

## INTERIM REPORT JANUARY-JUNE 2014

### The January–June period and the second quarter 2014 in brief

- Net sales amounted to MSEK 13.2 (16.2), whereof the second quarter amounted MSEK 6.8 (8.1)
- Net loss for the group was MSEK 27.6 (25.3), whereof the second quarter MSEK 14.2 (14.6)
- Loss per share was SEK 0.04 (0.04), whereof the second quarter SEK 0.02 (0.03)
- Cash flow from operating activities was MSEK -26.3 (-24.2), whereof the second quarter MSEK -13.1 (-14.3)
- Cash and cash equivalents and other short-term investments totaled MSEK 71.9 (33.8) at the end of the period

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

- Karo Bio was granted MSEK 3.8 from Vinnova for the development of ERbeta cancer

#### Conference call / audiocast today at 9.30 a.m. CET

CEO Per Bengtsson will present the report today at 9.30 a.m. in an audiocast, held in Swedish. The audiocast and slides are available through the corporate website <http://www.karobio.se/> or by telephone +468 51 999 351. Questions may be submitted over the internet or by telephone.

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The information in this report is such that Karo Bio is required to disclose under the Swedish Securities Market Act. The information was disclosed on July 11, 2014 at 8.30 a.m. CET.

## Summary of key financial data

(MSEK)	April-June		January -June		January-December
	2014	2013	2014	2013	2013
Net sales	6.8	8.1	13.2	16.2	47.0
Operating expenses	-21.1	-22.8	-40.9	-41.6	-69.3
- of which R&D expenses	-15.9	-17.3	-30.0	-30.9	-52.5
Net earnings for the period	-14.2	-14.6	-27.6	-25.3	-22.1
Earnings per share (SEK)	-0.02	-0.03	-0.04	-0.04	-0.04
Cash flow from operating activities	-13.1	-14.3	-26.3	-24.2	-33.4
<b>Cash and cash equivalents and other short term investments at the period end</b>	<b>71.9</b>	<b>33.8</b>	<b>71.9</b>	<b>33.8</b>	<b>22.8</b>

## About Karo Bio

Karo Bio is a research and development company focused on drugs for important medical needs.

Karo Bio is active in preclinical development focused on the areas of neuropsychiatry, inflammation, autoimmune diseases and cancer. The company has a number of strategic agreements and collaborations with international pharmaceutical companies and academic research centers.

Karo Bio is based in Huddinge, Sweden. The company has 40 employees and is listed on NASDAQ OMX Stockholm.



## CEO COMMENTARY

### MAINTAINED REVENUE FOCUS

The first half of 2014 has resulted in a strengthening of Karo Bio in a number of respects. Activities in our three main projects have progressed well. The collaboration with Pfizer in the RORgamma project is in an exciting phase with a number of important tests. Continued positive development of the project may also trigger further milestone payments from Pfizer to Karo Bio.

Our position in the two ERbeta projects has also strengthened. In order to reach a deal in ERbeta MS, we have now taken measures to intensify discussions with companies that have shown interest in the project. In our other project, ERbeta cancer, we are now entering the phase in which the safety of the substance we have chosen to advance into clinical

trials is documented.

In the first half of the year, we strengthened our finances through the rights issue that raised net proceeds of MSEK 77. We have created revenue through the collaboration with Pfizer and implemented cost reductions. Moreover, we have been granted a total of more than MSEK 8 in “soft money” since last fall. In addition to our current operations, we will actively seek additional business opportunities in the form of attractive late projects or products.

In summary, we face an exciting period with the potential in our current projects and that which additional business opportunities may bring.

CEO Per Bengtsson

## PROJECT PORTFOLIO

### ERbeta selective compounds – a platform with many opportunities

The estrogen receptor (ER) is activated by estrogen and regulates a number of functions in the body. Estrogen has several positive effects but its medical use has been limited by the associated increased risk for uterine and breast cancer as well as thrombosis. These risks are mainly linked to the estrogen receptor's ERalpha subtype, while ERbeta, which Karo Bio was involved in discovering in the 1990's, seems to account for many of the positive effects of estrogen without the side effects. For ERbeta selective compounds there are clinical opportunities within a number of fields.

