50%	
Kancera share	50%	50%	
Kancera treated	35190	46410	81600
Net income per treated, USD	8000	4000	
Revenue, MUSD	282	186	467

Source: Carlsquare

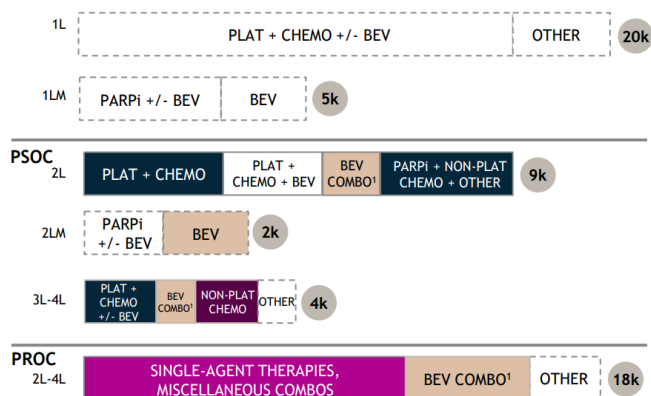
All in all, we have calculated possible peak sales amounting to 470 MUSD.

### Fractalkine inhibitors for advanced ovarian cancer

As we described above, Kancera primarily aims to develop a fractalkine inhibitor for advanced platinum-resistant ovarian cancer. In a phase Ib study, KAND567 will be combined with carboplatin.

In the USA, the first-line drug market amounts to around 20,000 treated patients per year (Source: Roche, ImmunoGen). The number of treated patients with resistant cancer in later lines is estimated to be somewhat smaller.

### US market for advanced ovarian cancer



Source: ImmunoGen. PSOC: Platinum-sensitive ovarian cancer. PROC: Platinum-resistant/refractory ovarian cancer. xL: Treatment in line x. xLM: Maintenance treatment. PLAT: Platinum-based chemotherapy. BEV: Bevacizumab. PARPi: PARP inhibitor.

At this early stage, it is difficult to assess what the competitive landscape will look like. Simplistically, we assume that mirvetuximab or bevacizumab will be the main competitors. There is however a theoretical potential to also combine with, for example, bevacizumab, even if it is limited by the fact that the antibody treatment is already used in earlier lines. The PARP inhibitors, on the other hand, are primarily maintenance treatments and we therefore regard them as complementary.

We make smaller amendments to our estimates as we see that competition could become tougher than previously anticipated, mainly pertaining to antibody conjugates targeting folate receptor alpha and new combination treatments. This results in us lowering our estimated penetration from 30 per cent to 25 per cent in the platinum-resistant ovarian cancer market. On the flipside pricing could be higher than what was estimated previously, especially considering that we

assume higher dosages used against cancers. The high cost for mirvetuximab also supports the more aggressive pricing assumptions. Considering all the above, we raise our assumption regarding peak sales by around 10 per cent to around USD 600 million.

### Assumptions regarding peak sales for ovarian cancer

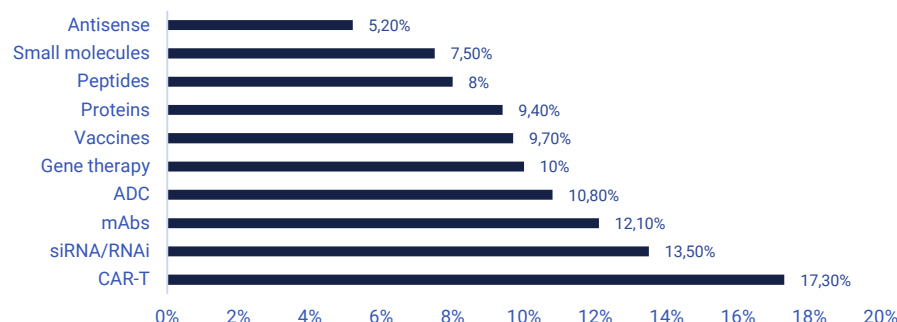
2041E	USA	EU+UK+JP	Total
Advanced ovarian cancer, incidence	23409	42240	
Platinum resistant, treated	20065	36206	
Kancera share	25%	25%	
Kancera treated	5016	9051	14068
Net revenue per treated patient (USD)	64 000	32 000	
<b>Revenues (USDm)</b>	<b>321</b>	<b>290</b>	<b>611</b>

