

## **FULL YEAR REPORT 2005 QUARTERLY REPORT OCTOBER – DECEMBER 2005**

- **Per Olof Wallström was appointed President of Karo Bio in March**
- **Karo Bio decided in September to modify its strategy. In addition to the current partnership based model, Karo Bio will bring selected compounds to late stage clinical development**
- **Phase I clinical study with KB2115 successfully completed. The goal is to initiate phase II clinical studies in the second half of 2006**
- **Clinical and preclinical development organization strengthened with specific competences to increase the chances of being successful in bringing the prioritized projects into clinical trials**
- **The collaboration with Wyeth Pharmaceuticals was extended in August for an additional year until August 31, 2006.**
- **Significant milestone from Merck & Co. was triggered in January for initiation of phase I clinical trials. In April, the development was discontinued due to adverse findings in animals. Additional compounds continue to be evaluated in preclinical studies for their potential to advance to clinical study**
- **Successful new share issue completed in December 2005, generating MSEK 263.4 after transaction costs**
- **Net sales for the full year amounted to MSEK 51.9 (39.0)**
- **The loss for the full year amounted to MSEK 111.0 (107.3)**
- **Cash flows from operating activities for the full year amounted to MSEK -90.0 (-111.7)**
- **Cash and bank balances and short-term investments amounted to MSEK 346.9 (181.0) at the end of the year**
- **Loss per share for the full year amounted to SEK 2.37 (3.41)**

### **Operations**

Karo Bio is an innovative drug discovery and development company specializing in the development of novel pharmaceuticals with focus on metabolic diseases.

The Company has expanded from being a drug discovery company by adding in-house preclinical and clinical development resources and competence for development of drugs to treat metabolic diseases. With its new strategy Karo Bio now has the intention of bringing selected compounds in niche areas into the market or late stage clinical

trials. For compounds aimed at treatment of broad patient populations, Karo Bio intends to develop these to clinical proof of concept before outlicensing.

A new share issue was performed in the fall of 2005 to secure financing for the development programs.

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

## **Research and Development**

Karo Bio has a portfolio of four prioritized internal projects and two ongoing partnerships with major pharmaceutical companies.

### **Thyroid Hormone Receptor - TR**

#### **KB2115**

Through a number of animal studies Karo Bio has previously shown that KB2115 increases the body's energy consumption and reduces body weight and markedly reduces blood lipids and blood glucose. Karo Bio's extensive preclinical safety documentation shows that KB2115 has efficacy over a broad dose range with excellent tolerability.

During the fall of 2005 Karo Bio successfully completed a phase I study with KB2115 in healthy but overweight individuals with dyslipidemia. The primary objective of the phase I study was to determine the short-term safety and tolerability of single (phase Ia) and multiple oral doses of KB2115 administered daily over a 14-day period (phase Ib). No adverse events were recorded, and KB2115 was well tolerated. Also, excellent bioavailability and pharmacokinetic properties were documented. No negative effects on the heart were reported. In addition to the clean safety profile of KB2115, significant lowering of total and LDL cholesterol has been documented. Thus, the compound has the potential to become an important agent for the treatment of severe dyslipidemia. A bioavailability study of an improved formulation will be performed in the first half of 2006. The goal is to initiate phase II clinical trials in the second half of 2006, which means that the compound will be evaluated in patients.

#### **TR STAD (Selective Thyroid hormone Agonists for Dyslipidemia)**

Karo Bio has developed a new series of compounds intended for treatment of different forms of dyslipidemia. Significant progress has been made during the past year. Potent compounds which lower LDL cholesterol and triglycerides with no effect on the heart have been discovered. Regarding LDL lowering, these compounds act synergistically with statins in an animal model. The compounds also have the ability to lower independent risk factors for development of cardiovascular disease such as lipoprotein(a). There is still significant medical need for treatments that can significantly lower blood lipids, either as single therapy or in combinations with other drugs. STADs are therefore promising for treatment of broad patient populations with dyslipidemia.

