

## INTERIM REPORT JANUARY-SEPTEMBER 2014

### The January–September period and the third quarter 2014 in brief

- Net sales amounted to MSEK 22.0 (37.4), whereof the third quarter amounted MSEK 8.8 (21.2)
- Net loss for the group was MSEK 37.5 (18.7), whereof the third quarter MSEK 9.9 (net profit 6.5)
- Loss per share was SEK 0.06 (0.04), whereof the third quarter SEK 0.01 (EPS 0.01)
- Cash flow from operating activities was MSEK -35.7 (-25.5), whereof the third quarter MSEK -9.4 (-1.4)
- Cash and cash equivalents and other short-term investments totaled MSEK 62.3 (32.1) at the end of the period
- GLP toxicity studies commenced in the ERbeta cancer project
- In ERbeta MS, preclinical studies for the selection of a drug candidate financed by MS Society were completed with positive outcome

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

- At the end of the fourth quarter, the research collaboration on RORgamma will according to plan enter a new phase in which Pfizer will carry out continued development efforts on its own. Consequently, Karo Bio plans to adjust its organization.

#### 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 51 999 358. Questions may be submitted over the internet or by telephone.

#### For further information, please contact

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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 October 29, 2014 at 8.30 a.m. CET.

## Summary of key financial data

(MSEK)	July-September		January-September		January-December
	2014	2013	2014	2013	2013
Net sales	8.8	21.2	22.0	37.4	47.0
Operating expenses	-18.8	-14.7	-59.6	-56.2	-69.3
- of which R&D expenses	-14.4	-9.8	-44.4	-40.7	-52.5
Net profit/loss for the period	-9.9	6.5	-37.5	-18.7	-22.1
Earnings/Loss per share (SEK)	-0.01	0.01	-0.06	-0.04	-0.04
Cash flow from operating activities	-9.4	-1.4	-35.7	-25.5	-33.4
<b>Cash and cash equivalents and other short term investments at the period end</b>	<b>62.3</b>	<b>32.1</b>	<b>62.3</b>	<b>32.1</b>	<b>22.8</b>

## About Karo Bio

Karo Bio is a research and development company focused on innovative drugs for important medical needs. The world-leading knowledge of nuclear receptors as target proteins for the development of pharmaceuticals and their related mechanisms of action, are utilized for developing novel, more effective and safer pharmaceuticals.

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 39 employees and is listed on NASDAQ OMX Stockholm.



## CEO COMMENTARY

In our three main projects, activities have reached key stages in several respects. The collaboration with Pfizer in the RORgamma project is entering a new phase at year-end in which Pfizer will carry out the development work on its own. Work is proceeding on a broad front within Pfizer and payments to Karo Bio will be triggered when the project reaches specific milestones. Since Pfizer's need for our research resources diminishes considerably going forward, Karo Bio plans to implement an adjustment of its organization.

In the project ERbeta cancer, we currently perform GLP toxicity studies and some other activities that are part of the final stage of preclinical development. So far it looks good and when all results are available, we are in a position to inform about the

project status.

In the fall, we have intensified our efforts in our ER-beta MS project to find a partner. We are talking with several of the leading MS companies that want to develop new forms of MS therapy to meet the large needs that are not fulfilled by the anti-inflammatory drugs that are currently the only available option on the market. We continue to maintain a dialogue with interested companies and await certain requested and supplementing results which illustrate the balance between efficacy and risk in the project.

Summing-up, we have an interesting portfolio of early projects. We now direct the company towards projects in a more advanced phase, closer to the market.

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 2014.

Karo Bio has been granted a total of MSEK 4.8 from Vinnova for the continued preclinical development of the project. The funds, paid out in stages, are to finance toxicological and safety pharmacological studies. The studies are intended to finalize preclinical documentation in order to enable 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 MUS\$ 0.5. The funding has enabled the selection of a drug candidate during the third quarter 2014.

In the third quarter, qualified discussions have been held with several companies about a potential licensing agreement.

### 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 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, and are prioritized according to assessed interest among various pharmaceutical companies. 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.