Source: SEER, Roche, ImmunoGen, Carlsquare estimates

### Probability of success

Based on statistics on drug development, the probability of reaching the market is estimated to be 7.9 percent for an average drug project in phase I. For oncology, the corresponding probability is 5.4 percent ("Clinical Development Success Rates and Contributing Factors 2011–2020", Bio/ Informa Pharma/QLS). Even for cardiovascular diseases, the window is narrow at 4.8 percent. Factors that influence the possibilities are indication, target molecule and modality.

### Likelihood of approval from phase I, per modality



Source: Bio/Informa Pharma/QLS

We have used historical probabilities for each indication. We have adjusted the probability for KAND145 with regards to completed clinical studies with KAND567, which we believe justifies an assumption of a higher probability compared to other projects in phase I.

### Assumptions for likelihood of approval

Project	Indication	Precl.	Phase I	Phase II	Phase III	NDA	LOA
KAND567	Myocardial infarction	100%	100%	21%	55%	83%	10%
KAND145	Oncology	100%	75%	25%	50%	92%	9%

Source: Bio/Informa Pharma/QLS, Carlsquare LOA: Likelihood of approval

## Our forecasts are predicated on licensing starting in 2025

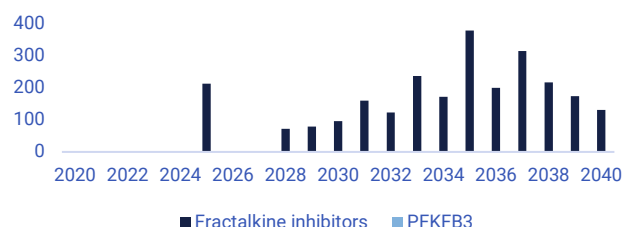
For our revenue forecasts, we assume the fractalkine project will be licensed following proof of concept in humans, which we estimate will occur in 2025.

### Forecast, income from royalties (SEKm)



Source: Company information and Carlsquare estimates

### Forecast, risk-adjusted net revenues (SEKm)



Source: Company information and Carlsquare estimates

We have assumed licensing deals totalling around USD 700 million for the fractalkine project. Seeing as KAND567 and KAND145 are approximately similar we believe it is logical that a licensor would prefer to license and control both fractalkine inhibitors. However, this scenario is not pivotal for our analysis. We account for an upfront payment upwards of USD 50 million for the fractalkine inhibitors. We have assumed royalty rates of 20 to 25 per cent, as can be viewed below. Our assumptions build upon the, albeit limited, selection of licensing deals covered in our [initial report](#).

## Valuation

### Expanded clinical program gives upside

#### Progress in cancer project boosts fair value

Our valuation, in a base case scenario, is built upon the sales assumptions that have been described above. We have utilized a risk adjusted DCF valuation, as can be seen below. The risk adjustment is based on the previously mentioned risks associated with development, resulting in a likelihood of approval of around 10 per cent. In our model we have used a discount rate of 14.8 per cent, a slight increase from our previous rate of 14.3 per cent. This is based on a risk-free rate of 2.4 (1.9) per cent, a beta of 1.2 and a risk premium of 10.3 per cent. The latter being derived from PwC's Risk premium Study 2022, consisting of a market risk premium of 6.7 per cent and a size-based variable of 3.6 per cent.

We estimate a higher enterprise value of around SEK 330 (290) million. The increase is mainly attributable to the heightened likelihood of approval for the oncology indication of the fractalkine project following approval for the initiation of a study by the Swedish medical products agency. We have also increased our estimated peak sales, as previously described. This is tempered to a lesser extent by a higher required rate of return.

Our valuation assumes that Kancera can find a partner for the fractalkine inhibitors after a successful outcome in phase II. To reach that point, the company will need financing that, to some extent, the TO6 warrants can provide, given they are fully subscribed. To account for the dilutionary effects of the expected financing, including the warrants, we have applied a discount of 10 per cent. Taken together the risk-adjusted fair value, after assumed dilution, reaches 4.7 (4.1) SEK per share in our base case.

