kancera

Interim Report Third Quarter 2023

July 1 – September 30 2023
Kancera AB (publ.), org.no. 556806-8851

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About Kancera

Kancera is developing a new class of drugs for life-threatening diseases that lack effective treatment

Kancera develops pharmaceutical drugs for life-threatening diseases that currently lack effective treatments. The company conducts its business at Karolinska Institutet Science Park in Solna. Kancera's vision is to develop new drugs that contribute to more efficient care and a normalized life for patients. The company is focusing its resources on developing a new class of small molecule drug candidates that target the fractalkine axis. Kancera is developing two drug candidates in this area, the small molecule fractalkine blockers KAND567 and KAND145, which control immune cells and cancer cells with high precision. The fractalkine axis plays an important role in promoting severe inflammatory diseases and cancers. Kancera primarily sees opportunities within two disease areas: organ injuries caused by excessive inflammatory responses and treatment-resistant cancer, both with significant medical need and market potential.

Kancera is operated by a management team and board of directors, with solid expertise and experience in translating discoveries of new disease mechanisms into drug candidates and developing these through clinical studies up to and including market approval. Since its foundation in 2010, Kancera has researched, patented and published several new disease mechanisms and preclinical drug candidates. The company has subsequently demonstrated the ability to advance these preclinical projects into clinical development phase and demonstrate pharmacological effect in human.

Kancera has three ongoing clinical development projects with significant value potential:

- The FRACTAL study: a phase IIa study of KAND567 in myocardial infarction patients undergoing percutaneous coronary intervention
- The KANDOVA study: a combined phase Ib/IIa study of KAND567 in ovarian cancer patients with relapsed disease
- The KAND145 First-In-Human study: a phase 1 study of Kancera's second generation fractalkine blocker

Business model

Kancera's business model is to develop innovative drug candidates with solid IP, demonstrate efficacy in patients in clinical studies and, based on these, enter into collaboration agreements with other pharmaceutical companies, that are focusing on specialty care. Through this business model, the portfolio risk and need for capital is reduced. Partner agreements allow Kancera to out-license rights to development and commercialization in defined territories in exchange for revenue in the form of payment at signing, milestone payments and royalty revenues on partner sales.

The period in brief

July – September
Financial summary for the third quarter

- Net sales amounted to SEK 0 million (SEK 0).
- R&D expenses amounted to SEK 9,2 million (SEK 8,7 million).
- Operating income for the third quarter amounted to SEK -10,5 million (SEK -10,7 million).
- Income after financial items for the third quarter amounted to SEK -10,7 million (SEK -10,9 million).
- Earnings per share, before and after dilution, for the third quarter amounted to SEK -0.13 (SEK -0.19).
- Cash flow from operating activities for the third quarter amounted to SEK -8,8 million (SEK -14,1 million).
- As of September 30, equity amounted to SEK 66,1 million (SEK 84,1 million) or SEK 0.81 (SEK 1.50) per share.
- The equity/assets ratio on September 30, was 84 percent (89 percent).
- Cash and cash equivalents on September 30, amounted to SEK 58,2 million (SEK 68,2 million).

January – September
Financial summary for the period January - September

- Net sales amounted to SEK 0 million (SEK 0).
- R&D expenses amounted to SEK 40.9 million (SEK 34.0 million).
- Operating income for the period amounted to SEK -46.1 million (SEK -38,0 million).
- Income after financial items for the period amounted to SEK -46.4 million (SEK -38,5 million).
- Earnings per share, before and after dilution, for the period amounted to SEK -0.57 (SEK -0.69).
- Cash flow from operating activities for the period amounted to SEK -42,5 million (SEK -38,3 million).

Significant events during the third quarter

- Peter Selin started as new CEO of Kancera AB on July 1.
- Kancera announced that Dr. Markus Jerling has been appointed as new CMO, effective as of September 1.
- Kancera reported that all lab analyses of data related to the primary and secondary endpoints have been completed, the study database has been validated and locked and the study sponsor, NHS, is conducting statistical analysis. Further, Kancera reported that top line results are expected to be presented in Q4.
- Kancera reported that the USPTO has granted a product patent for KAND567, manufactured according to Kancera's patented manufacturing process, which enables Kancera to apply for data exclusivity and market protection for up to 7.5 years for the first indication approved in the United States.
- Kancera reported that the regulatory review of Kancera's application to conduct a phase I study of KAND145 is ongoing and that approval is expected in Q4 2023.

Significant events after the end of the reporting period

- Kancera has reported that the application to conduct a phase I study of KAND145 has received regulatory approval.
- Kancera has reported that the top line results from the FRACTAL study will be delayed to the end of December this year, due to lack of resources within the NHS to finalize the statistical analysis.
- Kancera is reporting that the first subjects in the phase I study have been dosed with KAND145.
- Kancera is reporting that the preclinical projects KAN571 (ROR1 inhibitor) and KAN757 (PFKFB3 inhibitor) have been terminated on commercial grounds.

CEO statement

Focus on ongoing clinical studies within the fractalkine program

With three ongoing clinical studies, all with near term upcoming milestones, Kancera is in a very busy and important phase in its transformation from a research-focused to a development -focused biotech company:

- The FRACTAL study – an ongoing phase IIa study of our fractalkine blocker KAND567 in myocardial infarction, in which the final statistical analysis prior to presentation of top line results is ongoing,

- The KANDOVA study – a combined phase Ib/IIa-study of KAND567 in combination with carboplatin in ovarian cancer, in which the first part of the study, phase Ib, was initiated in Q2 this year, and patient recruitment is ongoing, and

- The KAND145 First-in-human study – a phase I study of our second generation fractalkine blocker, for which we recently received regulatory approval and the first subjects have been dosed with KAND145.