## **Glucocorticoid receptor - GR**

### **KB3305**

KB3305, intended for treatment of type 2 diabetes, has a favorable pharmacological profile in animal diabetes models and acts by selectively antagonizing the action of glucocorticoid hormone. By developing compounds that are liver selective the pharmacological effects in other organs can be minimized. KB3305 demonstrates significant anti-diabetic effects in three separate animal disease models. As a consequence, KB3305 normalizes the hyperglycemia associated with type 2 diabetes. Preclinical safety and toxicity studies suggest that KB3305 is a safe and well-tolerated drug with a 100-fold safety margin over the expected clinical dose.

The preclinical development of KB3305 is progressing and during 2005 improvements have been made regarding the pharmaceutical formulation. The objective is to finalize the pharmaceutical formulation for clinical trials during spring 2006.

## **Estrogen Receptors - ER**

### **ER beta - Depression**

Karo Bio is concentrating its efforts on the ER beta receptor. ER beta selective compounds have potential for a number of important diseases such as depression. Proof of principle in animal models, for the use of ER beta selective agonists in depression, has been obtained during the year. Currently three different series of compounds are being optimized for selection of candidate drug.

## **Karo Bio partner projects**

### **Estrogen Receptors - Merck & Co., Inc.**

In the beginning of the year Karo Bio received a significant milestone from Merck for the initiation of phase I clinical trials. In April the clinical development was discontinued due to adverse findings in an animal study. Merck continues with evaluation of additional compounds in preclinical studies to assess suitability to progress to clinical study.

### **Atherosclerosis - Wyeth Pharmaceuticals**

The collaboration targets the liver X receptor (LXR) with the aim to develop new treatments for atherosclerosis. LXR is a regulator of cholesterol metabolism. It has been demonstrated that compounds that modulate the activity of LXR promote net cholesterol efflux from atherosclerotic blood vessels resulting in the regression of vascular plaque formation. In August 2005 the research term of the collaboration was extended for an additional year until August 31, 2006 with the intention of selecting additional drug candidates for development.

## Organization

Per Olof Wallström was appointed President of Karo Bio in March, replacing Björn Nilsson who then left the Company.

Karo Bio is strengthening its clinical and preclinical development organization with specific competences to increase the chances of being successful in bringing the prioritized projects into clinical trials. Consequently, Dr Jens Kristensen was recruited to be responsible for Karo Bio's clinical development activities. He joined Karo Bio as Chief Medical Officer and Vice President Clinical Development in November 2005. Dr. Anneli Hällgren was recruited in January 2006 to be responsible for preclinical development as Vice President of Preclinical Development from March 2006. Dr. Anders Berkenstam remains as Vice President of Discovery Research.

By the end of the period, Karo Bio had 73 (77) employed, of which 64 (67) are engaged in research and development.

## New Share Issue

Karo Bio's new share issue was completed in December. The rights issue of 46 447 677 shares generated MSEK 263.4 after transaction costs amounting to MSEK 15.3.

## Result and Financial Position

### Result

Net sales for the full year increased to MSEK 51.9 as compared to MSEK 39.0 for the same period last year. The corresponding figure for the fourth quarter amounted to MSEK 2.0 (6.0). Revenues during 2005 consist of the milestone payment triggered in January under the collaboration with Merck & Co in relation to initiation of phase I clinical trials and research funding from the research collaboration with Wyeth Pharmaceuticals. Revenues in 2005 from the research collaboration with Wyeth Pharmaceuticals decreased compared to 2004 as 2004 included the period's share of an upfront payment received at the initiation of the collaboration in September 2001, which was fully taken as income as of August 31, 2004. Revenues also decreased due to fewer Karo Bio scientists engaged and paid for in the collaboration, which also is the reason for the lower revenues in the fourth quarter.

Expenses for the full year increased by MSEK 7.3 to MSEK 160.6 (153.3) while expenses in the fourth quarter increased by MSEK 4.9 to 39.1 (34.2). The cost increase is attributable to costs for performing clinical trials as well as severance costs in relation to the change of presidents.