Karo Bio's efforts in the field have resulted in a world-leading position and a platform with many promising ERbeta selective compounds. These have slightly different properties and may thus be suitable for different indications. Karo Bio conducts advanced preclinical studies on two of these compounds.

#### ERbeta cancer

Preclinical data suggest that ERbeta has a very interesting potential in the field of cancer. The first drug candidate within the program, KB9520, has shown good efficacy in several preclinical models for different forms of cancer. These effects can be assumed to be of general character in several different forms of cancer tumors, provided they express ERbeta. This image, with positive effects that can be assumed to be general, has been reinforced through in depth preclinical studies in 2013 and 2014.

Karo Bio has been granted a total of MSEK 4.8 from Vinnova for the continued preclinical development of the project. In March, Vinnova granted MSEK 1 for advancing the project and at the end of June it granted a further MSEK 3.8. The funds are to finance toxicological and safety pharmacological studies. The studies are intended to be form the basis of an application to initiate clinical trials.

#### ERbeta MS

Since 2011, Karo Bio has a development project for ERbeta focused on the autoimmune disease multiple sclerosis (MS). In preclinical models, ERbeta agonists have demonstrated protective and reparative effects on the myelin sheaths that surround nerve cells, which is very promising since damaged myelin is involved in the symptoms and disability in MS. If treatment with ERbeta agonists proves capable of repairing damaged myelin also in patients this will represent a significant breakthrough in the treatment of patients with progressive MS, since current therapies only aim at reducing inflammation at early stages of the disease.

To further investigate ERbeta agonists' therapeutic effect, Karo Bio performed additional studies in disease models in animals in the beginning of 2013. The new results indicate that ERbeta has positive effects by protecting and repairing nerve tissue. Key opinion leaders in the MS field are expressing their interest in participating in advancing the project further.

Karo Bio continues the preclinical development of the project and has been granted financing with conditional repayment by the U.S. National MS Society totaling MUSD 0.5. The financing is paid out in stages as Karo Bio demonstrates successful results. Until and including June, MUSD 0.4 had been paid out. The funding is estimated to suffice to advance the project to the selection of a drug candidate, which may occur from the second half of 2014.

Karo Bio is in qualified discussions with several companies about a potential licensing agreement. Such discussions are expected to become more detailed after the selection of a drug candidate.

### RORgamma – a new opportunity to treat autoimmune diseases

Recent research reveals that the nuclear receptor RORgamma may play a critical role in the development of autoimmune disease, such as rheumatoid arthritis and psoriasis. In 2010, Karo Bio initiated a research program to develop and evaluate compounds that inhibit RORgamma activity, which may prove to be a novel concept for a potential new treatment alternative for autoimmune diseases. RORgamma has been shown to control the maturation of, and activity in, a certain type of immune cell,

believed to drive inflammatory and debilitating processes in such diseases.

In December 2011, Karo Bio entered into a research collaboration with Pfizer for RORgamma to discover and develop new compounds for the treatment of autoimmune diseases. Pfizer has exclusive rights for products developed as a result of the collaboration. Karo Bio receives funding for all its R&D expenses in the project. In addition, Karo Bio has the right to milestone payments as well as royalties on sales.

In June 2013, Pfizer decided to extend the two-year term of the research funding agreement one year until the end of 2014.

## Research

Karo Bio also conducts research at earlier stages on certain receptors with the aim of forming early collaborations with industrial partners. Ideas are gathered from academic research and other pharmaceutical research. In a typical case, it is investigated whether certain signaling pathways can be influenced through nuclear receptors and an assessment is made if Karo Bio can use its expertise and create projects with high commercial value at an early stage. Hence, this is very early research where some ideas can be dismissed relatively quickly, while others may be subject to more thorough investigation and eventually, if successful, pave the way for the start of interesting development projects.

