

#### Press release August 23, 2013

# Interim Report for Kancera AB (publ) Q2 2013 January 1 – June 30, 2013

All figures from the first quarter 2013 relate only to Kancera AB as a consequence of the liquidation of the subsidiary iNovacia AB in the beginning of 2013. Therefore there are no consolidated accounts for the Kancera Group produced which was done until the accounting year 2012. In connection with this Kancera has passed from the RFR2 regulations, applicable to companies in groups, to BFN;s complementary regulation K3. The full year report and consolidated accounts fulfill the requirements of Nasdaq OMX First North for the accounting of Kancera AB. The transition to K3 did not affect the income statement or the balance sheet for 2012. The result for the period January 1, 2013 - June 30, 2013 and the balance sheet as of June 30, 2013 correspond to those accounted for according to earlier accounting principles. Comparative figures from the preceding year relate to the mother company Kancera AB.

#### The period January to June and the second quarter 2013 in brief

- R&D expenses for the quarter totaled SEK 3.6m (SEK 11.9m) of which the second quarter constitute SEK 2.1m (SEK 5.9m).
- Operating income for the period totaled SEK -5.6m (SEK -15.8m) of which the second quarter constitute SEK -3.3m (SEK -8.0m).
- Income after financial items for the period totaled SEK -2.6m (SEK -15.7m) of which the second quarter constitute SEK -3.3m (SEK -8.0m).
- Earnings per share for the period were SEK -0.08 (SEK -1.03) of which the second quarter constitute SEK -0.10 (SEK -0.53).
- The income after financial items and earnings per share was affected by a profit of SEK 3m that occurred when realizing a claim acquired to a value less than the nominal amount. The claim has been recognized as income during the period.
- Cash flow from operating activities for the period totaled SEK -5.1m (SEK -15.2m) of which the second quarter constitute SEK -2.8m (SEK -7.3m).
- Equity as of June 30, 2013 totaled SEK 12.1m (SEK 13.0m) or SEK 0.37 (SEK 0.86) per share. The equity/assets ratio on the reporting date was 78 percent (79 percent).
- Cash and cash equivalents as of June 30, 2013 totaled SEK 4.0m (SEK 7.4m). Vinnova, Sweden's Innovation Agency awarded Kancera's ROR project a non-refundable grant of SEK 0.5m. This grant was disbursed to Kancera after the end of the period and is therefore not part of the accounted cash and cash equivalents.

#### Significant events during the period

- · Kancera reported through an update of the project portfolio that
  - Publications during the conference "American Society for Hematology" (ASH) in Atlanta, USA, from Kancera, its co-founder Professor Håkan Mellstedt at the Karolinska Institutet, and researchers at University of California, San Diego, showed the importance of ROR in the development of new pharmaceuticals against the most common forms of chronic and acute leukemia (CLL and AML, respectively).
  - Further patent protection investments in the ROR project were made by the registration of an international patent application (PCT/EP2013/051772) during January 2013. During the third quarter this application was revoked and replaced with a new patent application EP13180941.0. Further, Kancera acquired exclusive rights to a patent application on human monoclonal antibodies (WO 2012/076727).



- Complementing analyses of Kancera's earlier results showed that the level of inhibition of the PFKFB3
  protein within the cancer cell correlates well with the growth inhibition observed in both cancer cells as in
  a whole tumor. This further strengthens PFKFB3 as a target for cancer treatment.
- Kancera reported that agreements have been reached with the purpose to enable Kancera's new smaller organization access to a state-of-the-art laboratory. The agreements include an agreement with
  - Humlegården Fastigheter AB on the lease of smaller and more cost effective laboratories that are better adapted to the size and budget of the ROR project.
  - Sobi AB to take over Sobi AB:s SEK 5m claim on iNovacia. This claim is secured by for instance iNovacia's laboratory equipment and instruments via a floating charge on assets. The claim and the floating charge on assets was taken over against a payment to Sobi AB amounting to SEK 2m.
- Kancera reported that a decision was taken to terminate the reconstruction of iNovacia due to uncertainty
  regarding the possibilities to create external revenues that would allow the continued operation of iNovacia.
  Against this background, the company applied for bankruptcy and was declared bankrupt on February 21.
  Kancera has not provided financial guarantees relating to iNovacia.
- Kancera reported that the company has finalized a new and more effective organization. A complete arsenal of
  instruments and an internationally competitive library of drug prototypes have been acquired from the iNovacia
  bankrupt's estate. In parallel key persons have been recruited for the further development of a ROR-targeted drug
  against cancer. This combined resource is now operational in specially equipped laboratories at Karolinska
  Institutet Science Park.
- Kancera announced that a collaboration has been initiated with Professor Thomas Kipps and his research team at the University of California, San Diego. During the collaboration Kancera will provide its diagnostic antibodies that constitute a tool for Professor Kipps group in order to demonstrate how activation of ROR1 correlates with the properties of aggressive cancer forms.
- New knowledge on how Kancera's ROR inhibitors are metabolized in the liver provides important information on how to develop the synthesis of effective ROR inhibitors in order to deliver a drug candidate in 2013 according to plan.
- Kancera together with an international research team reported progress in the development of a drug against a serious parasitic disease. Kancera owns together with its partners in the project, the rights to jointly developed drugs against schistosomiasis.
- Kancera announced the initiation of a collaboration with Professor Thomas Helleday and his research group at Karolinska Institutet and the Science for Life Laboratory (SciLifeLab) in order to advance unique research on energy metabolism in cancer and Kancera's PFKFB3 project. Within the collaboration Kancera retains exclusive ownership of its PFKFB inhibitors. An agreement has been reached between Kancera and the researchers providing Kancera exclusive rights to acquire inventions that may arise within the framework of the collaboration. Professor Thomas Helleday is a highly regarded expert in the area of intractable cancer. He leads an interdisciplinary research team that conducts translational research aimed at understanding the fundamental questions about the occurrence of cancer and the development of new drugs for cancer treatment.
- On May 28, 2012 the Annual General Meeting approved the Board's proposal to authorize the Board, on one or several occasions until the next Annual General Meeting, to issue new shares against payment in cash and or in kind or by set-off. The total number of shares which may be issued under this authority shall not exceed 25 percent of the total number of shares. The authorization has not yet been used.