## FINANCIAL REPORT

### Consolidated earnings

Net sales for the nine month period were MSEK 22.0 (37.4), whereof the third quarter MSEK 8.8 (21.2). The difference is mainly explained by accrued prepayments from Pfizer in 2011 of MSEK 7.5 and a milestone of MUSD 2.0 received in September 2013, in the comparative nine-month figure.

Operating expenses for the first nine months was MSEK 59.6 (56.2). Research and development expenses accounted for 74 per cent of the costs for the period amounting to MSEK 44.4 (40.7), whereof the third quarter MSEK 14.4 (9.8). Administrative expenses for the nine month period were MSEK 15.3 (15.3), whereof the third quarter MSEK 4.3 (4.3).

The consolidated operating loss for the nine month period increased to MSEK 37.6 (18.9), whereof the third quarter MSEK 9.9 (net profit 6.5). This is an improvement of approximately MSEK 2 adjusted for the milestone and accrued prepayment included in the first nine months 2013.

Financial net for the nine month period amounted to MSEK 0.1 (0.1). Net loss for the period amounted to MSEK 37.5 (18.7), whereof the third quarter MSEK 9.9 (net profit 6.5).

### Capital investments and consolidated cash flow

Capital investments for the nine month period amounted to MSEK 1.4 (0.7) and comprised mainly of investments in laboratory and IT equipment.

Cash flow from operating activities for the nine month period amounted to MSEK -35.7 (-25.5), whereof the third quarter MSEK -9.4 (-1.4). Adjusted for the milestone of MUSD 2 received in September 2013, cash flow improved approx MSEK 3 compared with the same period last year.

### Financial position

Consolidated cash and cash equivalents amounted to MSEK 62.3 (32.1) at the end of the period. Including other short-term investments with durations exceeding 90 days, liquid assets amounted to MSEK 62.3 (32.1), which corresponds to a change in total cash position and other short-term investments of MSEK 39.5 (-22.0) in the year. Net proceeds from the equity issues completed in April amounted to MSEK 76.4.

Total shareholders' equity amounted to MSEK 62.7 (27.2) 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 0.06 (0.04). The Group's equity ratio at the end of the period was 80.4

(58.8) per cent and equity per share, based on fully diluted number of shares at the end of the period, was SEK 0.09 (0.05).

## Employees

At the end of the period, Karo Bio had 39 (39) employees, of whom 33 (34) are engaged in research and development, 2 (1) in business development and intellectual property rights and 4 (4) in administrative roles.

## CONSOLIDATED INCOME STATEMENT SUMMARY (KSEK)

	July-September		January-September		January-December
	2014	2013	2014	2013	2013
Net sales	8,813	21,168	21,998	37,377	47,029
<b>Operating expenses</b>					
Administration	-4,292	-4,329	-15,321	-15,330	-20,434
Research and development	-14,382	-9,802	-44,411	-40,697	-52,529
Other operating income/expenses	-83	-530	101	-207	3,676
	-18,757	-14,661	-59,631	-56,234	-69,287
<b>Operating profit/loss</b>	<b>-9,944</b>	<b>6,507</b>	<b>-37,633</b>	<b>-18,857</b>	<b>-22,258</b>
Financial net	34	12	130	125	180
<b>Earnings after financial items</b>	<b>-9,910</b>	<b>6,519</b>	<b>-37,503</b>	<b>-18,732</b>	<b>-22,078</b>
Tax	-	-	-	-	-
<b>NET EARNINGS FOR THE PERIOD</b>	<b>-9,910</b>	<b>6,519</b>	<b>-37,503</b>	<b>-18,732</b>	<b>-22,078</b>
<b>Net earnings for the period attributable to:</b>					
Shareholders of the parent company	-9,910	6,519	-37,503	-18,732	-22,078
Depreciation included in operating expenses	-471	-345	-1,400	-1,016	-1,434
<b>Earnings per share (SEK) <sup>1)</sup></b>	<b>-0.01</b>	<b>0.01</b>	<b>-0.06</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)