In 2013, Karo Bio entered into collaboration with Dr. Jörg Distler and his company 4D Science GmbH regarding fibrosis. Dr. Distlers research team has discovered that a specific nuclear receptor plays a key role in the pathogenesis of fibrotic diseases, which may have implications for the treatment of patients with this type of intractable diseases. The collaboration focuses on demonstrating that it is possible to address the receptor in question with a drug.

## FINANCIAL REPORT

### Consolidated earnings

Net sales for the six month period were MSEK 13.2 (16.2), whereof the second quarter MSEK 6.8 (8.1). The difference is mainly explained by accrued prepayments from Pfizer 2011 of MSEK 5 in the comparative numbers.

Operating expenses for the first six months decreased to MSEK 40.9 (41.6), mainly due to lower cost for preclinical projects that accounted for 73 per cent of the costs for the period, after a decrease to MSEK 30.0 (30.9), whereof the second quarter MSEK 15.9 (17.3). Administrative expenses for the six month period were MSEK 11.0 (11.0), whereof the second quarter MSEK 5.4 (5.7).

The consolidated operating loss for the six month period increased to MSEK 27.7 (25.4), whereof the second quarter MSEK 14.3 (14.7). This is an improvement of MSEK 3 adjusted for the accrued prepayment in the first half 2013.

Financial net for the six month period amounted to MSEK 0.1 (0.1). Net loss for the period amounted to MSEK 27.6 (25.3), whereof the second quarter MSEK 14.2 (14.6).

### Capital investments and consolidated cash flow

Capital investments for the six month period amounted to MSEK 1.3 (0.4) and comprise mainly investments in laboratory and IT equipment.

Cash flow from operating activities for the six month period amounted to MSEK -26.3 (-24.2), whereof the second quarter MSEK -13.1 (-14.3). Adjusted for timing differences in quarterly installments from Pfizer, cash flow improved approximately MSEK 3 from the same period last year.

## Financial position

Consolidated cash and cash equivalents amounted to MSEK 71.9 (23.8) at the end of the period. Including other short-term investments with durations exceeding 90 days, liquid assets amounted to MSEK 71.9 (33.8), which corresponds to a change in total cash position and other short-term investments of MSEK 49.1 (-20.3) in the year. Net proceeds from the equity issues completed in April amounted to MSEK 76.4.

Total shareholders' equity amounted to MSEK 72.6 (20.7) taking into account the period's earnings. In total, there were 676,263,158 shares outstanding, each with a pair value of SEK 0.02.

Loss per share amounted to SEK 0.04 (0.04). The Group's equity ratio at the end of the period was 81.3 (45.6.) per cent and equity per share, based on fully diluted number of shares at the end of the period, was SEK 0.11 (0.04).

## Employees

At the end of the period, Karo Bio had 40 (42) employees, of whom 34 (36) are engaged in research and development, 2 (1) in business development and intellectual property rights and 4 (5) in administrative roles.

## CONSOLIDATED INCOME STATEMENT SUMMARY (KSEK)

	April-June		January-June		January-December
	2014	2013	2014	2013	2013
Net sales	6,825	8,110	13,185	16,209	47,029
<b>Operating expenses</b>					
Administration	-5,434	-5,747	-11,029	-11,001	-20,434
Research and development	-15,887	-17,254	-30,029	-30,895	-52,529
Other operating income/expenses	205	209	184	323	3,676
	-21,116	-22,792	-40,874	-41,573	-69,287
<b>Operating profit/loss</b>	<b>-14,291</b>	<b>-14,682</b>	<b>-27,689</b>	<b>-25,364</b>	<b>-22,258</b>
Financial net	76	100	96	113	180
<b>Earnings after financial items</b>	<b>-14,215</b>	<b>-14,582</b>	<b>-27,593</b>	<b>-25,251</b>	<b>-22,078</b>
Tax	-	-	-	-	-
<b>NET EARNINGS FOR THE PERIOD</b>	<b>-14,215</b>	<b>-14,582</b>	<b>-27,593</b>	<b>-25,251</b>	<b>-22,078</b>
<b>Net earnings for the period attributable to:</b>					
Shareholders of the parent company	-14,215	-14,582	-27,593	-25,251	-22,078
Depreciation included in operating expenses	-480	-341	-929	-671	-1,434
<b>Earnings per share (SEK) <sup>1)</sup></b>	<b>-0.02</b>	<b>-0.03</b>	<b>-0.04</b>	<b>-0.04</b>	<b>-0.04</b>
<b>Number of shares outstanding (000)</b>	<b>676,263</b>	<b>583,185</b>	<b>676,263</b>	<b>583,185</b>	<b>583,185</b>