#### Significant events after the end of the reporting period

- Kancera announced that the company has been awarded a grant of SEK 500,000 and with the possibility of an additional SEK 1,000,000 for further development of the ROR project. The grant was awarded by the Swedish Innovation Agency VINNOVA which had identified Kancera as a young, innovative company with growth potential. Kancera's ROR project attacks cancer via a novel mechanism and is considered highly innovative.
- Kancera reported progress in the development of a ROR-inhibiting cancer drug.
  - The compound KAN0439365 has been shown to be effective against cancer cells from patients that are treatment-resistant today and has shown good metabolic stability in human liver cells and blood.
     KAN0439365 is the first in a new generation of ROR inhibitors to meet the requirements that the company places on a candidate drug in these respects
  - Kancera continues development of a compound to be used in efficacy and safety studies in animals.
  - Kancera has registered a new patent application EP13180941.0 for small molecule ROR inhibitors and registered national applications for human monoclonal antibodies against ROR in the U.S., Europe, India and China.



Kancera announced that the European Union Seventh Framework Programme has awarded Kancera € 950,000 for the development of drugs to treat severe parasitic diseases. From February 2014, Kancera together with international research groups in the project A-PARADDISE, will develop drugs against malaria, schistosomiasis, leishmaniasis and Chagas disease. The total budget for the three-year project is 6 M€ of which Kancera's part of ca € 950,000, is the largest.



## Statement from the CEO

The second quarter shows that Kancera's new organization has provided a sustained reduction in operating costs while at the same time the necessary expertise has been secured. In order to provide additional pressure behind the company's development of drug candidates, Kancera initiated two collaborations with highly qualified research groups at the University of California and the Science for Life Laboratory at the Karolinska Institute (SciLifeLab). The collaboration with Professor Thomas Kipps and his research team at the University of California gives us additional knowledge on how ROR inhibitors can be used in the treatment of breast cancer. The collaboration with Professor Thomas Helleday at SciLifeLab provides knowledge on how Kancera PFKFB inhibitors are best combined with other anticancer drugs. These two collaborations that are based on mutual exchange of expertise do not increase the operating costs for Kancera.

During the spring and summer, Kancera has received financial contributions from the three parties. In addition to a SEK 1.5m interest-free loan from Humlegården Fastigheter AB which enabled the acquisition of the pharmaceutical laboratory, Vinnova awarded Kancera's ROR project a grant aimed at innovative companies (SEK 0.5m for stage 1 has been granted, with a possible extension to a total of SEK 1.5m). Furthermore, EU has allocated € 950,000 to Kancera (spread over three years starting in February 2014) for the development of drug candidates targeting primarily malaria and schistosomiasis. Especially exciting is that some compounds directed against parasitic diseases also have a potential in anticancer treatment. Overall, I consider that the funding from Vinnova and the EU proves that Kancera's research is of the highest quality.

In parallel, within the ROR project, we have acted to prolong the period during which new ROR inhibitors may be patented. We have achieved this by registering a new in-depth patent application in August 2013, while at the same time withdrawing the first patent application from January 2012.

For the further development of Kancera's ROR project in 2013 and 2014, the assessment of the Board is that an additional financial injection is necessary. The Board is accordingly considering financing options.

The main purpose of the capital injection is to deliver a candidate drug for sale in the ROR project. During the spring, we have presented results supporting that the efficacy profile of our ROR inhibitors in cancer cells from patients is internationally competitive.

It is gratifying that we have been able to show that our ROR inhibitor KAN0439365 is sufficiently stable in human blood and liver to meet Kancera's requirements on a candidate drug in these respects. It is of course a great progress but it is not enough. Since a future clinical study is partly based on the documentation of efficacy and safety in the bodies of animals (rodents), we would also like to have a ROR inhibitor that is active and stable in these animals. That is now our next goal. The work towards this goal is performed by Kancera's own scientists, in collaboration with a group of experts in drug metabolism from Astra-Zeneca, now independent (Metasafe AB), giving Kancera the same quality of analyses that AstraZeneca today globally leans towards in their projects.

During the second quarter we have thus taken important steps towards a drug candidate in the ROR project.

Thomas Olin CEO of Kancera



#### About Kancera AB (publ)

Kancera develops the basis for new therapeutics, starting with new treatment concepts and ending with the sale of a drug candidate to international pharmaceutical companies. Kancera is currently developing drugs for the treatment of leukemia and solid tumors, based partly on blocking survival signals in the cancer cell and partly on metabolic strangulation. Kancera's operations are based in the Karolinska Institutet Science Park in Stockholm and the company employs around 7 people. Kancera shares are traded on NASDAQ OMX First North and are held by around 1700 shareholders. Remium Nordic AB is Kancera's Certified Adviser.