FRACTAL is conducted in collaboration with the British Newcastle Hospitals NHS Foundation Trust (NHS), sponsor of the study. In our previous interim report, we reported that all laboratory analyses of primary and secondary endpoints data have been completed and that the study database has been validated and locked. The remaining activity before Kancera can present the top line results is for NHS to finalize the statistical analysis and "unblinding" of data.

As Kancera has reported after the reporting period, this remaining activity has been delayed due to resource constraints within NHS. Our expectation now is that the top line results will be presented by Kancera by the end of December this year.

Obviously, the outcome of the FRACTAL study is of very high importance to Kancera, especially with regards to the opportunity to sign partnering deals with other specialty pharmas. Considering what can be expected from the study size we anticipate three main outcome scenarios:

- Data demonstrate that KAND567 has a heart protective effect, for example reduced infarction size. Such outcome will be a significant success for Kancera, having confirmed the strong rationale for further development and the opportunity to "revolutionize" the treatment of acute cardiovascular diseases.

- Data do not show evidence of heart protective effect, but demonstrate effect on inflammatory biomarkers known to be associated with increased risk of complications and mortality. Such a scenario is also considered to be a successful outcome and will motivate further clinical development, either within the field of cardiovascular diseases or other inflammatory conditions.

- Lack of signals of effect. Even though we expect to obtain valuable insights into the role of the fractalkine axis in inflammatory conditions, this scenario may lead to Kancera deciding not to pursue further development in the field of cardiovascular diseases, or inflammatory diseases in general. This scenario will most likely mean that the company will shift its focus solely to treatment of cancer.

KANDOVA is our second ongoing clinical study of KAND567. The study is a combined phase Ib/IIa study in patients with relapse from carboplatin-therapy. The first part of the study, a phase Ib study, has an intra-patient dose escalation design, aiming to identify the highest tolerable dose of KAND567 in combination with carboplatin. This dose will then be administered to all patients in the second part, phase IIa, where treatment effect is studied.

Five hospitals have been initiated in the first part of the study and two additional hospitals are planned to be added in the phase IIa part of the study. As of today, two patients have been enrolled to the study. Recruitment of patients has initially been somewhat slow, which is quite common when starting new clinical studies. There are several reasons for this, but the primary cause is believed to be having too strict criteria for patient inclusion an exclusion.

In collaboration with the primary investigator, we have analyzed the causes for screening failures and concluded that by modifying certain criteria in the protocol, recruitment can be increased. We are now filing a protocol amendment to the applicable competent authorities and expect that these modifications in the protocol will increase the recruitment pace, once approved and implemented during Q1.

With the amended protocol, our goal to roll over to phase IIa in Q2 remains. Our goal to present top line results in Q4 2024 also remains, assuming that the seven sites that will be part of the study in phase IIa are capable of enrolling 2-4 patients each. Having said that, we will very carefully monitor patient recruitment over the upcoming months and if deemed necessary, we may make additional adjustments of the protocol as well as add additional sites.

After the reporting period, Kancera has reported that the regulatory application to conduct a **phase I study of KAND145** has been approved by FIMEA. The two sites in Finland have now started to enroll subjects. and the first subjects have been dosed with KAND145.

KAND145, our second generation fractalkine blocker, has the same mechanism of action as our lead candidate drug KAND567 and improved product properties. We intend this candidate to be our primary drug candidate for treatment of cancer and hence, this study is of strategic importance to the company. Our overall plan is to switch over to KAND145, following a demonstration of safety and tolerability in the phase I study and a successful outcome of the treatment concept in the field of cancer through the KANDOVA study.

With regards to the **financial result** of the reporting period, the operating income was -10,7 million SEK and the negative cash flow amounted to 8,8 million SEK, which were lower than forecasted in our previous interim report. This is explained by postponed costs in our clinical studies. Another factor is that Kancera has implemented cost savings during the first three quarters, including a decrease in headcount and reduced occupancy costs.

The **cash position** amounted to 58,2 million SEK at the end of the reporting period. Based on the current business planning, with the key focus on the ongoing clinical studies, and the implemented cost savings we expect that current cash is sufficient to finance planned business throughout 2024.

In an operational update that we have provided in connection with this interim report, we have announced that Kancera has performed a **strategic review** of the **project portfolio** and decided to terminate the preclinical projects KAND571 (ROR1) and KAN757 (PFKFB3) on commercial considerations. This will allow the company to focus even more resources and efforts on clinical development within the fractalkine program. The decision is made strictly for commercial reasons as we do not see that there are sound business cases nor any opportunitites to outlicense these projects. The operating income for the period includes a write down of intangible assets at the amount of 3 MSEK concerning the ROR1 project.

Wrapping up, I would like to emphasize the significant opportunities we see for KAND567 in inflammatory driven cardiovascular diseases and for KAND145 in cancer – as there are significant needs for more effective therapies and there are strong scientific rationales for treatment with our fractalkine blockers in both these areas.

The fourth quarter will therefore continue to be an intense, eventful and very important period for Kancera.

Solna, November 17 2023

Kancera AB
Peter Selin, CEO

Kancera's research and development

A new class of drugs for the treatment of severe inflammatory diseases and treatment-resistant cancer

The fractalkine axis

Chemokines are a family of small cytokines, i.e. signaling proteins, that induce directional movement of leukocytes, as well as other cell types, including endothelial and epithelial cells, and they play a major role in the activation of immune responses. Chemokines are important for several biological processes, including morphogenesis and wound healing, as well as in the pathogenesis of diseases like cancers. Chemokines are divided into families depending on biological function and target protein. Fractalkine is one family of chemokines, characterized by the unique ligand-receptor pair CXRCL1-CX3CR1, the so called fractalkine axis.

