# KARO**₿**BIO

Press release October 23rd, 2008

# **INTERIM REPORT JANUARY-SEPTEMBER 2008**

# The period in brief

- Net sales for the nine month period amounted to MSEK 8.9 (5.7)
- Net loss for the nine month period amounted to MSEK 143.6 (148.8)
- Loss per share for the nine month period amounted to SEK 1.24 (1.45)
- Cash flow from operating activities for the nine month period amounted to MSEK -138.3 (-139.2). Cash and cash equivalents and other short-term investments totaled MSEK 286.7 (471.4) at the end of the period
- In the third quarter a phase IIb study with eprotirome as add-on to statin treatment has been successfully concluded. Data show that eprotirome was efficacious, safe and well tolerated
- In August, Karo Bio announced that the collaboration with Wyeth Pharmaceuticals was prolonged for an additional year until August 31, 2009
- A phase IIb study with eprotirome as add-on to the cholesterol-lowering drug ezetimibe has been concluded. Top-line data will be presented by the end of October

# Significant events after the end of the reporting period

• A multiple dose study in healthy volunteers with the type 2 diabetes compound KB3305 has been initiated

## For further information, please contact:

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# Selected financial information in summary

(MSEK)	July-September		January-Se	eptember	January-December	
	2008	2007	2008	2007	2007	
Net sales	1.7	1.9	8.9	5.7	7.5	
Operating expenses	-46.9	-36.6	-163.5	-162.4	-223.4	
- whereof of R&D expenses	-41.2	-30.6	-138.0	-137.3	-190.8	
Profit/loss for the period	-41.8	-30.6	-143.6	-148.8	-203.4	
Profit/loss per share (SEK)	-0.36	-0.26	-1.24	-1.45	-1.92	
Cash flow from operating activities	-32.6	-48.3	-138.3	-139.2	-178.3	
Cash and cash equivalents and other short term investments at end of period	286.7	471.4	286.7	471.4	432.3	
Equity ratio (%)	81.7	91.1	81.7	91.1	86.9	
Numbers of shares outstanding ('000)						
- weighted average during the period	116,119	116,119	116,119	102,490	105,897	
- at the end of the period, basic	116,119	116,119	116,119	116,119	116,119	
- at the end of the period, fully diluted	116,594	117,315	116,594	117,315	117,315	

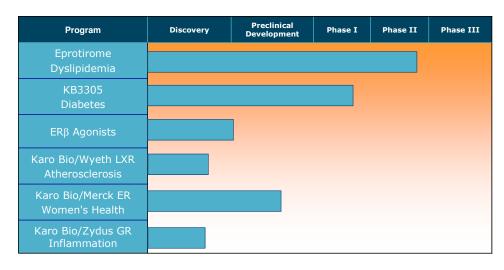
# **About Karo Bio**

Karo Bio is a drug discovery and development company specializing in nuclear receptors for the development of novel pharmaceuticals.

The company has a project portfolio with innovative molecules that primarily target metabolic diseases such as diabetes, atherosclerosis and dyslipidemia. In all of these areas there are significant market opportunities and a need for pharmaceuticals with new mechanisms of action. Karo Bio intends to bring selected compounds within niche therapeutic areas into late stage clinical development and, potentially, to the market. In addition to pursuing niche opportunities, Karo Bio continues to develop compounds aimed at treatment of broad patient populations to clinical proof of concept before out-licensing.

In addition to the proprietary projects, Karo Bio has three strategic collaborations with international pharmaceutical companies for development of innovative therapies for the treatment of common diseases.

Karo Bio is listed on the OMX Nordic Exchange Stockholm since 1998 (Reuters: KARO.ST).



# **Project portfolio**

# CEO'S COMMENTS ON THE FIRST NINE MONTHS OF 2008

# Eprotirome is delivering good data

Eprotirome moves forward in development according to plan and with excellent results. In August we announced that eprotirome is efficacious and safe when given as add-on to statin treatment. The results show that eprotirome has an advantageous product profile, indicating a great market potential. Scientific data from this study are expected to be published in a prestigious scientific journal.