	July-September		January-September		January-December
	2014	2013	2014	2013	2013
<b>NET EARNINGS FOR THE PERIOD</b>	<b>-9,910</b>	<b>6,519</b>	<b>-37,503</b>	<b>-18,732</b>	<b>-22,078</b>
Other comprehensive income for the year, net of tax	-	-	-	-	-
<b>TOTAL COMPREHENSIVE INCOME FOR THE PERIOD</b>	<b>-9,910</b>	<b>6,519</b>	<b>-37,503</b>	<b>-18,732</b>	<b>-22,078</b>
Total comprehensive income attributable to:					
<b>Shareholders of the parent company</b>	<b>-9,910</b>	<b>6,519</b>	<b>-37,503</b>	<b>-18,732</b>	<b>-22,078</b>

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION (KSEK)

	September 30		December 31
	2014	2013	2013
<b>Assets</b>			
Equipment	4,517	3,476	4,500
Other current assets	11,136	10,670	12,992
Cash and cash equivalents	62,303	32,119	22,799
<b>TOTAL ASSETS</b>	<b>77,956</b>	<b>46,265</b>	<b>40,291</b>
<b>Shareholders' equity and liabilities</b>			
Shareholders' equity	62,686	27,185	23,839
Current liabilities	15,270	19,080	16,452
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>	<b>77,956</b>	<b>46,265</b>	<b>40,291</b>

## CONSOLIDATED STATEMENT OF CASH FLOWS (KSEK)

	July-September		January-September		January-December
	2014	2013	2014	2013	2013
<b>Operating activities</b>					
Operating income/loss before financial items	-9,944	6,507	-37,633	-18,857	-22,258
Depreciation	471	345	1,400	1,016	1,434
Other items not affecting cash flows	-	-	7	-	-
	<b>-9,473</b>	<b>6,852</b>	<b>-36,226</b>	<b>-17,841</b>	<b>-20,824</b>
Financial items received and paid	-3	-4	-1	31	133
<b>Cash flow from operating activities before changes in working capital</b>	<b>-9,476</b>	<b>6,848</b>	<b>-36,227</b>	<b>-17,810</b>	<b>-20,691</b>
Changes in working capital	96	-8,201	565	-7,719	-12,698
<b>Cash flow from operating activities</b>	<b>-9,380</b>	<b>-1,353</b>	<b>-35,662</b>	<b>-25,529</b>	<b>-33,389</b>
<b>Investing activities</b>					
Net investment in equipment	-118	-302	-1,471	-785	-2,245
Net investment in other short-term investments	-	10,000	-	26,096	26,096
<b>Cash flow from investing activities</b>	<b>-118</b>	<b>9,698</b>	<b>-1,471</b>	<b>25,311</b>	<b>23,851</b>
<b>Financing activities</b>					
Net proceeds from rights issue	-	-	84,748	7,665	7,665
Transaction costs rights issue <sup>1)</sup>	-128	-	-8,111	-3,352	-3,352
<b>Cash flow from financing activities</b>	<b>-128</b>	<b>-</b>	<b>76,637</b>	<b>4,313</b>	<b>4,313</b>
<b>Cash flow for the period</b>	<b>-9,626</b>	<b>8,345</b>	<b>39,504</b>	<b>4,095</b>	<b>-5,225</b>
Cash and cash equivalents at the beginning of the period	71,929	23,774	22,799	28,024	28,024
<b>Cash and cash equivalents at the end of the period</b>	<b>62,303</b>	<b>32,119</b>	<b>62,303</b>	<b>32,119</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	-	-	-18,732	-18,732
Current rights issue	2,178	-2,178	-	0
<b>Amount at September 30, 2013</b>	<b>9,919</b>	<b>1,006,818</b>	<b>-989,552</b>	<b>27,185</b>
Amount at January 1, 2014	9,919	1,006,818	-992,898	23,839
Loss for the period	-	-	-37,503	-37,503
Current rights issue	3,606	72,744	-	76,350
<b>Amount at September 30, 2014</b>	<b>13,525</b>	<b>1,079,562</b>	<b>-1,030,401</b>	<b>62,686</b>

## KEY EQUITY DATA

	September 30		December 31
	2014	2013	2013
Equity ratio	80.4%	58.8%	59.2%
Equity per share at the end of period - basic, SEK	0.09	0.05	0.05
<b>Equity per share at the end of period - diluted, SEK</b>	<b>0.09</b>	<b>0.05</b>	<b>0.05</b>



## The Parent Company

Net sales for the Parent Company for the nine month period amounted to MSEK 22.0 (37.4), whereof the third quarter MSEK 8.8 (21.2). Loss after financial items for the parent company was MSEK 37.5 (18.7), whereof the third quarter MSEK 9.9 (net profit 6.5).