#### Kancera's history

In 2006, Pharmacia's and Biovitrum's unit for the development of drug candidates was spun-out to create iNovacia AB. In 2008, a collaboration was started with the Karolinska Institute's cancer research center (CCK); and later, a collaboration was initiated with Sprint Bioscience AB. In May 2010, Kancera AB was formed by iNovacia AB, Sprint Bioscience AB, expertise from the Karolinska Institute and a group of private investors through capital contributions and two developed drug projects focusing on cancer. NASDAQ OMX approved Kancera's listing on First North with the first day of trading being February 25, 2011. In March 2013 Kancera acquired a complete drug development laboratory from its former subsidiary iNovacia AB and the drug development is since then performed within Kancera AB at the Karolinska Institutet Science Park, Stockholm.



# Financial development, summary

#### Financial development, summary

Kancera AB	1 Jan-3	1 April-30 June		1 Jan-30 June		1 Jan-31 De	
	2013	2012	2013	2012	2013	2012	2012
Net turnover	-	-	218	-	218	-	-
R&D expenses	-1 492	-6 013	-2 071	-5 930	-3 563	-11 943	-14 723
Operating Income	-2 311	-7 737	-3 274	-8 021	-5 585	-15 758	-21 245
Income after financial items	690	-7 700	-3 274	-8 007	-2 584	-15 707	-23 502
Net income	690	-7 700	-3 274	-8 007	-2 584	-15 707	-23 502
Cash-flow from operating activities	-2 236	-7 882	-2 844	-7 313	-5 080	-15 195	-22 535
Earnings per share, before and after dilution	0,02	-0,51	-0,10	-0,53	-0,08	-1,03	-1,42
Cash on hand at closing date	5 316	6 676	3 972	7 416	3 972	7 416	5 107
Solvency ratio	93%	83%	78%	79%	78%	79%	90%
Key ratios							
Return on equity, %	5,4%	neg	neg	neg	neg	neg	neg
Return on capital employed, %	5,4%	neg	neg	neg	neg	neg	neg
Solvency ratio	93%	83%	78%	79%	78%	79%	90%
Net investments in tangible assets	2 000	-	-	-	2 000	-	-
in relation to net turnover, %	-	-	-	-	917,4%	-	-
No. of employees	7	-	7	-	7	-	-
Earnings per share, before dilution	0,02	-0,51	-0,10	-0,53	-0,08	-1,03	,
Earnings per share, after dilution	0,02	-0,51	-0,10	-0,53	-0,08	-1,03	-1,42
Equity by share, kr	0,48	0,85	0,37	0,86	0,37	0,86	0,62
Cash-Flow by share, kr	0,01	-0,52	-0,04	0,05	-0,04	-0,47	-0,57

# Comments on financial development

The reduced costs and decreased negative cash flow for the period compared to the same period in 2012 can be attributed to the concentration of operations and the liquidation of the subsidiary conducted in the first quarter of 2013. This has resulted in an increased financial flexibility while at the same time maintaining the company's technical resources through the acquisition of the subsidiary's drug development laboratory. The income after financial items and earnings per share were affected by a profit of SEK 3 million arising from the realization of a claim that was acquired for a value less than the nominal amount. The claim has been recognized as income during the period. Comparative figures from the preceding year relate to the mother company Kancera AB.

#### Net sales

The Kancera activities have mainly covered internal drug development projects alongside smaller consultancy projects which raised net sales during the period of SEK 0.2m (SEK 0).

#### Expenses

Expenses in the second quarter totaled SEK 3.5m (SEK 8.0m), which breaks down into costs of services sold of SEK 0.1m (SEK 0), research and development expenses of SEK 2.1m (SEK 5.9m) and other sales and administrative expenses of SEK 1.3m (SEK 2.1m). Expenses during the period January 1 to June 30 2013 totaled SEK 5.8m (SEK 15.8m), which breaks down into costs of services sold of SEK 0 .1m (SEK 0), research and development expenses of SEK 3.6m (SEK 11.9m) and other sales and administrative expenses of SEK 2.1m (SEK 3.9m).

#### Earnings

Income after financial items for the second quarter totaled SEK -3.3m (SEK -8.0m) and for the period SEK -2.6m (SEK -15.7m).

#### Cash flow and liquidity

Cash flow totaled SEK -1.3m (SEK 0.7m) in the second quarter. Cash flow from operating activities for the second quarter



totaled SEK -2.8m (SEK -7.3m). Cash flow from financing activities for the second quarter amounted to SEK 1.5m (SEK 0).

Cash flow for the period totaled SEK -1.1m (SEK -7.1m). Cash flow from operating activities for the period totaled SEK - 5.1m (SEK -15.2m). Cash flow from financing activities for the period amounted to SEK 1.5m (SEK 0).

In connection with the acquisition of iNovacia's assets, the requirements for an interest free and installment free loan from Humlegården Fastigheter AB to Kancera were fulfilled. The loan amounts to SEK 1.5m and does not expire as long as Kancera runs its laboratory activities in the current premises. This loan was disbursed to Kancera during the second guarter and is therefore part of the accounted cash and cash equivalents.

The Swedish Innovation Agency VINNOVA awarded Kancera's ROR project a grant of SEK 0.5m (not to be repaid). This grant was disbursed to Kancera after the period and is therefore not part of the accounted cash and cash equivalents.

Kancera's cash and cash equivalents as of June 30, 2013 totaled SEK 4.0m (SEK 7.4m).

The assessment of the Board is that additional capital needs to be procured in order to implement planned projects in 2013 and 2014.