Operating loss for the full year amounted to MSEK 108.7 (114.3) and MSEK 37.1 (28.2) in the fourth quarter. Financial net for the full year amounted to MSEK -2.3 (7.0), including a currency effect of MSEK -5.2 (2.4) related to financial items. The reported loss for the full year amounted to MSEK 111.0 (107.3) and MSEK 37.4 (23.8) for the fourth quarter.

### **Cash Flow**

Cash flows from operating activities for the full year amounted to MSEK -90.0 (-111.7). The corresponding figure for the quarter amounted to MSEK -29.0 (-32.8).

Cash and bank balances and short-term investments with duration less than 90 days amounted to MSEK 307.3 (65.6) at the end of the year. If including short-term investments with duration exceeding 90 days, the assets amounted to MSEK 346.9 (181.0).

### **Capital Investments**

Capital investments in equipment for the full year amounted to MSEK 1.8 (4.1) including equipment financed with capital leases, and to MSEK 0.6 (0.2) for the fourth quarter.

### **Shareholders' Equity and Per Share Data**

At period-end, warrants representing 1 014 470 shares were outstanding. The warrants were issued in conjunction with the implementation of the 2001 and 2003 stock option programs (warrants representing 612 000 and 402 470 shares, respectively, after adjustment for the effect of rights issues in accordance with the terms of the programs). The remaining warrants issued in conjunction the acquisition of Karo Bio USA, Inc. in year 2000 (warrants representing 3 219 shares) were cancelled in May 2005. No warrants were exercised during 2005.

The share capital at the end of the period amounted to MSEK 154.8. The total number of shares amounted to 77 412 795 shares at a par value of SEK 2. The number of shares increased by 46 447 677 from the rights issue. The par value of the shares was reduced from SEK 5 to 2 through a resolution by the general meeting in April 2005 which was subsequently approved and registered by the Swedish Companies Registration Office in May 2005. Total consolidated shareholders' equity amounted to MSEK 336.5 after taking into account the loss for the period.

Loss per share for the full year, based on the weighted average number of shares outstanding, amounted to SEK 2.37 (3.41). The Group's equity ratio at the end of the year was 89.8 percent (83.6) and equity per share was SEK 4.35 (4.07).

### **Parent Company**

The Parent Company recorded revenues for the full year amounting to MSEK 51.9 (39.0) and is reporting a loss after financial items of MSEK 112.3 (116.0).

Capital investments in equipment for the full year amounted to MSEK 1.8 (1.6), excluding capital investments financed with capital leases.

Cash and bank balances and short-term investments amounted to MSEK 346.9 (181.0) at the end of the year.

**CONDENSED CONSOLIDATED INCOME STATEMENTS (kSEK)**

	<b>October-December</b>		<b>January-December</b>	
	<b>2005</b>	<b>2004</b>	<b>2005</b>	<b>2004</b>
Net sales	1 970	6 015	51 913	38 953
<b>Operating expenses</b>				
Administrative expenses	-6 516	-5 281	-34 572	-31 980
Research and development expenses	-32 698	-28 819	-125 226	-123 456
Other operating income and expenses	103	-132	-804	2 140
	-39 111	-34 232	-160 602	-153 296
<b>Operating loss</b>	<b>-37 141</b>	<b>-28 217</b>	<b>-108 689</b>	<b>-114 343</b>
Financial net	-211	4 376	-2 318	7 045
<b>Loss after financial items</b>	<b>-37 352</b>	<b>-23 841</b>	<b>-111 007</b>	<b>-107 298</b>
Tax	-	-	-	-
<b>LOSS FOR THE PERIOD</b>	<b>-37 352</b>	<b>-23 841</b>	<b>-111 007</b>	<b>-107 298</b>
<i>Depreciation included in operating expenses</i>	<i>-1 624</i>	<i>-2 131</i>	<i>-7 233</i>	<i>-12 369</i>
<b>Loss per share (SEK) <sup>*)</sup></b>				
- weighted average number of shares outstanding	-0.67	-0.57	-2.37	-3.41
<b>Number of shares outstanding (000)</b>				
- weighted average during period	55 455	42 058	46 802	31 510
- weighted average during period, incl warrants	56 465	43 071	47 812	32 525
- at end of period	77 413	43 918	77 413	43 918
- at end of period, including warrants	78 427	44 930	78 427	44 930

<sup>\*)</sup> The outstanding warrants lead to no dilution of earnings per share, as a conversion to shares would lead to an improvement of earnings per share.