Research conducted by Kancera as well as independent research groups has shown that the fractalkine axis, through its function as a master regulator of certain immune cells and cancer cells, plays an important role in a number of diseases. Examples of diseases in which the fractalkine axis has been proven to promote disease progression are organ injuries, e.g. to heart, kidney and lung, caused by excessive inflammatory responses, both acute and chronic, and autoimmune diseases. The fractalkine axis has also been shown to play a key role in a number of cancer diseases, both solid tumor cancers such as ovarian, lung and breast cancer, and blood cancers, such as B-cell malignancies.

Focus areas for Kancera

Kancera is developing two drug candidates targeting the fractalkine axis: KAND567 and KAND145. These drug candidates have the same mechanism of action which is to block the fractalkine receptor CX3CR1 and thereby control the expression of immune cells and cancer cells. Kancera's business strategy is to develop new drug therapies in diseases with high medical needs. Kancera has identified a number of inflammatory related diseases as well as cancer diseases where there are significant medical needs for more effective treatments. Initially the company is focusing on the following two areas:

- Prevention of heart injury in myocardial infarction patients undergoing percutaneous intervention (PCI)
- Treatment of ovarian cancer patients with relapse from platinum chemotherapy

The fractalkine axis and myocardial infarction

Myocardial infarction is the most serious acute manifestation of cardiovascular disease leading to heart failure, both short and long term. Despite the advanced treatments available today, such as the life-saving PCI, complications that can be life threatening are common following a myocardial infarction. The fractalkine axis, through its ability to control pro-inflammatory immune cells, plays an important role in promoting cardiovascular diseases. The objective for treating this patient group with fractalkine blockers is to prevent excessive inflammation and thereby reduce the risk of serious complications following myocardial infarction.

The fractalkine axis and treatment-resistant cancer

In the early phase of cancer, the cancer is in most cases treated with chemotherapy, e.g. platinum compounds. Initially, chemotherapy can effectively cause damage to the cancer cell's DNA. In advanced disease, however, cancer cells develop the ability to repair the DNA damage created by chemotherapy and the patient develops resistance to treatment. Kancera's fractalkine blockers have the potential to inhibit this resistance through two different mechanisms of action, both of which contribute to reducing tumor growth:

- *Blocking DNA damage repair*

Kancera has published results showing that its fractalkine blockers can block the cancer's ability to repair the damage that platinum-chemotherapy cause to the cancer's DNA. A similar effect is sought in treatment with the PARP inhibitor drug class. However, KAND567 and KAND145 may supplement PARP inhibitors where these fail to be effective, as Kancera's drug candidates act through another pathway (the Fanconi anemia pathway) and target (CX3CR1). Kancera sees significant opportunities for its fractalkine blockers in solid tumors such as ovarian cancer, lung cancer and breast cancer.

- *Blocking of tumor promoting cells in the tumor microenvironment*

The microenvironment of a tumor consists of various supporting cells. Levels of these supporting cells impact how the tumor grows, spreads and responds to drug therapies. In ovarian cancer, certain immune cells and tissue cells, so-called tumor-associated macrophages and fibroblasts, have been shown to negatively affect the development of the disease and increase the tumor's resistance to chemotherapy. In preclinical studies, Kancera has shown that fractalkine blockers have the ability to prevent these disease-promoting cells. Thereby, Kancera's drug candidates have the potential to deprive the tumor of supporting cells that contribute to the tumor growth, spread and resistance to chemotherapy.

Kancera's fractalkine-blocking drug candidates

Kancera is developing two small molecule-based drug candidates, KAND567 and KAND145, having the same mechanism of action which is to inhibit the fractalkine receptor CX3CR1. KAND567 and KAND145 represent a new class of drugs, meaning that there are no approved pharmaceutical drugs with the same mechanism of action. Kancera's drug candidates thereby have the potential to become "first in class".

This is both a *challenge*, as the treatment concept is less validated, creating a greater uncertainty about the pharmacological effects in human, and an *opportunity* to become the first product on the market with a new unique treatment option.

KAND567 is Kancera's most advanced drug candidate. The compound was initially developed by Astra Zeneca and intended for treatment of multiple sclerosis. Seeing opportunities in inflammatory diseases and cancer, Kancera acquired the project in 2016. So far, Kancera has demonstrated safety and tolerability in three phase I studies and one phase IIa study in COVID patients. In the latter, pharmacological effect in human was also demonstrated. Currently KAND567 is studied in two ongoing trials; the FRACTAL and KANDOVA studies.

KAND145 is Kancera's second generation fractalkine blocker, solely developed by the company. KAND145 is a so called "pro drug", i.e. after administration the compound is metabolized to KAND567 in the human body. As a result, KAND567 and KAND145 have the same mechanism of action. The compounds differ in their product properties: KAND145 has certain improved product properties, such as higher solubility in water, enabling formulation in higher peroral doses and longer i.v. infusion time. However, compared to the pro drug, KAND567 has one advantage and that is the ability, when given intravenously, to more or less instantly be present in the targeted tissue and provide protection. Taking the FRACTAL study as an example, this means that when the bolus dose of KAND567 is given, the drug is present in the heart after only a few minutes and prior to the PCI being conducted.

Targeted indications and development strategies

Kancera's overall strategy is to develop

- KAND567 for treatment of organ injuries caused by excessive inflammatory responses, such as myocardial infarction patients undergoing PCI
- KAND145 for treatment of cancer, where higher peroral dosing is perceived to be required

However, based on the fact that KAND145 can be given as i.v. infusion during a longer period of time vs KAND567, Kancera sees a potential role for KAND145 also in the treatment of inflammation diseases, in combination with KAND567. Important to note though, is that this will require further clinical development. As Kancera's objective is to reach market approval as quickly as possible, no modifications of the development plan in cardiovascular disease will be made that will have a negative impact on the timeline and delay launch.

