# KARO**₿**BIO

# YEAR-END REPORT 2014

# The full year 2014 and the fourth quarter in brief

- Net sales amounted to MSEK 30.1 (47.0), whereof the fourth quarter MSEK 8.1 (9.7)
- Net loss for the group was MSEK 59.3 (22.1), whereof the fourth quarter MSEK 21.8 (3.3)
- Loss per share was SEK 0.09 (0.04), whereof the fourth quarter SEK 0.03 (0.01)
- Cash flow from operating activities was MSEK -46.3 (-33.4), whereof the fourth quarter MSEK -10.7 (-7.9)
- Cash and cash equivalents and other short-term investments totaled MSEK 51.6 (22.8) at the end of the period
- The marketing company Karo Pharma was established during the fourth quarter
- Continued investment in the ERbeta cancer project for advancement towards the clinic
- Pfizer has taken over development of the RORgamma project, which means that the project has taken a step further into a new phase

# Significant events after the end of the reporting period

• On February 4, Anders Lönner was appointed Executive Chairman of the Board and Maria Sjöberg CEO after Per Bengtsson

# Conference call / audiocast today at 11.00 a.m. CET

A presentation of the report (in Swedish) will take place today 11.00 a.m. The presentation and slides are available through the corporate website <a href="http://www.karobio.se/">http://www.karobio.se/</a> or by telephone +468 566 426 94. 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 February 13, 2015 at 8.30 a.m. CET.

#### Summary of key financial data

(MSEK)	October-December		January -December	
	2014	2013	2014	2013
Net sales	8.1	9.7	30.1	47.0
Operating expenses	-29.9	-13.1	-89.5	-69.3
- of which R&D expenses	-24.2	-11.8	-68.6	-52.5
Net earnings for the period	-21.8	-3.3	-59.3	-22.1
Earnings per share (SEK)	-0.03	-0.01	-0.09	-0.04
Cash flow from operating activities	-10.7	-7.9	-46.3	-33.4
Cash and cash equivalents and other short term investments at the period end	51.6	22.8	51.6	22.8

# 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. In addition to the qualifications that Karo Bio has built up in nuclear receptors, the company has an ambition to broaden the scope of activities with projects and products that are closer to market.

Karo Bio is based in Huddinge, Sweden. The company has 24 (39) employees and is listed on NASDAQ OMX Stockholm.

# COMMENTARY

Development of Karo Bio's three main projects are advancing, while efforts continue to find and evaluate new activities and projects closer to market. In practice, this means that Karo Bio is under transformation in order to create long-term profitable operations.

Since the start of the year according to plan, Pfizer carries out all development work in the RORgamma project on its own, which means that the project has taken a step further into a new phase. Consequently, Karo Bio has as previously announced, adapted its organization. Together with other implemented savings in 2014, costs have been reduced by about 25 MSEK annually.

Karo Bio remains entitled to compensation when Pfizer reaches certain milestones in the RORgamma project.

In the ERbeta cancer project, GLP toxicology studies and other activities that fall into the latter phase of the preclinical development work are being finalized. Thereafter, further preparatory work is required before it is possible to make a decision to initiate the clinical development phase.

In the ERbeta MS project, a drug candidate was selected in the third quarter. During fall, active discussions took place with potential partners for the ERbeta MS project. In order to provide a clearer picture of the drug candidate's properties, work is being carried out to verify some results more thoroughly. Moreover, the possibility of finding a partner is affected by how other companies succeed in their ongoing testing of new potential therapies that do not act by counteracting inflammation. Our focus to seek external funding for ERbeta project remains.

At the end of the year, the marketing company Karo Pharma was established. The company will be expanded gradually as new products are procured.

In early February, the Board decided to appoint Anders Lönner Executive Chairman of the Board, focusing on developing Karo Bio's business operations and to broaden the company's product portfolio with projects and products that are closer to market.

On February 4, the CEO Per Bengtsson left his position and Maria Sjöberg, current research director, was appointed CEO of Karo Bio with responsibility for R & D activities.