#### Investments

Investments in property, plant and equipment in the second quarter totaled SEK 0 (SEK 0) and for the period net SEK 2.0m (SEK 0) as instruments and the library of prototype drugs were acquired from the iNovacia bankrupt's estate to a price assessed by the Board to be favorable.

Investments in intangible assets in the second quarter 2013 totaled SEK 0 (SEK 0). Current investments in intangible assets, R & D costs, are expensed as R & D and these amounted to SEK 2.1m (SEK 5.9m) for the second quarter.

#### Equity and share data

Total equity as of June 30, 2013 was SEK 12.1m (SEK 13.0m).

Share capital as of June 30, 2013 amounted to SEK 2 688 973 spread over 32 267 674 shares with a quotient value (rounded off) of SEK 0.0833 per share.

Earnings per share for the first quarter, based on a weighted average of the number of outstanding shares, were SEK -0.10 (SEK -0.53). In connection with the share issue a bonus element was identified, which means that the weighted average number of shares used to calculate earnings per share has been adjusted. Prior periods have been recalculated to reflect the bonus element.

Kancera's equity/assets ratio as of June 30, 2013 was 78 percent (79 percent). Equity per share was SEK 0.37 (SEK 0.86), based on equity divided by the number of shares outstanding at the balance sheet date at the end of the quarter.

#### Deficits for tax purposes

Kancera's operations are expected to initially result in negative earnings and deficits for tax purposes. There are no sufficiently convincing evidence at present that tax surpluses will exist in the future that may justify capitalization of the value of the deficit, and no deferred tax claim has therefore been reported. In the event a drug candidate is sold, profits will be reported which may be offset for tax purposes against the deficits. This signifies a low tax burden for the company when a project is sold.

#### Personnel

Kancera AB had 7 employees (0) as of June 30, 2013 of which 5 are men and 2 are women.

## Pharmaceutical Development

Kancera develops cancer drugs, starting with a new treatment concept and ending with a patent-pending drug candidate that is offered for sale to larger pharmaceutical and biotech companies before it has reached the clinical phase in the product development chain.

The product development in the ROR project has advanced so far that the company now sets the goal to deliver a drug candidate in 2013 with the potential to treat refractory solid cancers such as pancreatic, breast or lung cancer as well as hematologic cancers.

In line with the Board's goal to increase the financial flexibility of the company it was decided to focus the activities on one project. The ROR project, where the company has an internationally unique leadership position, was prioritized.



Thus for the time being there will be no significant additional investments in the PFKFB3 project until adequate funding has been secured. However, following the detection of a tumor-inhibiting effect in an animal model of pancreatic cancer, the PFKFB3 project has been valued to SEK 3 million in the balance sheet which was the original purchase value of the project. It is the opinion of the Board that the value, based on the currently known results of Kancera's research, can be defended on the basis of currently prevailing prices of comparable projects and the potential to further develop the project in the future.

Kancera also develops drugs against severe parasitic diseases in collaboration with highly qualified international research groups. These drugs are directed against target proteins in the parasite. Inhibitors against the corresponding human target proteins are possible therapies also against cancer and may constitute new business opportunities for Kancera AB. For the project, Kancera has been awarded funding of  $\leq$  950,000 from EU's 7th Framework Programme for research and product development. This funding covers 75% of the project costs, including "overhead" such as rent and administration which means that the project also bears a part of Kancera's administrative costs.

Kancera's Board of Directors has decided not to communicate financial goals for the pharmaceutical development because Kancera's projects are in the early phases of development, which means the risk is high and the overall financial goals are difficult to assess.

#### ROR technology - drug candidate is developed for the treatment of leukemia and solid tumors

Kancera is developing synthetic compounds that enter the tumor cell and work on the part of the ROR-1 receptor that is inside the tumor cell, with the aim of blocking the cell's survival signal.

Since ROR is selectively found in cancer cells and not in the surrounding healthy tissue, the Kancera project offers good possibilities to develop effective drugs with fewer side effects that may contribute to increased quality of life for patients and lower costs for society. Against this background, a comparative study has been performed with four successful drugs (Dasatinib, Gefitinib, Sorafinib, Sunitinib) in order to examine the competitiveness of ROR inhibitors. The results show that these four drugs are unable to efficiently inhibit ROR1 and that they kill cancer cells from leukemia patients less selectively. Further, the study shows that these drugs also kill healthy white blood cells, which cause the patient to become more susceptible to infections. According to the study Kancera's ROR inhibitors spare the healthy white blood cells. Thus a future patient receiving this drug may withstand severe infections better compared to those receiving today's medications.

Kancera has also shown that the company's ROR-inhibiting substances are capable of killing leukemia cells from 50% of the patients that are no longer helped by Fludarabine, the drug primarily prescribed for the treatment of chronic lymphocytic leukemia. This opens the way for a possible breakthrough in the treatment of the most common form of chronic leukemia. Independent of Kancera, Professor Thomas Kipps at University of California San Diego has showed that ROR inhibition may be an important treatment for the severe cancer form Acute Myeloid Leukemia (AML). Along with Kancera's own studies this shows that substances that block ROR have the potential to combat both the most widespread chronic form as well as the acute form of leukemia (CLL and AML, respectively).

Studies of ROR1 directed antibodies, developed by Professor Håkan Mellstedt and his research group at Karolinska Institutet, show that they have the ability to kill cancer cells in an animal model for chronic lymphocytic leukemia (CLL) with an efficacy comparable to the effect of Rituxan. Rituxan is the most commonly used antibody drug against CLL today. Although the ROR1 antibody does not demonstrate a direct benefit compared to Rituxan for CLL, the potential use of ROR inhibitors against solid cancers speaks for the development of a ROR-targeted drug. In addition, ROR represents a new mechanism that can break the resistance in advanced stages of CLL.

