

Active Biotech AB
Interim report
January – March 2009

- **Laquinimod — Fast Track status granted by the FDA**
- **57-57 — planning of exploratory study in progress**
- **RhuDex™ — preclinical tests under way**
- **ANYARA — Phase III trial proceeding as planned**
- **TASQ — safety profile assessed by independent international expert group, Phase II trial proceeding as planned**
- **Net sales SEK 2.2 M (3.2)**
- **Operating loss SEK 63.7 M (loss: 52.2)**
- **Loss after tax SEK 62.2 M (loss: 52.7)**
- **Loss per share for the period was SEK 1.21 (loss 1.11)**

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This report is also available at www.activebiotech.com

Laquinimod – a novel oral immunomodulatory compound for the treatment of autoimmune diseases

*Laquinimod is a quinoline compound in Phase III development for the treatment of [multiple sclerosis \(MS\)](#). Active Biotech has entered into an agreement with the Israeli pharmaceutical company [Teva Pharmaceutical Industries Ltd](#) (June 2004) covering the development and commercialization of laquinimod. Positive data from a [Phase IIb trial](#) of relapsing-remitting multiple sclerosis (RRMS) has been published in the scientific journal *The Lancet* (2008; 371:2085-92). In September 2008, data from the post-Phase IIb [extension study](#) showed a significant decrease in the mean number of gadolinium-enhancing (GdE) lesions in the brains of both the patients who had switched from placebo to laquinimod and the patients who had continued with their initial laquinimod dose. At present, laquinimod is undergoing two global clinical Phase III trials, which will encompass a total of 2,200 MS patients in 175 clinics worldwide. In November 2008, Teva completed patent enrolment to the first of two Phase III studies ([Allegro](#)) and, for the second study ([Bravo](#)), global enrolment of patients with RRMS is under way. Information regarding the ongoing clinical trials is available at www.TevaClinicalTrials.com and www.clinicaltrials.gov.*

– In February 2009, laquinimod received a [“Fast Track” designation](#) from the US Food and Drug Administration, FDA. Drugs designated for Fast Track are intended for the treatment of a serious or life-threatening condition and have demonstrated the potential to satisfy major medical needs. Fast-Track status can facilitate the development and accelerate the registration process, which may mean that laquinimod will be available in the market as early as the end of 2011.

57-57 – a novel oral immunomodulatory compound for the treatment of Systemic Lupus Erythematosus

57-57 is a quinoline compound primarily intended for the treatment of [Systemic Lupus Erythematosus \(SLE\)](#), a disease that causes inflammation and damage to connective tissue throughout the body, with serious secondary symptoms, such as kidney failure. Earlier documentation from [preclinical trials](#) indicates that 57-57 can prevent relapses and reduce steroid use in SLE patients. At the American College of Rheumatology’s Annual Scientific Meeting in October 2008, new data from the [Phase I trial](#) of 57-57 were presented. The new results show that by treating patients with 57-57, it is possible to affect signaling pathways that are essential for the development of SLE.

– In February 2009, Active Biotech decided not to initiate a Phase II/III clinical development program for 57-57 on a proprietary basis. A complete Phase II/III clinical development program has been prepared in cooperation with European and US regulatory authorities. The company will actively seek a partner for the continued development of the project during 2009.

A small-scale exploratory study in SLE patients will be conducted during 2009 and 2010.

RhuDex[™] – a novel oral compound for the treatment of rheumatoid arthritis

In the project covering Active Biotech’s patented CD80 antagonists, the RhuDex candidate drug is under development for the treatment of [rheumatoid arthritis \(RA\)](#). In April 2002, Active Biotech entered a licensing agreement with Avidex Ltd, now a wholly owned subsidiary of the German biotechnology company [MediGene](#), according to which MediGene has the exclusive rights to develop CD80 antagonists and market products in which these compounds are included. Two [Phase I trials](#) have already been successfully implemented in which the RhuDex candidate drug’s safety, tolerability and pharmacokinetic properties in healthy volunteers were studied. In June 2008, MediGene announced that a clinical [Phase IIa trial](#) had achieved its objective. For further information and the latest news concerning RhuDex, visit www.medigene.com.

– RhuDex[™] is being [studied](#) in a series of laboratory tests under the supervision of the UK Medicines and Healthcare Products Regulatory Agency. These tests will examine any potential detrimental interactions between RhuDex and arteriosclerotic blood vessels. MediGene plans to complete these tests in mid-2009 and subsequently initiate supplementary Phase IIb clinical trials.