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (KSEK)

	April-June		January-June		January-December
	2014	2013	2014	2013	2013
<b>NET EARNINGS FOR THE PERIOD</b>	<b>-14,215</b>	<b>-14,582</b>	<b>-27,593</b>	<b>-25,251</b>	<b>-22,078</b>
Other comprehensive income for the year, net of tax	-	-	-	-	-
<b>TOTAL COMPREHENSIVE INCOME FOR THE PERIOD</b>	<b>-14,215</b>	<b>-14,582</b>	<b>-27,593</b>	<b>-25,251</b>	<b>-22,078</b>
Total comprehensive income attributable to:					
<b>Shareholders of the parent company</b>	<b>-14,215</b>	<b>-14,582</b>	<b>-27,593</b>	<b>-25,251</b>	<b>-22,078</b>

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION (KSEK)

	June 30		December 31
	2014	2013	2013
<b>Assets</b>			
Equipment	4,882	3,535	4,500
Other current assets	12,474	7,968	12,992
Financial assets at fair value through profit or loss	-	10,017	-
Cash and cash equivalents	71,929	23,774	22,799
<b>TOTAL ASSETS</b>	<b>89,285</b>	<b>45,294</b>	<b>40,291</b>
<b>Shareholders' equity and liabilities</b>			
Shareholders' equity	72,596	20,666	23,839
Current liabilities	16,689	24,628	16,452
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>	<b>89,285</b>	<b>45,294</b>	<b>40,291</b>

## CONSOLIDATED STATEMENT OF CASH FLOWS (KSEK)

	April-June		January-June		January-December
	2014	2013	2014	2013	2013
<b>Operating activities</b>					
Operating income/loss before financial items	-14,291	-14,682	-27,689	-25,364	-22,258
Depreciation	480	341	929	671	1,434
Other items not affecting cash flows	6	-	7	-	-
	<b>-13,805</b>	<b>-14,341</b>	<b>-26,753</b>	<b>-24,693</b>	<b>-20,824</b>
Financial items received and paid	-1	2	2	35	133
<b>Cash flow from operating activities before changes in working capital</b>	<b>-13,806</b>	<b>-14,339</b>	<b>-26,751</b>	<b>-24,658</b>	<b>-20,691</b>
Changes in working capital	661	83	469	482	-12,698
<b>Cash flow from operating activities</b>	<b>-13,145</b>	<b>-14,256</b>	<b>-26,282</b>	<b>-24,176</b>	<b>-33,389</b>
<b>Investing activities</b>					
Net investment in equipment	-286	-64	-1,353	-483	-2,245
Net investment in other short-term investments	-	15,999	-	16,096	26,096
<b>Cash flow from investing activities</b>	<b>-286</b>	<b>15,935</b>	<b>-1,353</b>	<b>15,613</b>	<b>23,851</b>
<b>Financing activities</b>					
Net proceeds from rights issue	84,748	-	84,748	7,665	7,665
Transaction costs rights issue <sup>1)</sup>	-7,983	-	-7,983	-3,352	-3,352
<b>Cash flow from financing activities</b>	<b>76,765</b>	<b>-</b>	<b>76,765</b>	<b>4,313</b>	<b>4,313</b>
<b>Cash flow for the period</b>	<b>63,334</b>	<b>1,679</b>	<b>49,130</b>	<b>-4,250</b>	<b>-5,225</b>
Cash and cash equivalents at the beginning of the period	8,595	22,095	22,799	28,024	28,024
<b>Cash and cash equivalents at the end of the period</b>	<b>71,929</b>	<b>23,774</b>	<b>71,929</b>	<b>23,774</b>	<b>22,799</b>

1) Comprises the portion of transaction related costs that have been paid in the period.