# **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's program Forska & Väx 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). The project represents a new treatment principle for the disease, something that is highly demanded, but also places high requirements on documenting how the principle works and how it can be influenced.

In preclinical models, ERbeta agonists have demonstrated protective and reparative effects on the myelin sheaths that surround nerve cells, and that are essential for efficient conduction of nerve signals. 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, since damaged myelin is involved in symptoms and disability. ERbeta agonists seem to slow down or even reverse the disease progression and may be used to treat progressive forms of MS. They may also have positive effect on certain symptoms associated with MS such as cognition, sleep and depression. Proof-of-concept has been achieved in an animal model. Key opinion leaders in the MS field have expressed 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 funding has enabled the selection of a drug candidate during the third quarter 2014. Qualified discussions are underway 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 future sales.

After having extended the research collaboration for one year, Pfizer took over all development work on its own at the start of 2015.

#### **Innovation projects**

Karo Bio is also active in explorative innovation projects on certain receptors in order to create ideas for radical innovations. Such projects are often derived from innovative smaller companies or academic research. These projects are prioritized according to the extent to which their indication areas fit into Karo Bio's field of expertise. Strong focus will be on identifying and developing pharmaceutical projects involving radically new therapeutic principles at as low risk as possible.

# FINANCIAL REPORT

# **Consolidated earnings**

Net sales for 2014 were MSEK 30.1 (47.0), whereof the fourth quarter MSEK 8.1 (9.7). The difference is mainly explained by accrued prepayments from Pfizer in 2011 of MSEK 10.0 and a milestone of MUSD 2.0 received in September 2013, in the comparative full year figure.

Operating expenses for the year was MSEK 89.5 (69.3), whereof the fourth quarter MSEK 29.9 (13.1). Research and development expenses accounted for 77 per cent of full year costs amounting to MSEK 68.6 (52.5), whereof the fourth quarter MSEK 24.2 (11.8). The increase in expenses was primarily attributable to provisions for employee layoffs and advancement primarily of the cancer project, which together represented an increase of MSEK 21 compared with 2013. Administrative expenses for the year were MSEK 21.0 (20.4), whereof the fourth quarter MSEK 5.7 (5.1).

The consolidated operating loss for 2014 increased to MSEK 59.5 (22.3), whereof the fourth quarter MSEK 21.8 (3.4). This is in line with the loss in 2013 adjusted for the milestone and accrued prepayment included in 2013. In the fourth quarter 2013, an acquisition contributed to decrease the operating loss with MSEK 3.6.

Financial net for the year amounted to MSEK 0.2 (0.2). Net loss for the period amounted to MSEK 59.3 (22.1), whereof the fourth quarter MSEK 21.8 (3.3).

# Capital investments and consolidated cash flow

Capital investments for the year amounted to MSEK 1.4 (2.2) and comprised mainly of investments in laboratory and IT equipment.

Cash flow from operating activities for year amounted to MSEK -46.3 (-33.4), whereof the fourth quarter MSEK -10.7 (-7.9). Adjusted for the milestone of MUSD 2 received in September 2013 and the acquisition made in the fourth quarter 2013, cash flow improved approx. MSEK 4 compared with the same period last year.

# **Financial position**

Consolidated cash and cash equivalents amounted to MSEK 51.6 (22.8) at the end of the period. Net proceeds from the equity issues completed in April amounted to MSEK 76.4.

Total shareholders' equity amounted to MSEK 40.9 (23.8) taking into account the period's loss. In total, there were 676,263,158 shares outstanding, each with a par value of SEK 0.02.

Loss per share amounted to SEK 0.09 (0.04). The Group's equity ratio at the end of the period was 67.5 (59.2) percent and equity per share, based on fully diluted number of shares at the end of the period, was SEK 0.06 (0.04).