ANYARA – a fusion protein for immunological treatment of renal cancer

ANYARA is a [TTS](#) (Tumor Targeting Superantigens) compound that makes the treatment of cancer tumor-specific. The development of ANYARA is mainly focused on [renal cancer](#). Positive data was reported in connection with the [interim analysis in Phase II/III](#) and from clinical Phase I trials in lung cancer, renal cancer and pancreatic cancer. The median survival of 26.2 months observed for patients with advanced renal cancer and treated with ANYARA is twice the expected length. Pivotal [Phase III trials](#) in patients with advanced renal cancer are currently under way. The primary clinical efficacy parameter from this trial is overall survival and it will include a total of approximately 500 patients at about 50 clinics in Europe. ANYARA has been granted [orphan-drug status](#) by the EMEA for the indication renal cancer. Information concerning the ongoing clinical trial is available at www.activebiotech.com and www.clinicaltrials.gov.

– Patient enrolment to the ongoing, pivotal Phase III trial of ANYARA in combination with interferon-alpha, compared with interferon-alpha alone, in patients with advanced renal cancer is proceeding as planned. At the end of the period, 485 patients had been enrolled in the trial.

TASQ – an antiangiogenic compound for the treatment of prostate cancer

The development of TASQ is principally focused on the treatment of [prostate cancer](#). TASQ is an antiangiogenic compound, meaning that it cuts off the supply of nutrients to the tumor and does not belong to the most frequently occurring group of tyrosine kinase inhibitors. Positive results for the concluded [Phase I trial](#) show that TASQ is well-tolerated and has a favorable safety profile. In September 2008, the follow-up efficacy data from the Phase Ib trial of TASQ was presented. Patients treated with TASQ developed few new bone metastases and displayed a reduced rate of increase of the disease marker PSA (Prostate-Specific Antigen). For further information, view the [presentation](#) from the UBS Global Life Sciences conference. Within this project, a placebo-controlled [Phase II trial](#) is being performed in the US, Canada and Sweden. Information about the ongoing clinical trial is available at www.activebiotech.com and www.clinicaltrials.gov.

– In February 2009, an independent international expert group, a Data Safety Monitoring Board (DSMB), evaluated the ongoing clinical Phase II trial of TASQ, the prostate cancer project. The board had access to the study's unblinded safety data and studied the side effect profile of TASQ. After analyzing long-term data concerning more than 50 patients treated with TASQ, DSMB recommended that the trial continue in accordance with the established protocol.

– The ongoing Phase II trial is proceeding as planned and results are expected in the second half of 2009.

ISI – new project based on the mode of action of quinoline compounds

Active Biotech recently initiated a new research project. The aim of the project is to utilize the company's own preclinical results that were generated around a target molecule for the quinoline (Q) compounds and their biological mode of action. The project aims at producing new, patentable chemical substances that interact with the target molecule of the Q compounds.

– During the period, a "lead" compound has been identified for further preclinical tests. The aim is to select a candidate drug in 2010.

– The manuscript describing a target molecule for the Q compounds has been accepted for publication in a scientific journal and is estimated to be published presently.

EVENTS AFTER THE END OF THE PERIOD

Rights issue

The Board of Directors proposes that the Annual General Meeting on May 7, 2009 resolve to approve a guaranteed rights issue in an approximate amount of SEK 256 M with the aim of strengthening the company's financial position and driving development of the company's clinical portfolio. It is proposed that the issue shall entitle existing shareholders with preferential rights to subscribe for one new share for each four shares held at an issue price of SEK 20 per share.

The principal owners, MGA Holding AB (30.0%) and Nordstjernan AB (15.3%), have undertaken to subscribe for the full amount of shares corresponding to their preferential rights. In addition, MGA

Holding AB and Nordstjernan AB have undertaken, should the issue not be fully subscribed, to subscribe for any additional shares not taken up with the support of preferential rights. Accordingly, the issue is guaranteed in its entirety.

FINANCIAL INFORMATION

Comments on the Group's results for the period January – March 2009

Net sales for the period amounted to SEK 2.2 M (3.2) and comprised service and rental revenues. The figure for the year-earlier period also included research grants of SEK 0.8 M from Vinnova.