As described, the strategy is to develop KAND145 for treatment of cancers. Despite this strategy, Kancera has initiated the clinical development in the field of cancer based on KAND567, through the ongoing KANDOVA study. The rationale for this approach is that this will allow for a shorter overall development lead time. As KAND567 has the same mechanism of action as KAND145, we can evaluate the treatment concept based on KAND567. In the scenario that the treatment concept can be confirmed in the KANDOVA study and the phase I study of KAND145 demonstrates safety and tolerability, the plan is to switch over from KAND567 to KAND145 for the further clinical development in cancer.

Kancera's development projects

Since the acquisition of the fractalkine program, Kancera's resources have primarily been allocated to the drug candidates KAND567 and KAND145. After the recently performed portfolio review and termination of the ROR1 and PFKFB3 projects, Kancera is focusing all of its resources on the fractalkine program. With current financing, Kancera intends to advance the project portfolio according to the following objectives:

- Finalize the FRACTAL study, a phase IIa study of KAND567 in STEMI undergoing PCI, with expected reporting of top line results in December 2023.
- Conduct the KANDOVA study, a combined phase Ib/IIa study of KAND567 in ovarian cancer aiming to report top line results in Q4 2024.
- Conduct the first-in-human study of KAND145 with expected top line results in Q2 2024.

FRACTAL - ongoing phase IIa study of KAND567 in myocardial infarction

The FRACTAL study is an ongoing clinical phase IIa study of Kancera's fractalkine blocking drug candidate KAND567 in myocardial infarction patients undergoing percutaneous coronary intervention. The study, a randomized, two-arm, placebo-controlled, double-blind study, is conducted in collaboration with the NHS Foundation, sponsor of the study, at the two hospitals Freeman Hospital in Newcastle and James Cook Hospital in Middlesbrough.

In the FRACTAL study, treatment with KAND567 starts with a bolus dose, given i.v. prior to the PCI. After PCI, the patient continues to receive KAND567 through i.v. infusion for approximately 6 hours, followed by peroral administration for up to 72 hours until the patient is discharged from the hospital after three days.

Patient enrollment has been completed with a total of 71 patients recruited. The primary objective is to evaluate safety and tolerability. The secondary objective is to evaluate signals of heart protective effects. In addition, the effects of treatment with KAND567 are evaluated in a number of exploratory endpoints. Kancera expects to present top line data in December 2023.

KANDOVA - combined phase Ib/IIa study of KAND567 in ovarian cancer

The KANDOVA-study is a one-arm, open-label, multi-centre combined phase Ib/IIa study of KAND567 in combination with carboplatin therapy in ovarian cancer patients with relapsed disease.

The study has received regulatory approvals to be conducted in Sweden, Norway and Denmark and is planned to be conducted at several leading university hospitals in these countries. The KANDOVA study is conducted in collaboration with the clinical trials unit of the Nordic Society of Gynaecological Oncology (NSGO-CTU), a society of leading academic hospitals and gynaecological clinicians in the Nordic countries. NSGO aims to set Nordic treatment guidelines for women with gynaecological cancers and through the collaboration Kancera aims to ensure that the KANDOVA study is designed and conducted in alignment with these guidelines.

In the KANDOVA study, patients receive KAND567 treatment during two weeks in connection with each carboplatin treatment cycle. Carboplatin treatment is given every third week, provided that the patient tolerates chemotherapy. The first part of the study (phase Ib) has a dose escalation design. This means that the patient starts to receive a low dose of KAND567. If this is tolerable the dose is increased in the next treatment cycle. The objective with this first part of the study is to identify the maximum tolerable dose of KAND567 which will then be the recommended dose for the second part (phase IIa).

Patient screening was initiated in April this year and treatment of the first enrolled patient started in June. The primary objective is to evaluate safety and tolerability. The secondary objective is to evaluate signs of KAND567 treatment efficacy. In addition, the effects of treatment with KAND567 are evaluated in a number of exploratory endpoints. Kancera's objective is to present top line results before end of 2024.

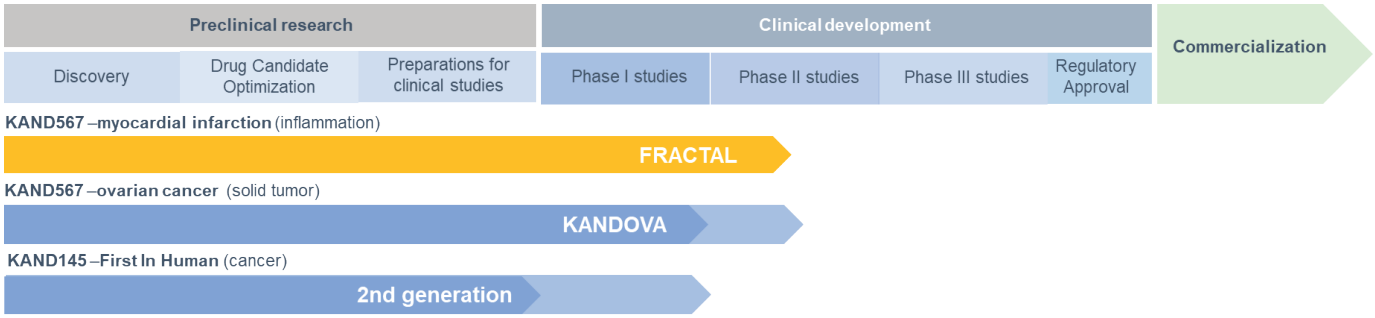
First in human study of KAND145

The study design is a randomized, double-blind and placebo-controlled phase I study of KAND145 in healthy subjects to evaluate safety, tolerability, pharmacological effect, food effect after oral single and multiple ascending dosing of KAND145 and drug interaction after multiple ascending dosing.