**CONDENSED CONSOLIDATED BALANCE SHEETS (kSEK)**

	<b>December 31</b>	
	<b>2005</b>	<b>2004</b>
<b>Assets</b>		
Licenses and similar rights	0	78
Equipment	13 124	18 531
Other current assets	14 811	14 533
Short-term investments	301 115	166 507
Cash and bank balances	45 765	14 482
<b>TOTAL ASSETS</b>	<b>374 815</b>	<b>214 131</b>
<b>Shareholders' equity and liabilities</b>		
Shareholders' equity	336 548	178 952
Non-current liabilities	1 644	2 573
Deferred revenue	1 327	2 681
Other current liabilities	35 296	29 925
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>	<b>374 815</b>	<b>214 131</b>

**CONDENSED CONSOLIDATED CASH FLOW STATEMENTS (kSEK)**

	<b>October-December</b>		<b>January-December</b>	
	<b>2005</b>	<b>2004</b>	<b>2005</b>	<b>2004</b>
<i><b>Operating activities</b></i>				
Operating loss before financial items	-37 141	-28 217	-108 689	-114 343
Depreciation	1 624	2 131	7 233	12 369
Other items not affecting cash flows	208	72	407	-76
	<b>-35 309</b>	<b>-26 014</b>	<b>-101 049</b>	<b>-102 050</b>
Financial items received and paid	1 094	-271	5 413	3 531
<b>Cash flow from operating activities before changes in working capital</b>	<b>-34 215</b>	<b>-26 285</b>	<b>-95 636</b>	<b>-98 519</b>
Changes in working capital	5 256	-6 549	5 686	-13 171
<b>Cash flow from operating activities</b>	<b>-28 959</b>	<b>-32 834</b>	<b>-89 950</b>	<b>-111 690</b>
<i><b>Investing activities</b></i>				
Investment in licenses and similar rights	-	-	-3 700	-3 775
Net investment in equipment	-797	-434	-2 699	-1 075
Net investment in short-term investments	21 600	-70 939	74 616	-57 292
<b>Cash flow from investing activities</b>	<b>20 803</b>	<b>-71 373</b>	<b>68 217</b>	<b>-62 142</b>
<b>Cash flow from operating and investing activities</b>	<b>-8 156</b>	<b>104 207</b>	<b>-21 733</b>	<b>-173 832</b>
<i><b>Financing activities</b></i>				
Proceeds from new share issues	263 413	113 422	263 413	113 482
<b>Cash flow from financing activities</b>	<b>263 413</b>	<b>113 422</b>	<b>263 413</b>	<b>113 482</b>
<b>Cash flow for the period</b>	<b>255 257</b>	<b>9 215</b>	<b>241 680</b>	<b>-60 350</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>307 270</b>	<b>65 590</b>	<b>307 270</b>	<b>65 590</b>
<b>Cash and cash equivalents consist of</b>				
Short-term investments with duration less than 90 days	261 505	51 108	261 505	51 108
Cash and bank balances	45 765	14 482	45 765	14 482
	<b>307 270</b>	<b>65 590</b>	<b>307 270</b>	<b>65 590</b>

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (kSEK)**

	<b>October-December</b>		<b>January-December</b>	
	<b>2005</b>	<b>2004</b>	<b>2005</b>	<b>2004</b>
<b>Amount at beginning of period</b>	<b>109 839</b>	<b>91 808</b>	<b>178 952</b>	<b>174 850</b>
Effect from changes in accounting principles	-	-	249	-
Currency translation difference	616	-2 481	4 815	-2 200
Employee stock option program - value of employee services	32	44	126	118
New issues of shares	263 413	113 422	263 413	113 482
Loss for the period	-37 352	-23 841	-111 007	-107 298
<b>Amount at end of period</b>	<b>336 548</b>	<b>178 952</b>	<b>336 548</b>	<b>178 952</b>