The operation's research and administration expenses totaled SEK 65.9 M (55.4), of which research costs amounted to SEK 61.5 M (49.8). The increase in costs was mainly due to the ongoing Phase III trial for the ANYARA renal cancer project, the ongoing Phase II trial for the TASQ prostate cancer project and the 57-57 project for the treatment of SLE. In addition, Active Biotech conducted studies to explain the mode of action and target molecules that are behind the pharmacological effects of the quinoline compounds currently in clinical development. The high level of costs for the period is not representative for the remainder of the year, since the period was charged with costs of a nonrecurring nature.

The clinical development of RhuDex™ for the treatment of RA and current clinical Phase III studies with laquinimod are fully financed by the relevant partner.

An operating loss of SEK 63.7 M (loss: 52.2) was reported. The change in earnings was attributable to higher costs for the more comprehensive clinical development program. Net financial income for the period totaled SEK 1.5 M (expense: 0.5). A loss of SEK 62.2 M (loss: 52.7) was reported after tax.

Cash flow, liquidity and financial position

At the end of the period, cash and cash equivalents amounted to SEK 71.8 M, compared with SEK 138.7 M at the end of 2008.

Accordingly, cash flow for the period was negative in the amount of SEK 67.0 M (neg: 46.4), of which cash flow from operating activities was a negative SEK 65.1 M (neg: 44.9) and cash flow from investing activities was SEK 0.0 M (neg: 0.3).

As a result of loan repayments, cash flow from financing activities amounted to a negative SEK 1.9 M (neg. 1.2).

Dividend

It is proposed that no dividend be paid.

Comments on the Parent Company's earnings and financial position

The operations of the Parent Company, Active Biotech AB, comprise Group-wide administrative functions. The Parent Company's net sales for the period amounted to SEK 0.9 M (1.7).

Operating expenses during the period amounted to SEK 4.7 M (6.8) and net financial items to income of SEK 0.4 M (1.1). Loss after financial items amounted to SEK 3.4 M (loss: 4.0). No investments in fixed assets were made during the period.

Cash and cash equivalents, including short-term investments, amounted to SEK 55.9 M at the end of the period, compared with SEK 131.6 M on January 1, 2009.

Share capital

Consolidated shareholders' equity at the end of the period amounted to SEK 101.2 M, compared with SEK 163.6 M at year-end 2008.

A total of 51,241,791 shares were outstanding at year-end. In the event of redemption of share warrants outstanding, the number of shares in Active Biotech would increase to a maximum of about 52.6 million.

At the end of the period, the equity/assets ratio for the Group was 24.7%, compared with 34.6% at year-end 2008. The corresponding figures for the Parent Company, Active Biotech AB, were 92.8% and 91.1%, respectively.

Organization

The average number of employees was 90 (89), of which the number of employees in the research and development operation accounted for 73 (73). At the end of the period, the Group had 90 employees (89).

Outlook, including significant risks and uncertainties

A vital factor for Active Biotech's financial strength and stability is the company's ability to develop pharmaceutical projects to the point at which partnership agreements can be entered into and the partner can assume responsibility for future development and commercialization of the project. During this development phase, the value of the project is increased. The development of partnership agreements already signed and the addition of new agreements are assumed to have a significant impact on revenues and cash balances. The Board of Directors is of the opinion that the present level of available liquidity, the by the Board proposed new share issue and other available financial alternatives will provide sufficient financial resources to finance the company's operations in line with current plans.

A research company such as Active Biotech is characterized by a high operational and financial risk, since the projects in which the company is involved are at the clinical phase, where a number of factors have an impact on the likelihood of commercial success. In brief, the operation is associated with risks related to such factors as pharmaceutical development, competition, advances in technology, patents, official requirements, capital requirements, currencies and interest rates. Since no significant changes took place with regard to risks and uncertainties during the period, refer to a detailed account of these factors in the directors' report in the 2008 Annual Report.