International research shows that many types of solid tumor cells can be ROR dependent. Kancera, in collaboration with Professor Håkan Mellstedt's and Professor Matthias Löhr's research groups at Karolinska Institutet, has found that Kancera's substances effectively kill pancreatic cancer cells. Pancreatic cancer affects more than 100,000 patients anually in Europe and USA. The survival rate among these patients is less than two per cent five years after diagnosis. As with leukemia it has been demonstrated also for pancreatic cancer that ROR1 levels increase in tumor cells of patients with progressive (aggressive) cancer.

In parallel, independent researchers from the U.S. and Japan have shown that ROR is a promising target for development of drugs also against breast cancer and lung cancer (Yamaguchi et al, Cancer Cell 2012, Zhang et al, PLoS One 2012), indicating a potentially wide range of use for a future ROR inhibiting drug.

Kancera has developed a first generation of diagnostic antibodies that allow the identification of patients who may



benefit from Kancera's future cancer treatment directed against ROR. This will guide future clinical studies and demonstrate the commercial value of the ROR-inhibiting drug.

#### Events during the period

Kancera reported that Kancera's most recently developed ROR1 inhibitors now are more effective and more selective in killing cancer cells from leukemia patients than two classes of comparable reversible cancer drugs that inhibit the kinases PI3K and Syk, both in clinical development. In comparison with a drug that is expected to revolutionize the market for blood cancer, Ibrutinib which permanently binds its target BTK, Kancera's ROR inhibitors are less potent but, according to our study, more selective against cancer cells.

In collaboration with Professor Håkan Mellstedt and his research group at Karolinska Institutet, Kancera also studied how effective these competing candidate drugs kill cancer cells derived from CLL patients whose cancer is no longer sensitive to today's most widely used small molecule drug (Fludarabine). In Figure 1 the results from this study are shown. The study indicates that there is a group of refractory patients whose cancer cells are significantly more sensitive to Kancera's ROR inhibitors compared to the competing substances, including lbrutinib. It should, however, be emphasized that the study does not indicate whether the competing substances have an improved effect over a longer time course.

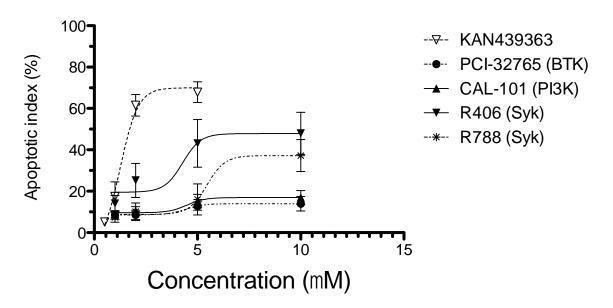


Figure 1. The figure shows how effective Kancera ROR inhibitors and competing kinase inhibitors kill CLL cancer cells that are resistant to today's most widely used drug Fludarabine. The percentage killed cancer cells is expressed as "percent apoptosis" after 24 hours exposure to each kinase inhibitor. Figure a) shows the effect of four competing drugs now being tested in clinical development, including Ibrutinib (PCI-32765). The competing kinase inhibitors reach maximum ca 15-50% killed cancer cells at a concentration of about 5  $\mu$ M while *Kancera's ROR inhibitor show higher effect at a lower concentration* (70% killing of cancer cells at about 3  $\mu$ M). Note that the maximum killing effect on cancer cells is negligible after 24 hours for the BTK inhibitor (Ibrutinib) and the PI3K inhibitors. These studies include samples from seven patients.

Kancera announced that a collaboration has been initiated with Professor Thomas Kipps and his research team at the University of California, San Diego. During the collaboration Kancera will provide its diagnostic antibodies that constitute a tool for Professor Kipps'group in order to demonstrate how activation of ROR1 correlates with the properties of aggressive cancer forms. Since Professor Kipps research group has published leading research on the significance of ROR in breast cancer and acute myeloid leukemia, the collaboration is expected to increase the knowledge of how Kancera's ROR inhibitors can be used to treat an increasing number of severe cancer forms.

Furthermore, Kancera announced that new knowledge has been generated on how Kancera's ROR inhibitors are metabolized in the liver and in the blood. This provides important information on how to develop the synthesis of effective ROR inhibitors in order to deliver a drug candidate in 2013. After the period, this new knowledge has resulted in a compound that meets Kancera's stability requirements for ROR inhibitors in humans.



Kancera also announced that the company, by an agreement with Bioinvent AB, has secured exclusive rights to the patent application WO 2012/076727 which includes human monoclonal antibodies against ROR1. The acquisition of the patent rights is based on an agreement with Bioinvent that does not involve any financial burden for Kancera (except future patent expenses) before revenues are generated. Kancera, through the company's co-founder Professor Håkan Mellstedt, has been involved in the development of these human monoclonal antibodies directed against ROR. These antibodies are currently used primarily to identify and validate new indications for future ROR-inhibiting drugs. Any further development of the ROR-targeted monoclonal antibodies for therapeutic purposes will only be done in a partnership with a company that specializes in antibody-based drugs.

#### Events after the end of the reporting period

Kancera reported progress in the development of the substance KAN0439365 which is effective against cancer cells from patients and show good metabolic stability in human liver cells and blood. Thus KAN0439365 is the first ROR inhibitor to meet the requirements that the company places on a candidate drug in these respects.