The study is being conducted at two sites in Finland and in total approximately 50 study subjects are expected to be enrolled, of which approximately ¾ of subjects will receive active substance and ¼ of subjects will receive placebo.

Patient recruitment started in Q4 2023. Top line results are expected to be reported in Q2 2024.

Kancera's pipeline



For additional information on projects and market prospects, see Annual Report 2022 on Kancera's website www.kancera.com/en

Financial development in summary

Financial development, a summary

Kancera Group	Jul-Sep		Jan-Sep		Jan-Dec
SEK 000´s (if otherwise not specified)	2023	2022	2023	2022	2022
Net turnover	0	0	0	0	0
Other operating revenues	0	220	592	726	753
Operating expenses	-10 546	-10 945	-46 648	-38 687	-52 687
R&D expenses	-9 239	-8 747	-40 933	-34 013	-45 608
Operating Income	-10 546	-10 725	-46 056	-37 961	-51 934
Income after financial items	-10 733	-10 903	-46 421	-38 473	-52 484
Net income	-10 733	-10 903	-46 421	-38 473	-52 484
Cash-flow from operating activities	-8 752	-14 065	-42 547	-38 327	-47 562
Cash on hand	58 220	68 221	58 220	68 221	95 149
Equity	66 119	84 065	66 119	84 065	106 912
Key ratios					
R&D costs / total costs, %	88%	80%	88%	88%	87%
Earnings by share, before and after dilution, kr	-0,13	-0,19	-0,57	-0,69	-0,90
Cash-Flow by share, kr	-0,11	-0,25	-0,52	-0,68	-0,83
Equity by share, kr	0,81	1,50	0,81	1,50	1,34
Total assets	78 320	94 273	78 320	94 273	120 738
Solvency, %	84%	89%	84%	89%	89%
No. of employees	4	5	4	5	5

See Note 5 for key ratio definitions.

Comments on financial developments

As is described in the About Kancera section, Kancera's business model is to develop drug candidates, demonstrate efficacy in patients in clinical studies and based on these, enter into collaboration agreements with other pharmaceutical companies by licensing out rights to development and commercialization in defined territories in exchange for milestone payments and royalties.

As Kancera has not yet established any collaboration agreements, the company has no revenues from milestone payments or royalties. Up until collaboration agreements are established, the company is financing its business on the stock market. As from 2013, Kancera is listed on the Nasdaq First North Premier Growth Market.

The company's operating expenses are primarily derived from research (preclinical development) and clinical development. The costs for conducting clinical development is significantly higher than for preclinical development and as the company has advanced its drug candidates from discovery to clinical stages, the company's operating expenses have increased. As of November 17, 2023, Kancera has three ongoing clinical studies.

Income and profit

Third quarter, July to September 2023

- Net sales during the quarter amounted to SEK 0 million (MSEK 0).
- Costs during the quarter amounted to SEK 10,5 million (SEK 10,9 million), divided between costs for research and development costs SEK 9,2 million (SEK 8,7 million), and other sales and administration expenses SEK 1,3 million (SEK 2,2 million). Kancera does not have any product sales and sales expenses refer to costs for business development and market access planning.
  The costs during the quarter include a write down of SEK 3 million for the ROR1 project. Adjusted for this one time event, the total operating expenses were 7,5 million and total R&D costs were 6,2 million. Having three ongoing clinical studies, the operating expenses, adjusted for the SEK 3 million write down, were lower than expected. This is however explained by postponed costs in the KANDOVA and KAND145 FIH studies. In addition, Kancera has reduced its operating expenses through a reduction of fixed personnel and occupancy costs.
- Income after financial items amounted to SEK -10.7 million (SEK -10.9 million) during the quarter.
- Earnings per share for the quarter, based on a weighted average of the number of shares outstanding, amounted to SEK -0.13 (SEK -0.19).

January to September 2023

- Net sales during the period amounted to SEK 0 million (MSEK 0).
- Costs during the period amounted to SEK 46.6 million (SEK 38.9million), divided between costs for research and development costs SEK 40.9 million (SEK 34.0 million), and other sales and administration expenses SEK 5.7 million (SEK 4.7 million).
  The costs during the period include a write down of SEK 3 million for the ROR1 project. Adjusted for this one time event, the total operating expenses were 43.7 million and total R&D costs were 37.9 million.
- Income after financial items amounted to SEK -46.4 million (SEK -38.5 million) during the period.
- Earnings per share for the period, based on a weighted average of the number of shares outstanding, amounted to SEK -0.57 (SEK -0.69).

Financial position and cash flow

Balance sheet and cash flow

- Total equity amounted to SEK 66.1 million (SEK 84.1 million).
- Kancera's equity/assets ratio was 84 per cent (89 per cent).
- Equity per share was SEK 0.81 (SEK 1.50).
- Cash flow from operating activities amounted to SEK -8,8 million (SEK -14,1 million) or SEK –0.11 per share (SEK -0.25). Adjusted for the write down of the ROR1 project, the operating cash flow is in line with the operating expenses. As described above, the operating expenses were lower than expected, due to postponed costs in the clinical studies, and accordingly, the negative cash flow was lower than expected.
- As of 30 September, cash and cash equivalents amounted to SEK 58,2 million (SEK 68,2 million). Based on current planning of business, the existing cash is sufficient to finance business throughout 2024.

Employees

Kancera AB had approximately 4 (5) full-time employees as of September 30 2023, of which 4 (5) are men and 0 (0) are women.