Recently we finalized a study where eprotirome was given as add-on to patients treated with the cholesterol absorption inhibitor ezetimibe. Top line data from this study will be presented during October this year.

Karo Bio has been invited to present at the BIO Investor Forum in San Francisco in late October and at the Windhover partnering conference in Philadelphia in early November. These presentations will expose the company to new investor groups and potential partners.

Our strategy is to bring eprotirome into phase III clinical trials with a partner. Discussions with potential partners are progressing.

# KB3305 is making progress in clinical development

KB3305, for treatment of type 2 diabetes, is our second compound in clinical development. In the first clinical phase I single ascending dose study we could show that KB3305 exhibited robust and predictable pharmacokinetics and was well tolerated. A multiple dose study in healthy volunteers is progressing and we expect to report the results later this year. Given that these results are positive, Karo Bio plans for a small multiple dose study in diabetes patients.

# Partnership events and progress in exploratory research

During the third quarter, we have announced yet another extension of the collaboration with Wyeth Pharmaceuticals, with the liver X receptor as a pharmaceutical target. The clinical indication for this collaboration is atherosclerosis but other clinical opportunities are being evaluated.

It is still early days in our collaboration with Zydus Cadila, which was initiated in February of this year, but the ambitions are high and we have come off to a good start. We have specific and clear objectives and both parties are committed to success.

Per Olof Wallström President and CEO

# SIGNIFICANT EVENTS AFTER THE END OF THE REPORTING PERIOD

In October, a phase I multiple dose study with KB3305 in healthy volunteers was initiated.

# **RESEARCH AND DEVELOPMENT**

#### Eprotirome (KB2115) - dyslipidemia

Karo Bio's compound eprotirome is a novel, liver selective thyroid hormone receptor agonist for treatment of dyslipidemia. In clinical phase II studies, eprotirome has shown a broad and unique efficacy profile with significant and clinically relevant reductions of LDL-cholesterol, triglycerides and lipoprotein(a). Eprotirome has proven safe and well tolerated in studies of up to three months duration. Sensitive markers for the body's thyroid hormone balance were unaffected by the treatment.

Karo Bio has generated pre-clinical data on blood sugar which suggest that eprotirome has potential for treatment of elevated blood lipids in type 2 diabetics.

In the period, Karo Bio finalized a clinical phase IIb, placebo controlled 10 week dose ranging study in 111 patients. Eprotirome was given once daily in addition to the cholesterol absorption inhibitor ezetimibe with the purpose to expand the commercial potential for eprotirome. Top line data will be presented in October this year.

The profile of eprotirome is unique in producing simultaneous and powerful reductions of three independent risk factors for the development of atherosclerotic cardiovascular diseases. This combined effect on LDL-cholesterol, triglycerides and lipoprotein(a) indicates that eprotirome has the potential for being an important new dyslipidemia drug.

A dialogue with the FDA is ongoing with the purpose to prepare initiation of phase III clinical trials. The intention is to initiate the phase III program with a partner.

# KB3305 - type 2 diabetes

KB3305 is a liver selective glucocorticoid antagonist that suppresses increased hepatic glucose production in pre-clinical type 2 diabetes models.

In pre-clinical studies, KB3305 was both efficacious and safe. In addition to glucose lowering, KB3305 also lowers other important risk factors for cardiovascular disease such as cholesterol, triglycerides and free fatty acid levels in plasma.

A first phase I study with promising results has previously been reported. In this study, KB3305 was administered in single ascending doses to healthy volunteers. The compound showed robust and predictable pharmacokinetics and the subjects were well exposed. No serious adverse events were recorded.

In the third quarter, a multiple dose study in healthy volunteers was initiated. On completion of this study, Karo Bio intends to dose the first type 2 diabetes patients in order to get preliminary proof of principle for clinical efficacy in diabetes.