## EQUITY DATA

	December 31	
	2005	2004
Equity ratio	89.8%	83.6%
Equity per share at the end of period, SEK	4.35	4.07
Equity per share at the of period, including warrants, SEK	4.29	3.98

## Accounting and Valuation Principles

Effective January 1, 2005, companies listed on a stock exchange within the European Union are required to present consolidated financial statements in accordance with International Financial Reporting Standards (IFRS) issued by International Accounting Standards Board (IASB).

This quarterly report has been prepared in accordance with International Accounting Standards 34 for interim reports and other effective IFRS standards and IFRIC interpretations enacted by the EU commission at the end of December 2005. The accounting and valuation principles applied are unchanged compared with what was applied in the Annual Report for 2004 with the exception of implementation of IFRS as described in the annual report for 2004 and as described below.

Other than presentational changes and increased disclosure requirements in the annual report, the transition to IFRS leads to changes in the following areas for the Company:

- IFRS 2 Share-based Payments – accounting for stock option programs
- IAS 39 Financial Instruments: Recognition and Measurement
  - Accounting for currency forward contract intended for hedging exposure to currency fluctuations
  - Valuation of short-term investments
- IAS 7 Cash Flow Statements – definition of cash and cash equivalents in the cash flow statement

IAS 39 became effective January 1, 2005. In accordance with the provisions of IFRS 1, Karo Bio has elected not to restate the periods prior to 2005 with regard to financial instruments in accordance with IAS 39. Financial instruments are, consequently, accounted for in accordance with previously adopted principles in restated financial statements for 2004.

Comparative figures for 2004 have been adjusted for changes in accounting principles except for changes from IAS 39 as described above.

### Stock Option Programs

Karo Bio has issued stock options to employees under two stock option programs, Program 2001 and Program 2003. Accounting for such stock options is regulated by



IFRS 2 Share-based payments. IFRS 2 applies to Program 2003, while Program 2001 is not covered by IFRS 2 under the transition rules since the options under this program were issued before November 7, 2002. Program 2003 is considered an equity-settled payment transaction under IFRS 2, where the fair value of the options granted is recognized in the income statement as a payroll expense over the vesting period. The fair value of the options granted under Program 2003, determined as of the grant date, amounted to MSEK 0.4 based on a valuation performed by Ernst & Young. The Black-Scholes model for option pricing was used for the valuation. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions, and behavioral considerations. Vesting conditions are included in assumptions about the number of options that are expected to become exercisable. These estimates are revised regularly. Karo Bio recognizes the impact of the revision of original estimate, if any, in the income statement, and a corresponding entry to equity over the remaining vesting period. The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium reserve when options are exercised.

The previously used accounting principle for stock-based compensation was to, upon exercise of stock option, credit nominal value to share capital and exercise price less nominal value to the share premium reserve. No charge was taken to the income statement for stock options granted as compensation for employees. This principle will continue to apply for the Program 2001.

### **Financial instruments**

The difference between the measurement according to IAS 39 and previously adopted principles are in the balance sheet as at January 1, 2005, reported in the shareholders' equity in accordance with the transition rules in IFRS 1. The effect amounts to kSEK 249 and consists of kSEK 171 regarding currency forward contracts and kSEK 78 regarding short-term investments. The amounts have as of January 1, 2005 increased other current assets and short-term investments, respectively.

#### *Currency forward contracts*

Karo Bio's policy is to hedge forecasted cash flows in foreign currencies from large currency rate fluctuations as provided in the Company's financial policy. In this respect, a certain level of assurance must exist in order to consider possible transactions and related cash flows. Currency hedging is accomplished primarily through currency forward contracts. These instruments were previously not required to be measured at fair value in the balance sheet. In accordance with IAS 39, all derivatives are to be measured at fair value. The derivatives currently used by the Company do not qualify for hedge accounting in accordance with IAS 39. As a result, changes in fair value of cash flow hedges in foreign currencies are included in other operating income and expenses.