Investments and depreciation

After the write down of the ROR1 project, intangible fixed assets in the balance sheet amount to SEK 18 million, which is related the fractalkine project. The item is the sum of three off-set issues carried out under acquisition agreements. I.e., the valuation of intangible fixed assets in the balance sheet is derived from the contractual terms of the acquisition of the project and not the market valuation of the fractalkine program. For a description of the market outlook for KAND567 and KAND145, please refer to this section of the Annual Report for 2022.

The Board conducts an impairment assessment on an ongoing basis and at least once a year to ensure that the values raised are justified. During the period, such impairment assessment has been conducted concerning the ROR1 project, resulting in a write down of SEK 3 million.

Group

Kancera consists of two companies, the parent company Kancera AB (publ), in which all research and product development takes place, and the wholly owned subsidiary Kancera Förvaltning AB. The parent company in the group is the Swedish public limited company Kancera AB (publ.) whose shares are listed on Nasdaq First North, Premier Segment from on 28 October 2016. Kancera Förvaltning AB is a dormant company.

Share capital and share

The share capital on September 30, 2023 amounted to SEK 67,9 million (SEK 46,8 million) divided into 81 505 799 (56 143 948) shares with a quotient value of, rounded off, SEK 0.83 (0.83) per share. The increase in the number of shares is attributable to the new issue of shares carried out in November 2022.

Tax deficits

Kancera AB's current operations are initially expected to result in negative results and fiscal deficits. There are currently not sufficiently convincing reasons to believe that tax surpluses will exist in the future that can justify a capitalization of the value of the deficits, and no deferred tax asset has been reported. In the event of a sale of a drug candidate, it is expected that profits can be reported, which are currently deemed to be able to be taxed against previous years' tax losses, which would mean a low tax burden for the Company when a project is sold. The fiscal deficits amounted to SEK 397 636 000 as of December 31, 2022. No deferred tax asset is recognized for these tax losses.

Consolidated Statement of Comprehensive Income

Consolidated Statement of Comprehensive Income

SEK 000´s (if otherwise not specified)

	1 jul - 30 sep		1 jan - 30 sep		1 jan - 31 dec
	2023	2022	2023	2022	2022
Kancera Group					
Net sales	0	0	0	0	0
Other operating revenues	0	220	592	726	753
Total revenues	**0**	**220**	**592**	**726**	**753**
Operating Expenses					
General & administrative expenses	-1 068	-1 456	-4 560	-3 392	-4 685
Selling expenses	-239	-742	-1 155	-1 282	-2 394
Research & development expenses	-9 239	-8 747	-40 933	-34 013	-45 608
Total operating expenses	**-10 546**	**-10 945**	**-46 648**	**-38 687**	**-52 687**
Operating income	**-10 546**	**-10 725**	**-46 056**	**-37 961**	**-51 934**
Income from Financial Investments					
Other interest income and similar profit	50	0	402	0	68
Other interest expense and similar loss	-237	-178	-767	-512	-618
Financial net	**-187**	**-178**	**-365**	**-512**	**-550**
Income after financial items	**-10 733**	**-10 903**	**-46 421**	**-38 473**	**-52 484**
Taxation	0	0	0	0	0
Net income	**-10 733**	**-10 903**	**-46 421**	**-38 473**	**-52 484**
Average number of shares (thousands), before and after dilution	81 506	56 144	81 506	56 144	58 158
Number of shares at closing date (thousands)	81 506	56 144	81 506	56 144	79 528
Earnings per share, before and after dilution	-0,13	-0,19	-0,57	-0,69	-0,90

Condensed Consolidated Statement of Financial Position

Condensed Consolidated Statement of Financial Position

SEK 000´s

Kancera Group	30 Sep 2023	30 Sep 2022	31 Dec 2022
Assets			
Non-current Assets			
Intangible assets			
Capitalized R&D	18 000	21 000	21 000
Tangible assets			
Lease assets	0	0	0
	0	337	247
Financial assets			
Financial placements	1	1	1
Total non-current assets	**18 001**	**21 338**	**21 248**
Current Assets			
Trade receivables and other receivables	2 099	4 714	4 341
Cash and cash equivalents	58 220	68 221	95 149
Total current assets	**60 319**	**72 935**	**99 490**
TOTAL ASSETS	**78 320**	**94 273**	**120 738**
Equity and Liabilities			
Equity			
Equity	66 119	84 065	106 912
total equity	**66 119**	**84 065**	**106 912**
Liabilities			
Long-term liabilities	0	0	0
Short-term liabilities	12 201	10 208	13 826
Total liabilities	**12 201**	**10 208**	**13 826**
TOTAL EQUITY and LIABILITIES	**78 320**	**94 273**	**120 738**

Statement of changes in equity

Consolidated report on changes in equity

Kancera Group, Jan 1 2022 - Sep 30 2022 SEK 000´s	Sharecapital	Ongoing share issue	Other capital contributions	Accumulated deficit	Total equity
Third quarter					
Opening balance 2022-07-01	46 786		75 750	-27 570	94 967
Comprehensive income					
Net income for the period				-10 903	-10 903
Total comprehensive income	0		0	-10 903	-10 903
Transactions with shareholders					
Capital injections					
Capital injection costs					
Ongoing share issue					
Total transactions with shareholders	0	0	0		0
Closing balance 2022-09-30	**46 786**	**0**	**75 750**	**-38 473**	**84 065**
The period Jan-Sep					
Opening balance 2022-01-01	**46 786**	**0**	**121 436**	**-45 686**	**122 536**
Comprehensive income					
Appropriation of last year´s net income			-45 686	45 686	
Net income for the period				-38 473	-38 473
Total comprehensive income	0	0	-45 686	7 214	-38 473
Transactions with shareholders					
Capital injections					
Capital injection costs					
Ongoing share issue					
Total transactions with shareholders	0	0	0	0	0
Closing balance 2022-09-30	**46 786**	**0**	**75 750**	**-38 473**	**84 065**