#### ERbeta selective compounds - depression, cancer, inflammation

Significant progress has been made regarding improvement of selectivity and bioavailability of the Karo Bio lead compounds in the ERbeta program. The pre-clinical evaluation of lead compounds is ongoing with the intention to select a candidate drug for CNS disorders. Additional clinical opportunities for selective ERbeta selective ligands are also explored.

# Atherosclerosis - Wyeth Pharmaceuticals

The collaboration with Wyeth Pharmaceuticals, initiated in 2001, is aimed at new treatments of atherosclerosis with the liver X receptor (LXR) as a target. Pre-clinical studies have shown that compounds which stimulate LXR have anti-atherogenic effects. Apart from atherosclerosis other clinical opportunities for LXR ligands are being explored. The collaboration was recently prolonged until August 31, 2009.

# Estrogen Receptors - Merck & Co., Inc.

Estrogen receptors are important targets for several diseases in the field of women's health. The collaboration with Merck was initiated in 1997. The joint drug discovery phase in the collaboration with Merck was concluded in 2002, with Merck responsible for development of selected compounds. A candidate compound is in pre-clinical development.

#### Inflammatory diseases - Zydus Cadila

In February, Karo Bio and Zydus Cadila, one of India's leading healthcare companies, initiated a three year research collaboration with the purpose to discover and develop novel, selective glucocorticoid receptor (GR) modulators for the treatment of inflammatory diseases. Design, synthesis, screening and pre-clinical evaluation of compounds is making good process.

# **RESULT AND FINANCIAL POSITION**

The operations of the Group are mainly conducted in the parent company. The parent company holds only one subsidiary with assets of MSEK 0.1 (0.1), liabilities of MSEK 0.0 (0.0) and shareholders' equity of 0.1 (0.1). The assets held by the subsidiary comprise intra-group receivables. The subsidiary has had no revenue or expenses. The accounting principles applied for the parent company differs from those applied for the Group only regarding accounting of leasing agreements. The Group's accounts correspond, in all material respects, to that of the parent company why this is not separately disclosed.

#### Revenue

Net sales for the nine month period increased to MSEK 8.9 as compared to MSEK 5.7 for the same period last year. The reported net sales for the first nine months consist of research payments from collaborations and a license fee of MSEK 3.7 from a non-exclusive license to specific intellectual property rights granted by Karo Bio to an un-disclosed company.

#### **Expenses**

Operating expenses for the nine month period increased by MSEK 1.1 to MSEK 163.5 (162.4). For the third quarter, reported research and development expenses totaled MSEK 41.2 (30.6), which is an increase of MSEK 10.6. For the nine months period, however, total research and development expenses of MSEK 138.0 (137.3) is in line with last year. Administrative expenses for the first nine months 2008 amounts to MSEK 21.8 (25.8). The cost reduction of MSEK 4.0 is to a large extent an effect of the overall reduction of the company's internal cost base that was initiated in 2007. Other operating income and expenses of MSEK -3.7 mainly comprises costs incurred in strategy related projects.

# **Profit/loss**

Operating loss for the nine month period amounted to MSEK 154.7 (156.7), which is an improvement of MSEK 2.0. Financial net for the nine month period amounted to MSEK 11.1 (7.9). The reported loss for the nine month period decreased with MSEK 5.2 to MSEK 143.6 (148.8).

#### **Capital investments**

Capital investments in equipment for the nine month period amounted to MSEK 4.7 (2.2) and comprise mainly laboratory equipment financed with capital leases.

## **Cash flow**

Cash flow from operating activities for the nine month period amounted to MSEK -138.3 (-139.2).

#### **Financial position**

Cash and cash equivalents amounted to MSEK 110.8 (453.4) at the end of the period. Including other short-term investments with duration exceeding 90 days, these assets amounted to MSEK 286.7 (471.4). At the beginning of the year, cash and cash equivalents including other short-term investments totaled MSEK 432.3, which implies a change in total cash position of MSEK -145.6 during the nine month period. As stipulated in the company's finance policy, Karo Bio's funds are invested solely in low risk, interest bearing assets.