	Octobe	r-December	January -De	cember
	2014	2013	2014	2013
Net sales	8,062	9,652	30,060	47,029
Operating expenses				
Administration	-5,693	-5,104	-21,014	-20,434
Research and development	-24,182	-11,832	-68,593	-52,529
Other operating income/expenses	-9	3,883	92	3,676
	-29,884	-13,053	-89,515	-69,287
Operating profit/loss	-21,822	-3,401	-59,455	-22,258
Financial net	43	55	173	180
Earnings after financial items	-21,779	-3,346	-59,282	-22,078
Tax	-	-	-	
NET EARNINGS FOR THE PERIOD	-21,779	-3,346	-59,282	-22,078
Net earnings for the period attributable to:				
Shareholders of the parent company	-21,779	-3,346	-59,282	-22,078
Depreciation included in operating expenses	-467	-418	-1,867	-1,434
Earnings per share (SEK) $^{\nu}$	-0.03	-0.01	-0.09	-0.04
Number of shares outstanding (000)	676,263	583,185	676,263	583,185

## CONSOLIDATED INCOME STATEMENT SUMMARY (KSEK)

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (KSEK)

	October-December		January -December	
	2014	2013	2014	2013
NET EARNINGS FOR THE PERIOD	-21,779	-3,346	-59,282	-22,078
Other comprehensive income for the year, net of tax	-	-	-	-
TOTAL COMPREHENSIVE INCOME FOR THE PERIOD	-21,779	-3,346	-59,282	-22,078
Total comprehensive income attributable to:				
Shareholders of the parent company	-21,779	-3,346	-59,282	-22,078

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION (KSEK)

	December 31	
	2014	2013
Assets		
Equipment	4,050	4,500
Other financial assets	14	-
Other current assets	4,948	12,992
Cash and cash equivalents	51,609	22,799
TOTAL ASSETS	60,621	40,291
Shareholders' equity and liabilities		
Shareholders' equity	40,907	23,839
Current liabilities	19,714	16,452
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES	60,621	40,291

### CONSOLIDATED STATEMENT OF CASH FLOWS (KSEK)

	October-	December	January -D	ecember
	2014	2013	2014	2013
Operating activities				
Operating income/loss before financial items	-21,822	-3,401	-59,455	-22,258
Depreciation	467	418	1,867	1,434
Other items not affecting liquid assets	18	-	25	-
	-21,337	-2,983	-57,563	-20,824
Financial items received and paid	172	102	171	133
Cash flow from operating activities before changes in working capital	-21,165	-2,881	-57,392	-20,691
Changes in working capital	10,497	-4,979	11,062	-12,698
Cash flow from operating activities	-10,668	-7,860	-46,330	-33,389
Investing activities				
Net investment in other financial items	-14	-	-14	-
Net investment in equipment	-12	-1,460	-1,483	-2,245
Net investment in other short-term investments	-	-	-	26,096
Cash flow from investing activities	-26	-1,460	-1,497	23,851
Financing activities				
Net proceeds from rights issue	-	-	84,748	7,665
Transaction costs rights issue $^{11}$	-	-	-8,111	-3,352
Cash flow from financing activities	-	-	76,637	4,313
Cash flow for the period	-10,694	-9,320	28,810	-5,225
Cash and cash equivalents at the beginning of the period	62,303	32,119	22,799	28,024
Cash and cash equivalents at the end of the period	51,609	22,799	51,609	22,799

1) Comprises the portion of transaction related costs that has 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	-	-	-22,078	-22,078
Current rights issue	2,178	-2,178	-	0
Amount at December 31, 2013	9,919	1,006,818	-992,898	23,839
Amount at January 1, 2014	9,919	1,006,818	-992,898	23,839
Loss for the period	-	-	-59,282	-59,282
Current rights issue	3,606	72,744	-	76,350
Amount at December 31, 2014	13,525	1,079,562	-1,052,180	40,907

# **KEY EQUITY DATA**

	December 31	
	2014	2013
Equity ratio	67.5%	59.2%
Equity per share at the end of period - basic, SEK	0.06	0.04
Equity per share at the end of period - diluted,		
SEK	0.06	0.04

#### **The Parent Company**

Net sales for the Parent Company for the year amounted to MSEK 30.1 (47.0), whereof the fourth quarter MSEK 8.1 (9.7). Loss after financial items for the parent company for the year was MSEK 59.3 (22.1), whereof the fourth quarter MSEK 21.7 (3.3).