Statement of changes in equity, continued

Kancera Group, Jan 1 2023 - Sep 30 2023 SEK 000´s	Sharecapital	Ongoing share issue	Other capital contributions	Accumulated deficit	Total equity
Third quarter					
Opening balance 2023-07-01	67 921		44 617	-35 688	76 851
Comprehensive income					
Net income for the period				-10 733	-10 733
Total comprehensive income	0	0	0	-10 733	-10 733
Transactions with shareholders					
Capital injections					0
Capital injection costs					0
Ongoing share issues					
Total transactions with shareholders	0	0	0	0	0
Closing balance 2023-09-30	**67 921**	**0**	**44 617**	**-46 421**	**66 119**
The period Jan - Sep					
Opening balance 2023-01-01	**66 273**		**93 122**	**-52 484**	**106 912**
Comprehensive income					
Appropriation of last year´s net income			-52 484	52 484	
Net income for the period				-46 421	-46 421
Total comprehensive income	0	0	-52 484	-46 421	-46 421
Transactions with shareholders					
Capital injections	1 648		4 284		5 932
Capital injection costs			-305		-305
Ongoing share issue					
Total transactions with shareholders	1 648	0	3 979	0	5 627
Closing balance 2023-09-30	**67 921**	**0**	**44 617**	**-46 421**	**66 119**

Cash flow statement

Condensed Consolidated Statement of Cash-Flow

SEK 000´s	1 jul -30 sep		1 jan-30 sep		1 jan-31 dec
Kancera Group	2023	2022	2023	2022	2022
Cash-flow from operating activities					
Operating income after financial items	-10 733	-10 903	-46 421	-38 473	-52 484
Depreciation	67	90	247	270	360
Taxes paid	26	-9	40	701	732
Other non-cash flow items	3 000	-40	3 000	-40	-40
Cash-flow from operating activities before working capital change	**-7 640**	**-10 862**	**-43 134**	**-37 542**	**-51 432**
Change in working capital	-1 112	-3 203	587	-785	3 870
Cash-flow from operating activities	**-8 752**	**-14 065**	**-42 547**	**-38 327**	**-47 562**
Investment activities					
Investments in financial assets	0	0	0	0	0
Investments in financial assets	0	0	0	0	0
Cash-flow from investment activities	**0**	**0**	**0**	**0**	**0**
FREE CASH-FLOW available to INVESTORS	**-8 752**	**-14 065**	**-42 547**	**-38 327**	**-47 562**
Financing activities					
Change in debt referrable to financing activities		0	-32	27	-596
Issue of shares/other capital infusions		0	5650	0	36 759
Repayment of loans	0	0	0	0	27
Increase in short-term financing	0	0	0	0	0
Cash-flow from financing activities	**0**	**0**	**5618**	**27**	**36 190**
CASH-FLOW for the PERIOD	**-8 752**	**-14 065**	**-36 929**	**-38 300**	**-11 372**
Cash and cash equivalents at the beginning of the period	66 972	82 286	95 149	106 521	106 521
Cash and cash equivalents at the end of the period	58 220	68 221	58 220	68 221	95 149

Condensed Income Statement – Parent company

Condensed Parent Company Income Statement

SEK 000´s (if otherwise not specified)

The Parent Company Kancera AB	1 Jul - 30 Sep		1 Jan - 30 Sep		1 jan - 31 dec
	2023	2022	2023	2022	2022
Revenues					
Net sales	0	0	0	0	0
Other operating revenues	0	220	592	726	754
Cost of sales & services	0		0	0	
Gross profit	**0**	**220**	**592**	**726**	**754**
Operating Expenses					
General & administrative expenses	-1 068	-1 456	-4 547	-3 392	-4 715
Selling expenses	-239	-742	-1 148	-1 282	-2 451
Research & development expenses	-9 239	-8 747	-40 953	-34 013	-45 522
Total operating expenses	**-10 546**	**-10 945**	**-46 648**	**-38 687**	**-52 688**
Operating income	**-10 546**	**-10 725**	**-46 056**	**-37 961**	**-51 934**
Income from Financial Investments					
Other interest income and similar profit item	50		403	0	68
Other interest expense and similar loss item	-237	-145	-782	-477	-618
Financial net	**-187**	**-145**	**-379**	**-477**	**-550**
Income after financial items	**-10 733**	**-10 870**	**-46 435**	**-38 438**	**-52 367**
Taxation	0	0	0	0	0
Net income	**-10 733**	**-10 870**	**-46 435**	**-38 438**	**-52 367**

Condensed Balance Sheet – Parent company

Condensed Parent Company Balance Sheet

SEK 000´s

The Parent Company Kancera AB

	30 Sep		31 Dec
Assets	2023	2022	2022
Non-current Assets			
Intangible assets			
Capitalized R&D	18 000	21 000	21 000
Financial assets			
Shares in subsidiaries	50	50	50
Financial placements	1	1	1
Total non-current assets	**18 051**	**21 051**	**21 051**
Current Assets			
Intercompany receivables	1		
Trade receivables and other receivables	2 099	1	1
Cash and cash equivalents	58 172	5 314	4 342
Total current assets	**60 272**	**118 649**	**95 101**
		123 964	99 444
TOTAL ASSETS	**78 322**		
		145 015	120 494
Equity and Liabilities			
Equity			
Equity	66 119	133 081	107 059
Total equity	**66 119**	**133 081**	**107 059**
Liabilities			
Short-term liabilities	12 203	11 934	13 434
Total liabilities	**12 203**	**11 934**	**13 434**
TOTAL EQUITY and LIABILITIES	**78 322**	**145 015**	**120 494**

Notes

Note 1: Accounting and valuation principles

The interim report has been prepared in accordance with IAS 34 and the Annual Accounts Act. The Group's and the Parent Company's accounting principles and valuation principles as well as the calculation bases for the report are unchanged compared with the most recent annual report for the financial year which ended on 31 December 2022 and must be read in conjunction with it.