In order to reduce risk in the further development of ROR inhibiting drugs, Kancera also intends to produce a compound that works in animals/rodents to be used in efficacy and safety studies.

After 24 hours in vitro, KAN0439365 shows a significantly higher killing effect against cancer cells from treatmentresistant patients than the new and groundbreaking drug Ibrutinib \* which is soon entering the market (see Figure 1). The studies were performed in blood samples derived from patients with an advanced stage of the cancer disease CLL at which today's most widely used drug for this disease, Fludarabine, lacks clinical efficacy.

Kancera has also taken actions to strengthen its patent portfolio in the ROR project. In order to extend the time during which Kancera can protect new inventions related to its ROR inhibitors, the company's first patent application (EP12153357) has been revoked and replaced by a new application EP13180941.0 with refined coverage. Furthermore, Kancera has registered national applications for human monoclonal antibodies against ROR in the U.S., Europe, India and China.

#### The PFKFB3 project - a candidate that blocks glycolysis in solid tumors

The project aims to develop PFKFB3 enzyme inhibitors to strangulate the energy metabolism in cancer cells, thereby rendering the cancer cells more sensitive to chemotherapy and radiotherapy. Kancera has through extensive crystallography studies been established as an international leader in structure-based design of drugs targeting the PFKFB family of enzymes. Kancera has also reported a synergistic inhibitory effect on cancer cells of PFKFB3 inhibitors in combination with cisplatin (a commonly used cytostatic) in the laboratory and reported an inhibitory effect of Kancera's PFKFB3 inhibitors on tumor growth in an animal study of pancreatic cancer. Two independent patent applications are registered in order to protect Kancera's PFKFB3 inhibitors. The next step in the project is to improve the ability of the PFKFB3 inhibitors to penetrate the tumor.

#### Events during the period

Kancera announced the initiation of a collaboration with Professor Thomas Helleday and his research group at Karolinska Institutet and the Science for Life Laboratory (SciLifeLab) in order to advance unique research on energy metabolism in cancer and Kancera's PFKFB3 project. During the collaboration Professor Helleday and Kancera combine their strengths in research on disease mechanisms and product development in order to deliver a new treatment against cancer with the goal to break down the resistance of the cancer to existing drugs. The partnership means that Kancera contribute know-how and drug-like PFKFB3 inhibitors while Professor Helleday's research team invest their own resources in the project to investigate the best combination with other drugs, mechanisms of how PFKFB3 inhibitors act, as well as markers that show how and when a future drug is best used. In a future out-licensing or sale of the project Kancera shall compensate the scientists in proportion to the work performed. Within the collaboration Kancera retains exclusive ownership of its PFKFB inhibitors. An agreement has been reached between Kancera and the researchers providing Kancera exclusive rights to acquire inventions that may arise within the framework of the collaboration.

However, for the time being there will be no significant additional investments in the chemical development part of the PFKFB3 project until adequate funding has been secured.

#### Anti Parasite Project - an EU-funded international cooperation against deadly diseases

In February 2014, Kancera along with international research groups in the project A-PARADDISE (Anti-Parasitic Drug Discovery in Epigenetics), will launch the next phase in the development of these drugs. This phase will run for three years and result in one or more lead substances and drug candidates.



The project focus on target proteins in the following diseases (parasites): Malaria (*Plasmodium falciparum*), Schistosomiasis (*Schistosoma mansoni*), Leishmaniasis (*Leishmania*) and Chagas disease (*Trypanosoma cruzi*).

The A-PARADDISE project builds on the recently completed and highly successful SEtTReND project in which Kancera together with international research teams reported success in the development of drugs against Schistosomiasis.

Kancera is the only pharmaceutical development company in the A PARADDISE consortium and is well positioned to commercialize the drug candidates that the company develops and owns together with its partners. For clinical development and commercialization of drugs for neglected diseases, it is likely that Kancera will seek cooperation with internationally established pharmaceutical companies and nonprofit organizations that have chosen to take social responsibility by investing in the development therapies against diseases that primarily affect poor countries in tropical and subtropical areas.

In addition to parasitic diseases, analyses at Kancera shows that some of the lead substances now being developed against targets in the parasite also inhibit similar human target proteins that are linked to cancer.

Overall, the project's potential application in cancer and the fact that countries that currently suffer from serious parasitic diseases have an increasing financial capacity to invest in drugs, show that the project's future drug candidates have a good commercial potential.

#### Market outlook for Kancera's development projects

The international pharmaceutical industry organization "BIO Industry Organization (<u>http://www.bio.org/</u>) reports that 2012 has been a great year for the approval of new drugs by the FDA. Not since 1990 have there been so many new drugs approved as in 2012, when 40 new products were made available to patients. Given that Kancera is focused on developing small molecule drugs against cancer it is interesting to note that out of the 40 new drugs as many as 35% were targeted against cancer and 70% were small molecule drugs. More than 50% of the approved products are directed against rare diseases, so-called "Orphan designations." The industry's interest in these rare diseases has increased since the patient group is clearly defined, which facilitates clinical studies and since they still represent significant medical needs. This has prompted the authorities to facilitate the development and protection of products against these diseases. Kancera's ROR project has in preclinical studies shown to be a possible way to treat a number of blood cancers that meet the requirements for classification as "Orphan" (in the United States fewer than 200,000 affected individuals).

In April 2012 an agreement between Boston-based Epizyme and Celgene regarding a preclinical drug development project against gene regulation in cancer was announced. The agreement involved an upfront payment of USD 90m including equity. Epizyme is a biotech company that has been a frontrunner for a new cancer treatment concept and has managed to close a series of preclinical deals in the cancer area since early 2011 with GSK and Esai.