Condensed consolidated statement of comprehensive income SEK M	Jan-March		Full-Year
	2009	2008	2008
Net sales	2.2	3.2	53.5
Administrative costs	-4.4	-5.7	-30.7
Research and development costs	-61.5	-49.8	-207.4
Operating loss	-63.7	-52.2	-184.6
Net financial items	1.5	-0.5	4.0
Loss after financial items	-62.2	-52.7	-180.6
Tax	-	-	-1.0
Loss for the period	-62.2	-52.7	-181.6
Comprehensive loss attributable to:			
Equity holders of the Parent Company	-62.2	-52.7	-181.6
Minority interests	-	-	-
Loss for the period	-62.2	-52.7	-181.6
Other comprehensive income during the period			
Change in revaluation reserve	-	-	1.0
Change in translation reserve	-	-0.6	-0.6
Comprehensive loss for the period	-62.2	-53.4	-181.3
Comprehensive loss attributable to:			
Equity holders of the Parent Company	-62.2	-53.4	-181.3
Minority interests	-	-	-
Comprehensive loss for the period	-62.2	-53.4	-181.3
Depreciation/amortization is included in an amount of	2.4	4.6	11.5
Investments in tangible fixed assets	-	0.3	2.9
Earnings per share before dilution (SEK)	-1.21	-1.11	-3.66
Earnings per share after dilution (SEK)	-1.21	-1.11	-3.66
Weighted number of common shares outstanding before dilution (thousands)	51 242	47 300	49 605
Weighted number of common shares outstanding after dilution (thousands)	51 242	47 300	49 605
Number of shares at period end, thousands	51 242	47 300	51 242
Number of shares at period end, including warrants, thousands	52 572	48 630	52 572

Condensed consolidated statement of financial position SEK M	March 31		Dec 31
	2009	2008	2008
Tangible fixed assets	325.5	326.6	324.6
Financial fixed assets	0.0	2.5	0.0
Total fixed assets	325.5	329.0	324.6
Current receivables	13.2	8.6	9.7
Cash and cash equivalents	71.8	92.2	138.7
Total current assets	84.9	100.8	148.4
Total assets	410.4	429.8	472.9
Shareholder's equity	101.2	137.1	163.6
Long-term liabilities	253.3	250.6	251.7
Current liabilities	55.9	42.2	57.6
Total equity and liabilities	410.4	429.8	472.9
Consolidated statement of changes in equity			
Opening amount	163.6	189.6	189.6
Employee stock option program	–	0.9	1.5
New share issue	-0.2	–	153.9
Consolidated loss for the period	-62.2	-53.4	-181.3
Closing amount	101.2	137.1	163.6
Condensed consolidated cash flow statement			
SEK M	Jan-March		Full-Year
	2009	2008	2008
Loss after financial items	-62.2	-52.7	-180.6
Adjustments for non-cash item, etc.	2.4	4.8	5.4
Cash flow from operating activities before changes in working capital	-59.9	-47.9	-175.3
Changes in working capital	-5.2	3.1	15.8
Cash flow from operating activities	-65.1	-44.9	-159.5
Investment in tangible fixed assets	–	-0.3	-2.9
Investment in financial fixed assets	–	–	–
Decrease in financial fixed assets	–	–	9.8
Cash flow from investing activities	–	-0.3	7.0
New share issue	-0.2	–	153.9
Loans raised/amortization of loan liabilities	-1.7	-1.2	-1.2
Cash flow from financing activities	-1.9	-1.2	152.6
Cash flow during the period	-67.0	-46.4	0.1
Cash flow and cash equivalents, opening balance	138.7	138.6	138.6
Exchange rate difference in cash and cash equivalents	–	–	–
Cash and cash equivalents, closing balance	71.8	92.2	138.7
Key figures			
	March 31		Dec 31
	2009	2008	2008
Shareholder's equity, SEK M	101.2	137.1	163.6
Shareholder's equity per share, SEK M	1.98	2.90	3.19
Equity/assets ration in the Parent Company	92.8%	64.7%	91.1%
Equity/assets ration in the Group	24.7%	31.9%	34.6%
Average number of annual employees	90	89	89

Active Biotech - Parent Company

Condensed income statement SEK M	Jan-March		Full-Year 2008
	2009	2008	
Net sales	0.9	1.7	46.4
Administrative costs	-4.7	-6.8	-33.2
Operating profit/loss	-3.8	-5.1	13.1
<i>Profit/loss from financial items:</i>			
Profit from participations in Group companies	-	-	37.6
Profit from other securities and receivables classed as fixed assets	-	-	7.4
Interest income and similar income-statement items	0.4	1.1	5.5
Interest expense and similar income-statement items	0.0	-	0.0
Profit/loss after financial items	-3.4	-4.0	63.6
Tax	-	-	-
Profit/loss for the period	-3.4	-4.0	63.6
Condensed balance sheet			
SEK M	March 31		Dec 31
	2009	2008	2008
Tangible fixed assets	0.4	0.4	0.4
Financial fixed assets	202.5	231.9	202.5
Total fixed assets	202.8	232.2	202.8
Current receivables	11.3	66.4	10.3
Short-term investments	-	59.8	-
Cash and bank deposits	55.9	18.7	131.6
Total current assets	67.1	144.9	141.9
Total assets	269.9	377.1	344.7
Shareholder's equity	250.5	244.1	314.1
Current liabilities	19.4	133.1	30.6
Total equity and liabilities	269.9	377.1	344.7