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY (KSEK)

Attributable to shareholders of the parent company	Share capital	Other contributed capital	Accumulated losses	Total
Amount at January 1, 2013	7,741	1,008,996	-970,820	45,917
Loss for the period	-	-	-25,251	-25,251
Current rights issue	2,178	-2,178	-	0
<b>Amount at June 30, 2013</b>	<b>9,919</b>	<b>1,006,818</b>	<b>-996,071</b>	<b>20,666</b>
Amount at January 1, 2014	9,919	1,006,818	-992,898	23,839
Loss for the period	-	-	-27,593	-27,593
Current rights issue	3,606	72,744	-	76,350
<b>Amount at June 30, 2014</b>	<b>13,525</b>	<b>1,079,562</b>	<b>-1,020,491</b>	<b>72,596</b>

## KEY EQUITY DATA

	June 30		December 31
	2014	2013	2013
Equity ratio	81.3%	45.6%	59.2%
Equity per share at the end of period - basic, SEK	0.11	0.04	0.05
<b>Equity per share at the end of period - diluted, SEK</b>	<b>0.11</b>	<b>0.04</b>	<b>0.05</b>

## The Parent Company

Net sales for the Parent Company for the six month period amounted to MSEK 13.2 (16.2), whereof the second quarter MSEK 6.8 (8.1). Loss after financial items for the parent company was MSEK 27.6 (25.3), whereof the second quarter MSEK 14.2 (14.6).

The Parent Company's capital investments in equipment for the six month period amounted to MSEK 1.3 (0.4). Cash, cash equivalents and other short term investments for the parent company amounted to MSEK 71.7 (33.7) at the end of the period.

### PARENT COMPANY INCOME STATEMENT SUMMARY (KSEK)

	April-June		January-June		January-December
	2014	2013	2014	2013	2013
Net sales	6,825	8,110	13,185	16,209	47,029
<b>Operating expenses</b>					
Administration	-5,434	-5,747	-11,029	-11,001	-20,434
Research and development	-15,902	-17,272	-30,044	-30,914	-52,547
Other operating income/expenses	205	209	184	323	117
	-21,131	-22,810	-40,889	-41,592	-72,864
<b>Operating income/loss</b>	<b>-14,306</b>	<b>-14,700</b>	<b>-27,704</b>	<b>-25,383</b>	<b>-25,835</b>
Financial net	78	104	101	121	3,751
<b>Earnings after financial items</b>	<b>-14,228</b>	<b>-14,596</b>	<b>-27,603</b>	<b>-25,262</b>	<b>-22,084</b>
Tax	-	-	-	-	-
<b>NET EARNINGS FOR THE PERIOD</b>	<b>-14,228</b>	<b>-14,596</b>	<b>-27,603</b>	<b>-25,262</b>	<b>-22,084</b>
<b>Depreciation included in operating expenses</b>	<b>-466</b>	<b>-321</b>	<b>-894</b>	<b>-631</b>	<b>-1,353</b>

### PARENT COMPANY BALANCE SHEET SUMMARY (KSEK)

	June 30		December 31
	2014	2013	2013
<b>Assets</b>			
Equipment	4,725	3,311	4,316
Shares in group companies	150	150	150
Other current assets	12,434	7,968	12,861
Financial assets at fair value through profit or loss	-	10,017	-
Cash and cash equivalents	71,749	23,714	22,619
<b>TOTAL ASSETS</b>	<b>89,058</b>	<b>45,160</b>	<b>39,946</b>
<b>Shareholders' equity and liabilities</b>			
Total restricted equity	13,525	9,919	9,919
Total non-restricted equity	59,070	10,751	13,929
Current liabilities	16,463	24,490	16,098
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>	<b>89,058</b>	<b>45,160</b>	<b>39,946</b>