As the rights issue in November failed to reach full subscription, we have altered our assumptions regarding financing needs. Should the current and expected phase IIa studies produce positive results, the outcome of the rights issue should

not be as heavy a downside. It is reasonable to assume that future financing will come with higher valuations on the back of increased clinical evidence.

We have marked down our valuation of the preclinical portfolio considerably, chiefly due to our belief that Kancera will prioritize the fractalkine project to a higher extent than before.

### Sum-of-the-parts valuation, base case, SEKm

Project	Indication	LOA*, %	Royalty, %	Peak Sales, USDm	Launch	rNPV, SEKm
KAND567	STEMI	10%	25%	470	2029	254
KAND145	Ovarian cancer	9%	20%	610	2031	231
Other	-	-	-	-	-	3
<b>Technology value before taxes</b>						<b>488</b>
Overhead and taxes						-158
<b>EV</b>						<b>330</b>
Net cash (23'Q1E)						85
<b>Fair value</b>						<b>415</b>
# shares						79.5
Per share, SEK						5.2
Discount for expected financing						10%
<b>Fair value per share, SEK</b>						<b>4.7</b>

Source: Carlsquare \*LOA: Likelihood of approval

## Valuation range

In an **optimistic Bull scenario**, we expect:

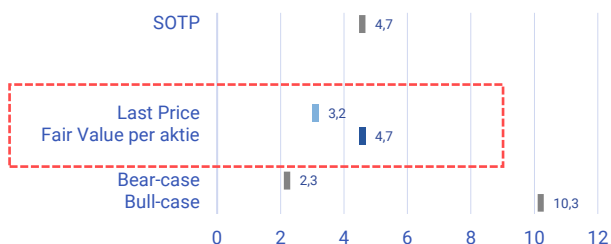
- Phase IIa in myocardial infarctions is completed with promising results and we raise the LOA to 27 percent from ten percent.
- Clinical studies in cancer with fractalkine inhibitors begin as planned

We calculate a justified operating value of approximately SEK 900m, or around 10 SEK per share after dilution.

In a **cautious Bear** scenario, we expect the results in myocardial infarction to be disappointing and accordingly set the value to zero for this indication. We assume that clinical studies in cancer begin according to plan. We calculate a value of just over two SEK per share after dilution.

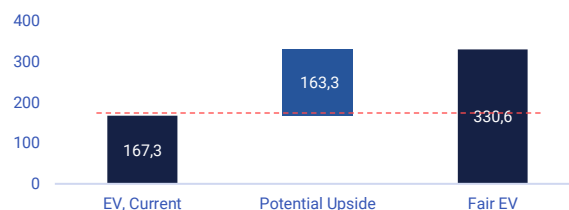


## Fair value within a range, SEK



Source: Carlsquare forecasts

## Visualization of market value, base scenario (SEK million)



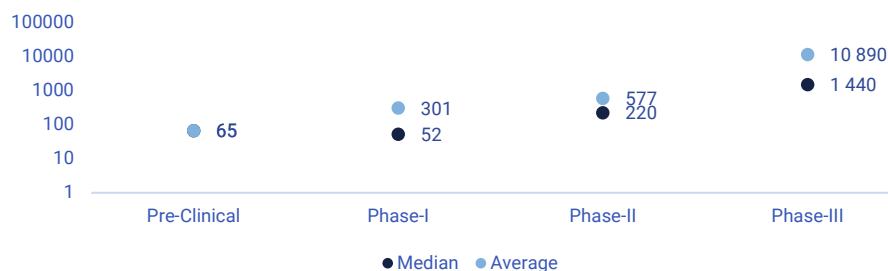
Source: Carlsquare forecasts

## Relative valuation gives support

Below we have estimated valuations (Enterprise values) of Nordic biotech companies per development phase, as of yearend 2022. For phase II companies, the median valuation was SEK 220 million and SEK 577 million on average. The comparison indicates that Kancera is valued lower than comparable companies on Nordic stock exchanges.