The Parent Company's capital investments in equipment for the year amounted to MSEK 1.4 (2.2). Cash, cash equivalents and other short-term investments for the parent company amounted to MSEK 51.5 (22.6) at the end of the period.

## PARENT COMPANY INCOME STATEMENT SUMMARY (KSEK)

	October-December		January -December	
	2014	2013	2014	2013
Net sales	8,062	9,652	30,060	47,029
Operating expenses				
Administration	-5,692	-5,104	-21,088	-20,434
Research and development	-24,182	-11,832	-68,607	-52,547
Other operating income/expenses	-9	324	92	117
	-29,883	-16,612	-89,603	-72,864
Operating income/loss	-21,821	-6,960	-59,543	-25,835
Financial net	87	3,614	262	3,751
Earnings after financial items	-21,734	-3,346	-59,281	-22,084
Tax			-	-
NET EARNINGS FOR THE PERIOD	-21,734	-3,346	-59,281	-22,084
Depreciation included in operating expenses	-453	-397	-1,804	-1,353

PARENT COMPANY BALANCE SHEET SUM	MARY (KSEK)	
	December	r 31
	2014	2013
Assets		
Equipment	3,921	4,316
Other financial assets	14	-
Shares in group companies	150	150
Other current assets	4,867	12,861
Cash and cash equivalents	51,549	22,619
TOTAL ASSETS	60,501	39,946
Shareholders' equity and liabilities		
Total restricted equity	13,525	9,919
Total non-restricted equity	27,392	13,929
Current liabilities	19,584	16,098
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES	60,501	39,946

# **OTHER INFORMATION**

# **Annual General Meeting 2015**

Karo Bio's Annual General Meeting will be held in Huddinge, Sweden on April 29, 2015. Information on how proposals to the Nomination Committee and Annual General Meeting may be submitted and how to give notice to attend the Meeting will be posted on the website www.karobio.com.

# **Annual Report**

Karo Bio's Annual Report for 2014 will be disclosed in week 15 2015. Karo Bio has decided, for both environmental and cost reasons, to primarily distribute the Annual Report on the company website. The printed version of the Annual Report will be available for order i.e. on the Company website.

# **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

Shareholders may submit proposals to the Nominating Committee on the following address: Nominating Committee, Karo Bio AB, Novum, 141 57 Huddinge, Sweden.

# Significant events after the end of the reporting period

February 4, Anders Lönner was appointed Executive Chairman of the Board and Maria Sjöberg was appointed CEO after Per Bengtsson.

# Dividend

In accordance with the dividend policy, the Board will propose to the AGM that there will be no dividend for the 2014 financial year.

# **Going concern**

The Company believes that there is potential for continued operation for 12 months from the closing date. Without additional funding or revenue, existing cash resources are expected to finance the current scope of operations until the end of the fourth quarter of 2015. Under the same conditions, equity may fall short of 50 percent of the registered share capital at the beginning of the fourth quarter of 2015.

The Company believes that there are opportunities for additional revenue in the coming quarters. Should this not occur, be displaced or limited in size, operations will need additional capital at the beginning of the fourth quarter 2015.

# **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

Annual Report 2014	Week 15, 2015
Annual General Meeting	April 29, 2015
Interim Report January-March 2015	April 29, 2015
Interim Report January-June 2015	July 10, 2015
Interim Report January-September 2015	October 29, 2015
Year-End Report 2015	February 12, 2016

Financial reports, press releases and other financial information are available on Karo Bio's web site 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 year-end report has not been subject to review by Karo Bio's auditors.

February 13, 2015

Maria Sjöberg <sub>CEO</sub>