## OTHER INFORMATION

### AGM May 8, 2014

The annual general meeting re-elected Christer Fåhraeus, Per-Anders Johansson, Sibylle Lenz, and Göran Wessman as Board Members and elected Thomas Hedner and Anders Lönner as new Board Members. Anders Lönner was elected Chairman of the Board.

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

Vinnova granted Karo Bio a further MSEK 3.8 for the continued preclinical development of ERbeta cancer. Hence Vinnova has granted the project a total of MSEK 4.8. The funding will be used mainly for toxicological and safety pharmacological studies. The funding will be paid out in stages.

### Continued operations

After the equity issues completed in April, Karo Bio assesses its liquid assets to cover continued operations for twelve months, even if no new cooperation agreement is entered into or other source of funding obtained. The Company believes, moreover, that there are opportunities for additional revenue in coming quarters.

### Risk factors

There is no guarantee that Karo Bio's research and development will result in commercial success. There can be no guarantee that Karo Bio will develop products that can be patented, that granted patents can be retained, that future inventions will lead to patents, or that granted patents will be sufficient to protect Karo Bio's rights.

There is no guarantee that Karo Bio will obtain approvals on its clinical trials applications or that the clinical trials conducted by Karo Bio, whether independently or in collaboration with its partners, can demonstrate sufficient safety and efficacy to obtain the necessary approvals from regulatory authorities, or that they will result in marketable products. It cannot be excluded that the approval process at regulatory level will involve requirements for increased documentation and thereby increased costs and delays in the projects or even discontinuation of projects. Increased total development costs and development time of a project could result in an increased project risk and reduce the product's potential to successfully reach the commercial stage or reduce the time from product launch to patent expiry.

There may be a need to turn to the capital market for additional funding in the future. Both the size and the timing of the company's potential future capital requirements are dependent on a number of factors, including opportunities to enter into collaboration or licensing agreements and the progress made in research and development projects undertaken. There is a risk that the required funding of the operations will not be available when needed or at a reasonable cost.

### Accounting and valuation principles

This interim report has been prepared in accordance with International Accounting Standards (IAS) 34 for interim reports and International Financial Reporting Standards IFRS as adopted by the EU. The accounting and valuation principles applied are unchanged compared to those applied in 2013.

For the parent company this interim report has been prepared in accordance with the Swedish Annual Accounts Act and compliance with RFR 2 Accounting for legal entities. The accounting principles applied for the parent company differ from those applied for the Group only regarding accounting of leasing agreements.

Amounts are expressed in KSEK, an abbreviation for thousands of Swedish Kronor, unless otherwise indicated. MSEK is an abbreviation for millions of Swedish Kronor. Amounts or figures in parentheses

indicate comparative figures for the corresponding period last year.

### **Scheduled releases of financial information**

Interim report January-September 2014	October 29, 2014
Year-end report 2014	February 13, 2015

Financial reports, press releases and other financial information are available on Karo Bio's web site [www.karobio.com](http://www.karobio.com). It is also possible to download and subscribe to Karo Bio's financial reports and press releases on the web site.

### **Legal disclaimer**

This financial report includes statements that are forward looking and actual future results may differ materially from those stated. In addition to the factors discussed, among other factors that may affect results are development within research programs, including development in preclinical and clinical trials, the impact of competing research programs, the effect of economic conditions, the effectiveness of the Company's intellectual property rights and preclusions of potential third party's intellectual property rights, technological development, exchange rate and interest rate fluctuations, and political risks.

### **Auditor's review**

This interim report has not been subject to review by Karo Bio's auditors.

Huddinge, July 11, 2014

Per Bengtsson  
CEO