Any errors in additions are attributable to rounding of figures.

Accounting and valuation principles

The interim report for the Group has been prepared in accordance with IAS 34, Interim Financial Reporting. In addition, relevant regulations from the Swedish Annual Accounts Act and the Securities Market Act have been applied. The same accounting policies and bases for calculations were applied in this interim report as in the most recent Annual Report.

Revised IAS 1 Presentation of Financial Statements is applied as of January 1, 2009. This amendment affected Active Biotech's accounting retroactively as of December 31, 2007. Among other consequences, this amendment results in revenues and costs that were previously recognized directly in equity now being reported in a separate statement immediately after the income statement. Another change is that new designations for the financial statements have been used.

The Parent Company interim report has been prepared in accordance with the Swedish Annual Accounts Act and the Securities Market Act, which complies with the Swedish Financial Reporting Board's recommendation RFR 2.2, Accounting for Legal Entities. The same accounting policies and bases for calculations were applied in this interim report as in the most recent Annual Report.

Legal disclaimer

This financial report includes statements that are forward-looking, and actual results may differ materially from those anticipated. In addition to the factors discussed, other factors that can affect results are developments within research programs, including clinical trials, the impact of competing research programs, the effect of economic conditions, the effectiveness of the company's intellectual patent protection, obstacles due to technological development, exchange-rate and interest-rate fluctuations, and political risks.

2009 Annual General Meeting

The Annual General Meeting of Active Biotech AB (publ) is to be held on May 7, 2009 at 5:00 p.m. at the company's premises at Scheelevägen 22 in Lund, Sweden. Shareholders who wish to participate in the Meeting must (a) be recorded in the register of shareholders maintained by Euroclear Sweden AB on Thursday, April 30, 2009 and (b), notify the company of their intention to participate in the Meeting not later than 4:00 p.m. on Thursday, April 30, 2009. Shareholders who have trustee-registered shares must temporarily re-register the shares in their own name with Euroclear Sweden to be entitled to participate in the Meeting. This registration must be completed not later than Thursday, April 30, 2009. Accordingly, shareholders must inform the trustee of this request in ample time prior to this date.

Notice of participation can be made in writing to Active Biotech AB (publ), Attn. Susanne Jönsson, PO Box 724, SE-220 07 Lund, Sweden, by fax +46 (0)46-19 20 50, by telephone to +46 (0)46-19 20 00 or by e-mail to susanne.jonsson@activebiotech.com. The notice shall include name, personal/corporate registration number, number of shares held, daytime telephone number and, if applicable, the number of advisors (two at the most) that will accompany the shareholder at the Meeting.

The notice of the Annual General Meeting is available in its entirety on the company's website www.activebiotech.com.

Financial calendar

Interim Report January-June 2009: August 6, 2009

Interim Report January-September 2009: November 5, 2009

Year-end Report 2009: February 11, 2010

The reports will be available from these dates at www.activebiotech.com.

Lund, April 23, 2009

Active Biotech AB (publ)

Tomas Leanderson

President and CEO

This interim report has not been audited by the company's auditors.

About Active Biotech

Active Biotech AB (NASDAQ OMX NORDIC: ACTI) is a biotechnology company with R&D focus on autoimmune/inflammatory diseases and cancer. Projects in pivotal phase are laquinimod, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, as well as ANYARA for use in cancer targeted therapy, primarily of renal cancer. Further key projects in clinical development comprise the three orally administered compounds TASQ for prostate cancer, 57-57 for SLE and RhuDex™ for RA. Please visit www.activebiotech.com for more information.

Active Biotech is obligated to publish the information contained in this year-end report in accordance with the Swedish Securities Market Act. This information was provided to the media for publication on April 23, 2009 at 8:30 a.m.

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