## Valuations, Nordic biotech companies

### Enterprise value by phase (SEKm log scale)



Source: S&P Capital IQ, Carlsquare

## Risks and challenges

### Challenging indications

Cancer and cardiovascular diseases are among the most challenging areas in clinical development with a relatively low probability of success. Clinical studies in cardiovascular diseases are extensive. Most likely Kancera will have to find a larger partner to carry out a possible phase III study. Although there is evidence for a biological effect in humans for Kancera's fractalkine inhibitors, it is not certain that it will translate into a relevant clinical effect in patient groups with acute myocardial infarction or advanced cancer. There is also a risk that the treatment is not sufficiently safe in patients with advanced cancer who, for example, may have metastases in the liver and impaired liver function. At high doses (above 1000 mg per day), oral KAND567 has shown transient hepatotoxicity in healthy volunteers.

### Funding for clinical development

There is a risk that outstanding warrants will not be exercised or will be exercised to a low degree. In that case, Kancera may be forced to ask the shareholders for new capital earlier than expected. In a positive scenario, future financing can occur via share issues priced at a higher valuation than the current situation, or alternatively by a larger partner taking responsibility for the further development in a licensing agreement.

### Competition

There is a clear medical need for treatments to improve outcomes in acute myocardial infarction. Although Kancera is a leader in the fractalkine blockers space, there are external projects in the pipeline with other mechanisms of action that are further along in clinical development than KAND567.

In cancer, there is a high level of clinical activity (for example, 4,700 clinical studies in immuno-oncology took place in 2021). Many companies and drug candidates compete for resources and to recruit patients for clinical studies.

# Key figures and accounts

## Income statement (SEKm), quarterly

	Q3, 22	Q4 22	Q1, 23	Q2, 23	Q3, 23	Q4, 23
<b>Net sales</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
Total revenue	0.2	0.0	0.0	0.0	0.0	0.0
<b>Gross profit</b>	<b>0.2</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
OPEX	-10.9	-14.0	-10.3	-13.6	-19.2	-24.0
<b>EBIT</b>	<b>-10.7</b>	<b>-14.0</b>	<b>-10.3</b>	<b>-13.6</b>	<b>-19.2</b>	<b>-24.0</b>
<b>EBITDA</b>	<b>-10.6</b>	<b>-13.9</b>	<b>-10.2</b>	<b>-13.5</b>	<b>-19.1</b>	<b>-23.9</b>
<b>EBT</b>	<b>-10.9</b>	<b>-14.0</b>	<b>-10.3</b>	<b>-13.6</b>	<b>-19.2</b>	<b>-24.0</b>
<b>EPS (SEK)</b>	<b>-0.19</b>	<b>-0.22</b>	<b>-0.13</b>	<b>-0.16</b>	<b>-0.22</b>	<b>-0.27</b>

Source: Company information and Carlsquare estimates

## Income statement (SEKm)

	2020A	2021A	2022E	2023E	2024E	2025E
<b>Net sales</b>	<b>2.7</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>213.0</b>
Other revenue	2.7	1.9	0.8	0.1	0.1	0.1
<b>Totala revenue</b>	<b>5.4</b>	<b>1.9</b>	<b>0.8</b>	<b>0.1</b>	<b>0.1</b>	<b>213.1</b>
COGS	0.0	0.0	0.0	0.0	0.0	0.0
<b>Gross profit</b>	<b>5.4</b>	<b>1.9</b>	<b>0.8</b>	<b>0.1</b>	<b>0.1</b>	<b>213.1</b>
Adj. Gross profit	2.7	0.0	0.0	0.0	0.0	213.0
R&D	-39.3	-43.1	-45.6	-59.9	-81.9	-8.0
SG&A	-6.2	-4.0	-7.1	-7.1	-7.3	-7.4
Dep. and amort.	-1.7	-0.3	-0.4	0.0	0.0	0.4
Other costs	0.0	0.0	0.0	0.0	0.0	0.0
Total operating costs	-45.5	-47.1	-52.7	-67.0	-89.2	-15.4
<b>EBIT</b>	<b>-40.1</b>	<b>-45.3</b>	<b>-51.9</b>	<b>-66.9</b>	<b>-89.1</b>	<b>197.7</b>
<b>EBITDA</b>	<b>-38.4</b>	<b>-44.9</b>	<b>-51.6</b>	<b>-66.9</b>	<b>-89.0</b>	<b>197.3</b>
Financial net	-0.3	-0.4	-0.6	0.0	0.0	0.0
<b>EBT</b>	<b>-40.5</b>	<b>-45.7</b>	<b>-52.5</b>	<b>-66.9</b>	<b>-89.1</b>	<b>197.7</b>
Taxes	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net profit</b>	<b>-40.5</b>	<b>-45.7</b>	<b>-52.5</b>	<b>-66.9</b>	<b>-89.1</b>	<b>197.7</b>
<b>EPS (SEK)</b>	<b>-1.3</b>	<b>-0.9</b>	<b>-0.9</b>	<b>-0.8</b>	<b>-0.9</b>	<b>1.9</b>