# Shareholders equity and per share data

The share capital at the end of the period amounted to MSEK 58.1. The total number of shares amounted to 116,119,192 shares with a ratio value of SEK 0.50. Total consolidated shareholders' equity amounted to MSEK 250.7 after taking into account the loss for the period.

Loss per share for the nine month period, based on the weighted average number of shares outstanding, amounted to SEK 1.24 (1.45). The Group's equity ratio at the end of the period was 81.7 per cent (91.1) and equity per share, based on fully diluted number of shares at the end of the period, was SEK 2.15 (3.83).

# Organization

At the end of the period, Karo Bio had 65 (74) employees, of which 57 (68) are engaged in research and development.

## **Risk factors**

There is no guarantee that Karo Bio's research and development will result in commercial success.

There is no guarantee 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.

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 may be a need to turn to the capital market 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 possibility of achieving success in research and development projects undertaken.

# CONDENSED CONSOLIDATED INCOME STATEMENTS (KSEK)

	July-September		January-September		January- December
	2008	2007	2008	2007	2007
Net sales	1,657	1,850	8,864	5,723	7,534
Operating expenses					
Administrative expenses	-5,882	-6,207	-21,810	-25,814	-33,320
Research and development expenses	-41,167	-30,581	-138,008	-137,316	-190,754
Other operating income and expenses	187	191	-3,730	750	712
	-46,862	-36,597	-163,548	-162,380	-223,362
Operating profit/loss	-45,205	-34,747	-154,684	-156,657	-215,828
Financial net	3,355	4,156	11,075	7,877	12,393
Profit/loss after financial items	-41,850	-30,591	-143,609	-148,780	-203,435
Tax	-	-	-	-	-
PROFIT/LOSS FOR THE PERIOD	-41,850	-30,591	-143,609	-148,780	-203,435
Depreciation included in operating expenses	-1,124	-1,550	-3,945	-4,006	-5,531
Profit/loss per share (SEK) *) - based on weighted average number of shares outstanding, basic and diluted	-0.36	-0.26	-1.24	-1.45	-1.92
Number of shares outstanding (000)					
- weighted average during the period	116,119	116,119	116,119	102,490	105,897
- at end of period, basic	116,119	116,119	116,119	116,119	116,119
- at end of period, fully diluted	116,594	117,315	116,594	117,315	117,315

\*) The outstanding warrants lead to no dilution of loss per share, as a conversion to shares would lead to a reduced reported loss per share

# CONDENSED CONSOLIDATED BALANCE SHEETS (KSEK)

	Septe	mber 30	December 31
	2008	2007	2007
Assets			
Licenses and similar rights	1,986	3,140	2,851
Equipment	7,450	7,123	5,884
Other current assets	10,877	11,117	12,580
Other short-term investments	175,872	18,040	233,093
Cash and cash equivalents	110,786	453,371	199,164
TOTAL ASSETS	306,971	492,791	453,572
Shareholders' equity and liabilities			
Shareholders' equity	250,662	448,909	394,263
Non-current liabilities	2,201	349	225
Current liabilities	54,108	43,533	59,084
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES	306,971	492,791	453,572

# CONDENSED CONSOLIDATED CASH FLOW STATEMENTS (KSEK)

	July-September		January-September		January- December	
	2008	2007	2008	2007	2007	
Operating activities						
Operating profit/loss before financial items	-45,205	-34,747	-154,684	-156,657	-215,828	
Depreciation	1,124	1,550	3,945	4,006	5,531	
Other items not affecting cash flows	28	36	119	108	154	
-	-44,053	-33,161	-150,620	-152,543	-210,143	
Financial items received and paid	9,044	6,159	13,498	10,099	16,029	
Cash flow from operating activities before changes in working capital	-35,009	-27,002	-137,122	-142,444	-194,114	
Changes in working capital	2,429	-21,265	-1,186	3,286	15,818	
Cash flow from operating activities	-32,580	-48,267	-138,308	-139,158	-178,296	
Investing activities						
Investment in licenses and similar rights	-	-	-	-3,460	-3,460	
Net investment in equipment	-1,208	-496	-2,039	-2,857	-3,087	
Net investment in other short-term investments	47,610	50,270	51,969	117,906	-96,933	
Cash flow from investing activities	46,402	49,774	49,930	111,589	-103,480	
Financing activities						
Proceeds from new share issues	-	-	-	387,161	387,161	
Cash flow from financing activities	-	-	-	387,161	387,161	
Cash flow for the period	13,822	1,507	-88,378	359,592	105,385	
Cash and cash equivalents at the beginning of the period	96,964	451,864	199,164	93,779	93,779	
Cash and cash equivalents at the end of the period	110,786	453,371	110,786	453,371	199,164	

# CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (KSEK)

1	July-Se	otember	January	-September	January- December
	2008	2007	2008	2007	2007
Equity at the beginning of the period	292,512	479,492	394,263	210,503	210,503
Employee stock option program - value of employee services	-	8	8	25	34
Share issuances	-	-	-	387,161	387,161
Profit/loss for the period	-41,850	-30,591	-143,609	-148,780	-203,435
Equity at the end of the period	250,662	448,909	250,662	448,909	394,263

# **EQUITY DATA**

	September 30	December 31
	2008 2007	2007
Equity ratio	81.7% 91.1%	86.9%
Equity per share at the end of period - basic, SEK	2.16 3.87	3.40
Equity per share at the end of period - diluted, SEK	2.15 3.83	3.36

## Accounting and valuation principles

This interim report has been prepared in accordance with International Accounting Standards 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 the Annual Report for 2007. A number of new or updated accounting standards and interpretations are applicable for financial years beginning January 1, 2008 or later. These accounting standards and interpretations are deemed not to have a significant impact on the consolidated financial statements other than presentational or disclosures presented in the reports. In addition, there are certain accounting standards and interpretations that are not relevant to Karo Bio.

Amounts are expressed in KSEK (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.

# Nominating committee

In accordance with principles for appointment of a nominating committee resolved by the Annual General Meeting 2008, the following persons have been appointed to, together with the chairman of the board Leon E. Rosenberg, be members of the nominating committee for the Annual General Meeting 2009: Ulrika Slåne (Third Swedish National Pension Fund) (chairman), Ragnhild Wiborg (Concepio), Bengt Belfrage (Nordea), and Bo Håkansson (Farstorps Gård). Shareholders can submit proposals to the nominating committee at the following address: Nominating Committee, Karo Bio AB, Novum, S-141 57 Huddinge, Sweden. The nominating committee's proposal will be published at the latest in connection with the notice for the Annual General Meeting. The term of office of the nominating committee runs until a new nominating committee has been appointed in accordance with the resolution on appointment of the nominating committee by the Annual General Meeting 2009.

# **Annual General Meeting 2009**

Karo Bio's Annual General Meeting 2009 will be held in Stockholm at 2:00 pm on April 24, 2009.

## Scheduled releases of financial information

- Year-end report 2008 February 6, 2009
- Annual report 2008 April 3, 2009
- Interim report January-March 2009 April 22, 2009

Financial reports, press releases and other 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 at www.karobio.com/finance. Financial reports are available on the web site upon release.

#### Legal disclaimer

This financial report includes statements that are forward looking and actual 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 pre-clinical 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.

#### Huddinge, October 23, 2008

Per Olof Wallström President and CEO

#### **Review report**

We have reviewed this report for the period January 1 to September 30, 2008, 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 Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

We conducted our review in accordance with the Swedish Standard on Review Engagements SÖG 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 Standards on Auditing in Sweden, RS, 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.

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 Swedish Annual Accounts Act.

# Stockholm, 23 October 2008

PricewaterhouseCoopers AB

Håkan Malmström Authorised Public Accountant

# Analyst coverage

ABG Sundal Collier, Stockholm Alexander Lindström

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The information is of a nature which Karo Bio shall need to disclose according to the Securities Market Act. The information was disclosed October 23, 2008, 08:30 am