The Group invests continuously in research and development projects that increase the Group's knowledge of technology and where intangible assets such as patent applications for technology can also be included. Intangible assets are capitalized and reported in the balance sheet if certain criteria are met, while expenses for research are expensed when they arise.

Kancera has continuously expensed all research costs when they arise because they mainly consisted of research efforts and the Group management has assessed that the criteria for capitalization have not been met.

Amounts are stated in Swedish kronor, rounded off to the nearest thousand unless otherwise stated. Rounding to thousands of kronor can mean that the amounts are not correct if they are summed up. Amounts and figures given in parentheses refer to comparative figures for the corresponding period last year.

Note 2: Transactions with related parties

During the period, Kancera AB paid compensation of SEK 90 000 (SEK 180 000) to Mellstedt Consulting AB for services including scientific advice and scientific marketing. Mellstedt Consulting AB is owned by Håkan Mellstedt, board member of Kancera AB.

During the period, Kancera AB paid compensation of SEK 20 000 (SEK 0) to MobitrIQE AB for services including scientific advice and scientific marketing. MobitrIQE AB is owned by Anders Gabrielsen, board member of Kancera AB.

These two transactions have been entered into on financial terms in line with market standards and in accordance with board approval procedures. Other than board fees and expenses no other compensations to related parties have been paid.

Note 3: Received grants to be finalized at a later time

Awarding body	Amount awarded tkr	Amount paid, tkr	Date for reporting
EU TOBEATPAIN1	2 900	1 970	Final report reviewed in June 2023

[1] Using EUR exchange rate SEK 11. Granted amount of approximately SEK 2,900 thousand. Paid amount of approximately SEK 1,970 thousand. The remaining amount of the grant, of which approximately SEK 273 thousand is used for administration and education to the coordinating university, will be paid in July 2023.

Note 4: The Group's operations and risk factors

When assessing the group's future development, it is important to consider risk factors in addition to potential profit growth. The group's operations are affected by a number of risks that can have an effect on the group's results and financial position to varying degrees. For a description of the group's risks, refer to the section Risks and risk management of the annual report for 2022. In addition to these reported risks, the prevailing macroeconomic situation, with higher inflation, increased interest and energy costs, generally means increased uncertainty. However, the company assesses that the effects of this uncertainty are relatively limited. Kancera has no loans, and its own operations have very limited energy consumption. However, the increased costs in these areas indirectly impact the company in the form of increased costs for contracted development and production. The company has taken this into account in the financial forecast developed for 2023 and 2024 and the company has concluded that it will be possible to execute the business plan as planned with existing funding.

Note 5: Definitions of key ratios

Alternative key ratios

In addition to the financial key ratios prepared in accordance with IFRS, Kancera AB presents financial key ratios that are not defined according to IFRS, such as return on equity, return on capital employed and cash flow per share. These alternative key ratios are considered to be important results and performance indicators for investors and other users of the interim report. The alternative key ratios should be seen as a complement to, but not a replacement for, the financial information prepared in accordance with IFRS. Because not all companies calculate financial measures in the same way, these are not always comparable to measures used by other companies.

R&D costs as share of total costs

The key ratio provides information on the share of the company's research and development costs in relation to the total cost of business. This gives a view of cost allocation and an indication of how resources are allocated to core business versus general administration.

Return on equity

Profit for the period as a percentage of average equity. The key figure shows the company's performance and gives an indication of how well equity has been used.

Return on capital employed

Calculated by dividing Equity by the number of shares on the balance sheet date. The change of this key ratio between years gives an indication that changes have taken place in the company's equity, for example if a new issue has been carried out and how much of such a capital injection remains per balance sheet date.

Equity per share

Calculated by dividing Equity by the number of shares on the balance sheet date. The change of this key ratio between years gives an indication that changes have taken place in the company's equity, for example if a new issue has been carried out and how much of such a capital injection remains per balance sheet date.

Cash flow per share from current operations

Cash flow from operating activities divided by average number of shares. Given the company's phase where revenues are still fictitious, the number, together with equity per share, provides information about the company's capital acquisition and financing.

Solidity

Equity as a percentage of total assets. The key ratio shows how much of the assets were financed via equity and thus indicates the company's financial robustness.

Declaration by the Board of Directors

The Board of Directors and the CEO ensure that the interim report provides a fair overview of the company's and the Group's operations, financial position and results and describes the significant risks and uncertainties facing the company and the Group.

Stockholm, November 17 2023

Erik Nerpin
Chairman

Håkan Mellstedt
Board member

Charlotte Edenius
Board member

Carl-Henrik Heldin
Board member

Anders Gabrielsen
Board member

Petter Brodin
Board member

Thomas Olin
Board member

Peter Selin
CEO

This interim report has been subject to a review by the company's auditors.

Therese Utengen
Authorised auditor
Grant Thornton Sweden AB

Upcoming reporting dates and Annual General Meeting

Interim Report Oct – Dec 2023	February 23, 2024
Annual Report 2023	May 6, 2024
Interim Report Jan – Mar 2024	May 17, 2024
Annual General Meeting 2024	May 27, 2024
Interim Report Apr – Jun 2024	August 23, 2024
Interim Report Jul – Sep 2024	November 15, 2024
Interim Report Oct – Dec 2024	February 21, 2025

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