The Parent Company's capital investments in equipment for the nine month period amounted to MSEK 1.4 (0.7). Cash, cash equivalents and other short term investments for the parent company amounted to MSEK 62.2 (32.1) at the end of the period.

### PARENT COMPANY INCOME STATEMENT SUMMARY (KSEK)

	July-September		January-September		January-December
	2014	2013	2014	2013	2013
Net sales	8,813	21,168	21,998	37,377	47,029
<b>Operating expenses</b>					
Administration	-4,367	-4,329	-15,396	-15,330	-20,434
Research and development	-14,381	-9,801	-44,425	-40,715	-52,547
Other operating income/expenses	-83	-530	101	-207	117
	-18,831	-14,660	-59,720	-56,252	-72,864
<b>Operating income/loss</b>	<b>-10,018</b>	<b>6,508</b>	<b>-37,722</b>	<b>-18,875</b>	<b>-25,835</b>
Financial net	74	16	175	137	3,751
<b>Earnings after financial items</b>	<b>-9,944</b>	<b>6,524</b>	<b>-37,547</b>	<b>-18,738</b>	<b>-22,084</b>
Tax	-	-	-	-	-
<b>NET EARNINGS FOR THE PERIOD</b>	<b>-9,944</b>	<b>6,524</b>	<b>-37,547</b>	<b>-18,738</b>	<b>-22,084</b>
<b>Depreciation included in operating expenses</b>	<b>-457</b>	<b>-325</b>	<b>-1,351</b>	<b>-956</b>	<b>-1,353</b>

### PARENT COMPANY BALANCE SHEET SUMMARY (KSEK)

	September 30		December 31
	2014	2013	2013
<b>Assets</b>			
Equipment	4,374	3,272	4,316
Shares in group companies	150	150	150
Other current assets	11,013	10,670	12,861
Cash and cash equivalents	62,243	32,059	22,619
<b>TOTAL ASSETS</b>	<b>77,780</b>	<b>46,151</b>	<b>39,946</b>
<b>Shareholders' equity and liabilities</b>			
Total restricted equity	13,525	9,919	9,919
Total non-restricted equity	49,126	17,275	13,929
Current liabilities	15,129	18,957	16,098
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>	<b>77,780</b>	<b>46,151</b>	<b>39,946</b>

## OTHER INFORMATION

### Annual General Meeting 2015

Karo Bio's Annual General Meeting will be held in Huddinge, Sweden on April 29, 2015.

### Nominating Committee

According to the principles established by the Annual General Meeting for appointment of Nominating Committee, the individuals below have been assigned to comprise the Nominating Committee for the 2015 Annual General Meeting.

- Anders Lönner
- Leif Edlund
- Per-Anders Johansson
- Johan Paulsson
- Göran Wessman

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

During the fourth quarter, Karo Bio will finalize its activities within the research collaboration with Pfizer. Consequently, Karo Bio plans to implement an adjustment of the organization.

### Continued operations

Karo Bio assesses its liquid assets to cover continued operations for twelve months, even if no new cooperation agreements are entered into or other source of funding obtained. Furthermore, the company believes that there are opportunities for additional revenue in coming four 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

Year-end report 2014	February 13, 2015
Annual Report 2014	March 2015
Annual General Meeting	April 29, 2015
Interim Report January-March 2015	April 29, 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.

October 29, 2014

Per Bengtsson  
CEO

## Report of review of Interim Financial Information

### **Report of Review of Interim Financial Information prepared in accordance with IAS 34 and chapter 9 of the Annual Accounts Act**

#### **Introduction**

We have reviewed this report for the period 1 January 2014 to 30 September 2014 for Karo Bio AB (publ). The board of directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

#### **Scope of Review**

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

#### **Conclusion**

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Annual Accounts Act, regarding the Group, and with the Annual Accounts Act, regarding the Parent Company.

Stockholm, 29 October 2014

PricewaterhouseCoopers AB

Håkan Malmström

Authorised Public Accountant