The previous accounting principle for forward currency contracts entered into for hedging purposes was to apply hedge accounting. This meant that unrealized gains and losses on forward currency contracts were deferred and reported when realized.

#### *Short-term investments*

Short-term investments consist of investments in money market instruments, highly liquid bonds with maturities of less than five years and investments in highly liquid

fixed income mutual funds. Short-term investments are classified as financial assets held for trading purposes. This entails that the assets are stated at fair value in the balance sheet, defined as market value. Changes in fair value are included in financial items in the income statement.

Previously, short-term investments in debt instruments were stated at the lower of cost or market value. Any premium or discount on investments intended to be held to maturity was amortized over the life of the instrument.

### **Cash flow statements**

Karo Bio has used the term liquid assets, defined as bank holdings and short-term investments, as the ending component of the cash flow statement. In accordance with IAS 7 Cash Flow Statements only investments with maturities of less than 90 days at the time of acquisition are to be included in the term cash and cash equivalents used by IAS 7. As a consequence, changes such as investments in and redemptions or sales of short-term investments with maturities exceeding 90 days are reported as cash flows from investing activities. As a result, cash and cash equivalents as of January 1 and December 31, 2004 is lower than liquid assets previously reported in the cash flow statement.

### **Reconciliation of reported loss and shareholders equity for comparative periods according to IFRS**

The Company's financial statements have been affected by the transition to IFRS in reporting periods relevant to this quarterly report in the following way:

Equity as at January 1, October 1 and December 31, 2004, was not affected.

The reported loss for the period October – December and for the full year 2004 increased by kSEK 44 and 118, respectively, related to the costs of share-based payments for the 2003 stock option program. The value of the options was credited to equity, leading to a neutral net effect in equity.

### **Other IFRS standards**

A review of all other IFRS standards not described in the previous sections was performed. The adoption of those standards did not have a material effect on Karo Bio's financial position or result.

### **The Parent Company**

Beginning January 1, 2005 the parent company implemented RR 32 Reporting for legal entities, which has led to the same effects in the financial statements as for the Group from IAS 39 and IFRS 2.

### **Other**

Amounts are expressed in kSEK (thousands of Swedish Kronor) unless otherwise indicated. MSEK is an abbreviation for millions of SEK. Amounts or figures in parentheses indicate comparative figures for the corresponding period last year, updated for changes in accounting principles as appropriate.

## Nominating Committee

A nominating committee consisting of Thomas Ehlin, appointed by Nordea's funds, Björn Franzon, Fourth Swedish National Pension Fund, Ragnhild Wiborg, Pecunia, and Carl Rosén, Second Swedish National Pension Fund, as well as Per-Olof Mårtensson, chairman of the Karo Bio board of directors, has been appointed in accordance with the decision at the shareholders' meeting in April 2005.

## General Meeting and Scheduled Releases of Financial Information

The Board of Directors intends to convene the Annual General Meeting on Wednesday May 3, 2006 at 4:00 p.m. at Wallenbergsalen, IVA Conference Center, Grev Turegatan 18, Stockholm, Sweden. Notice for the meeting will be available on Karo Bio's website at [www.karobio.com/agm](http://www.karobio.com/agm) from approximately April 5. In accordance with the Board's policy for dividend, the Board of Directors and the President will propose that no dividend be paid for the financial year 2005.

Karo Bio intends to distribute financial reports as follows:

- Annual Report 2005 April 12, 2006
- Quarterly Reports April 20, July 13 and October 19, 2006
- Earnings Report 2006 February 7, 2007

The annual report is planned to be available on the Karo Bio web site on or about April 6, 2006.

Financial reports, press releases and other information are available on Karo Bio's web site [www.karobio.com](http://www.karobio.com). Karo Bio's financial reports and press releases may be downloaded and subscribed to on the web site at [www.karobio.com/finance](http://www.karobio.com/finance). Financial reports are available on the web site upon release.

Huddinge February 7, 2006

Karo Bio AB  
The Board of Directors

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**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 developments 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.

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