Growth	2020	2021	2022	2023	2024	2025
Net sales	NA	NaN	NaN	NaN	NaN	NM
EBIT	NA	-13%	-15%	-29%	-33%	322%
EBITDA	NA	-17%	-15%	-30%	-33%	322%
EBT	NA	-13%	-15%	-28%	-33%	322%
Net profit	NA	-13%	-15%	-28%	-33%	322%
EPS	NA	31%	-3%	13%	-20%	306%

Margins	2020	2021	2022	2023	2024	2025
Gross margin	99.5%	100.0%	100.0%	100.0%	100.0%	100.0%
EBIT-margin						92.8%

Source: Company information and Carlsquare estimates

## Balance sheet (SEKm)

	2020A	2021A	2022A	2023E	2024E	2025E
<b>ASSETS</b>						
Tot. intangible assets	21.0	21.0	21.0	21.0	21.0	21.0
Tot. tangible assets	0.9	0.6	0.2	0.2	0.1	-1.6
Tot. other fixed assets	0.0	0.0	0.0	0.0	0.0	0.0
Total fixed assets	21.9	21.6	21.2	21.2	21.2	19.4
Inventories	0.0	0.0	0.0	0.0	0.0	0.0
Accounts Receivables	0.0	0.0	0.0	0.0	0.0	0.0
Other current assets	6.2	5.5	4.3	4.3	4.3	4.3
Prepaid expenses	0.0	0.0	0.0	0.0	0.0	0.0
Cash	55.0	106.5	95.1	48.6	2.3	201.8
Total current assets	61.2	112.0	99.5	52.9	6.6	206.1
<b>Total assets</b>	<b>83.1</b>	<b>133.6</b>	<b>120.7</b>	<b>74.1</b>	<b>27.8</b>	<b>225.5</b>
<b>Shareholder equity</b>						
<b>Total equity</b>	<b>72.3</b>	<b>122.8</b>	<b>106.9</b>	<b>60.4</b>	<b>14.1</b>	<b>211.8</b>
<b>DEBT</b>						
Debt to creditors	1.0	0.4	0.0	0.0	0.0	0.0
Tot. long-term liabilities	1.0	0.4	0.0	0.0	0.0	0.0
Debt to creditors	0.0	0.0	0.0	0.0	0.0	0.0
Accounts payable	9.8	10.4	13.8	13.8	13.8	13.8
Other short-term liabilities	0.0	0.0	0.0	0.0	0.0	0.0
Accrued expenses	0.0	0.0	0.0	0.0	0.0	0.0
Tot. short-term debt	9.8	10.4	13.8	13.8	13.8	13.8
<b>Tot. equity and debt</b>	<b>83.1</b>	<b>133.6</b>	<b>120.7</b>	<b>74.2</b>	<b>27.9</b>	<b>225.6</b>

Source: Company information and Carlsquare estimates

## Cashflow (SEKm)

	2020	2021	2022	2023	2024	2025
CF operating activities	-38.9	-43.6	-47.7	-66.9	-89.0	197.3
CF investing activities	0.0	0.0	0.0	0.0	0.0	2.1
CF financing activities	82.1	95.2	36.2	20.4	42.8	0.0
Cashflow	43.2	51.5	-11.5	-46.5	-46.3	199.5
Cash, BoP	11.8	55.0	106.5	95.1	48.6	2.3
Cash, EoP	55.0	106.5	95.1	48.6	2.3	201.8

Source: Company information and Carlsquare estimates



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