Deals in preclinical development, as exemplified between Epizyme and Celgene above, dominated over deals in the clinical phase in 2012 and represented 46% of global partnering agreement according to the analyst Burrill & Company (<u>http://www.burrillandco.com/</u>). Thus it can be concluded that the trend in 2009-2011, with a significant number of deals in the same early phase as the Kancera's projects, continues.

Of interest to Kancera's ROR project are two deals published in December 2011 and January 2012 in which J & J and Celgene Corp. acquired BTK inhibitors in clinical development for the treatment of leukemia from the biotech company Pharmacyclics, including chronic lymphocytic leukemia (CLL), and mantle cell lymphoma. As ROR, BTK is a kinase enzyme found in cancer. BTK inhibitors have mainly been developed against blood cancers. New knowledge about ROR indicates that the therapeutic use (unlike BTK) also includes solid tumors. In the current situation, BTK inhibitors appear to have a therapeutic profile that can make a big difference to many patients suffering from blood cancer. J & J paid USD 150m to Pharmacyclics for a BTK inhibitor in Phase II, in addition to future installments of USD 825m. Following the deal with J & J, the clinical development of Pharmacyclics' BTK inhibitors accelerated thanks in part to FDA's new system for drugs with "breakthrough potential" in the treatment of severe diseases. This allowed Pharmacyclics together with its partner J & J to apply for registration of the drug Ibritunib in July 2013, ahead of the original time plan. Ibrutinib is a new drug and a sharp competitor to Kancera's ROR inhibitors, primarily within leukemia. For this reason, we include Ibrutinib in our studies in order to identify the relative strengths of the ROR inhibitors. Learn more about these comparative studies in the sections on ROR, Figure 1.

That the pharmaceutical industry is in great need of innovation is clear from a report with the heading "lemming



migration" that was referenced by Bruce Booth from the venture capital firm Atlas Ventures (lifescivc.com/2012/06/cancer-drug-targets-the-march-of-the-lemmings/). The report found that out of 990 cancer projects in the industry worldwide, some 200 projects are targeted against only eight targets in the cancer cell. In contrast, ROR1 represents a new target in the cancer cell, in addition to these eight, which means that a drug directed against ROR1 can result in a drug that is unique.

Kancera's operational plan for 2013 includes the delivery of a ROR inhibitor as a candidate for an entirely new class of drugs for sale to the pharmaceutical industry and further clinical trials against intractable cancers.



Income Statement	1 Jan-3	81 March	1 April	-30 June	1 Jan	-30 June	1 Jan-31 De
SEK 000's (if otherwise not specified)	2013	2012	2013	2012	2013	2012	2012
Kancera AB							
Revenues							
Net sales	-	-	218	-	218	-	-
Cost of sales & services	-	-	-142	-	-142	-	-
Gross profit		-	76	-	76	-	-
Operating Expenses							
General & administrative expenses	-704	-961	-985	-1 401	-1 689	-2 362	-4 566
Selling expenses	-115	-763	-294	-690	-409	-1 453	-1 956
Research & development expenses	-1 492	-6 013	-2 071	-5 930	-3 563	-11 943	-14 723
Total expenses	-2 311	-7 737	-3 350	-8 021	-5 661	-15 758	-21 245
Operating income	-2 311	-7 737	-3 274	-8 021	-5 585	-15 758	-21 245
Income from Financial Investments							
Financial income	3 001	37		14	3 001	51	61
Financial expenses							-2 318
Financial net	3 001	37	0	14	3 001	51	-2 257
Income after financial items	690	-7 700	-3 274	-8 007	-2 584	-15 707	-23 502
Taxation	-	-	-	-	-	-	-
Net income	690	-7 700	-3 274	-8 007	-2 584	-15 707	-23 502
Earnings per share, before and after dilution	0,02	-0,51	-0,10	-0,53	-0,08	-1,03	-1,42



Balance Sheet	31 M	larch	30 、	June	31 dec
SEK 000's (if otherwise not specified)	2013	2012	2013	2012	2012
Kancera AB					
Assets					
Non-current Assets					
Intangible assets, activated R&D expenses	6 000	6 000	6 000	6 000	6 000
Tangible assets	5 000	-	4 750	-	-
Financial assets	0	2 320	0	2 320	0
Total non-current assets	11 000	8 320	10 750	8 320	6 000
Current Assets					
Receivables	137	688	781	753	194
Cash and cash equivalents	5 316	6 676	3 972	7 416	5 107
Total current asstes	5 453	7 364	4 753	8 169	5 301
TOTAL ASSETS	16 453	15 684	15 503	16 489	11 301
Equity and Liabilities					
Equity		4 000		4 = 00	4 500
Restricted equity	2 689	1 262	2 689	1 563	1 563
Non-restricted equity	12 671	11 681	9 397	11 426	8 662
Total equity	15 360	12 943	12 086	12 989	10 225
Provisions and liabilities					
Long-term liabilities	-	-	1 500	-	-
Short-term liabilities	1 093	2 741	1 917	3 500	1 076
Total provisions and liabilities	1 093	2 741	3 417	3 500	1 076
TOTAL EQUITY and LIABILITIES	16 453	15 684	15 503	16 489	11 301

Statement of Changes in Equity			
SEK 000's (if otherwise not specified) Kancera AB			
	2013		2012
Total equity, opening balance on the 1st of Jan 201	10 225	Total equity, opening balance on the 1st of Jan	201 20 643
Proceeds on issue of shares	4 834	Q1 net income	-7 700
Costs related to issue of shares	-389	Total equity, closing balance on the 31st of Mar	ch 2 12 943
Q1 net income	690	Proceeds on issue of shares	8 299
Total equity, closing balance on the 31st of March 2	15 360	Costs related to issue of shares	-250
Q2 net income	-3 274	Exercise of warrant	4
Total equity, closing balance on the 30th of June 20	12 086	Q2 net income	-8 007
		Total equity, closing balance on the 30th of June	e 20 12 989



Cash-Flow Statement	1 Jan-3	31 March	1 April	-30 June	1 Jan	-30 June	1 Jan-31 D
SEK 000´s (if otherwise not specified)	2013	2012	2013	2012	2013	2012	2012
Kancera AB							
Cash-flow from operating activities							
Operating income after financial items	690	-7 700	-3 274	-8 007	-2 584	-15 707	-23 502
Depreciation	-	-	-	-	-	-	-
Other non-cash-flow affecting items	-3 000	-	-	-	-3 000	-	2 320
Cash-flow from operating activities before working ca change	-2 310	-7 700	-3 274	-8 007	-5 584	-15 707	-21 182
Change in working capital	74	-182	430	694	504	512	-1 353
Cash-flow from operating activities	-2 236	-7 882	-2 844	-7 313	-5 080	-15 195	-22 535
Investment activities							
Investment in financial assets	-2 000	-	-	-	-2 000	-	-
Cash-flow from investment activities	-2 000	-	-	-	-2 000	-	-
FREE CASH-FLOW available to INVESTORS	-4 236	-7 882	-2 844	-7 313	-7 080	-15 195	-22 535
Financing activities							
Issue of shares	4 445	-	-	8 053	4 445	8 053	13 084
	-	-	1 500	-	1 500	-	-
Cash-flow from financing activities	4 445	-	1 500	8 053	5 945	8 053	13 084
CASH-FLOW for the YEAR	209	-7 882	-1 344	740	-1 135	-7 142	-9 451
Cash and cash equivalents at the beginning of the yea	5 107	14 558	5 316	6 676	5 107	14 558	14 558
Cash and cash equivalents at the end of the year	5 316	6 676	3 972	7 416	3 972	7 416	5 107



# Notes

## Note 1. Accounting and valuation principles

This interim report has been prepared in accordance with BFNAR 2007:1, Voluntary interim reporting. From 2013 Kancera applies the Swedish Annual Accounts Act and BFN:s supplementary regulations K3, Annual Report and consolidated accounts. The transition to K3 did not affect the income statement or the balance sheet for 2012. The result for the period January 1, 2013 - June 30, 2013 and the balance sheet as of June 30, 2013 correspond to those accounted for according to earlier principles.

The accounting principles of the company are described in the latest published Annual Report.

Unless otherwise indicated, amounts are reported in Swedish kronor and rounded off to the nearest thousand. As a result of the rounding off to the nearest thousand kronor, adding up the amounts stated may not correspond exactly to the total given. Amounts and figures in parentheses are comparison figures for the same period last year.

### Note 2. Related party disclosures

During the period, Kancera paid compensation to F:a Mellstedt Medical for scientific consulting and scientific marketing services at an amount of SEK 45,052. Håkan Mellstedt, a Board member at Kancera, is the Managing Director and owner of F:a Mellstedt Medical. No other remuneration was paid to related parties.

### Note 3. Incentive schemes

Following a resolution passed by the Annual General Meeting on May 26, 2011 Kancera introduced an incentive scheme for employees of the Group and certain contractors, involving the issue of 400,000 warrants. Within the incentive scheme, Carl-Henrik Heldin, newly appointed Board member of Kancera, has acquired 10 000 options at a price of 4,000 SEK in June 2012. The options have been sold at market price determined by the Black & Scholes valuation model. If all the warrants are exercised to subscribe for 400,000 new shares, the dilution of the share capital will amount to approximately 2.6 percent. All options can be exercised to purchase shares during the period 1 March to 31 May 2014.

## Note 4. Financial definitions

#### Return on equity (ROE)

Net profit for the period as a percentage of average equity.

#### Return on capital employed (ROCE)

Profit before tax plus financial expenses as a percentage of average capital employed.

#### Equity per share

Equity divided by the number of shares on the reporting date.

#### Cash flow per share

Cash flow from operating activities divided by the average number of shares.

#### **Option-based deal**

Agreement between two parties giving one party the right through prepayment to later acquire sole rights to the asset concerned.

#### Earnings per share

Profit for the period divided by average number of shares.

#### Capital employed

Total assets less non-interest bearing liabilities.

#### Equity/assets ratio

Equity as a percentage of total assets.



# The company's operations and risk factors

The Board of Directors and CEO give an assurance that the interim report provides a true and fair overview of the company's operations, financial position and results, and describes the significant risks and uncertainties faced by the company.

In assessing Kancera's future development it is important to consider risk factors alongside potential growth in earnings. Kancera's operations are affected by a number of risks that may affect Kancera's earnings and financial position to varying degrees. For further information regarding company risks, see the company's Annual Report 2012.

Stockholm, August 23, 2013

Erik Nerpin Chairman of the Board Håkan Mellstedt Director Bernt Magnusson Director

Carl-Henrik Heldin Director Thomas Olin CEO/Director

This Interim Report has not been reviewed by the company's auditors.

#### **Financial calendar**

Interim report January – September 2013 November 22, 2013

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