

**Active Biotech AB
Year-end Report
January - December 2008**

- **Laquinimod — Phase III Allegro study fully enrolled**
- **57-57 — Phase II/III program only to be initiated in cooperation with partner**
- **RhuDex™ — additional preclinical trials being performed**
- **ANYARA — presentation of data in combination with established tumor drug**
- **TASQ — Phase II study proceeding as planned**
- **Net sales SEK 53.5 M (12.1)**
- **Operating loss SEK 184.6 M (loss: 202.7)**
- **Loss after tax SEK 181.6 M (loss: 207.7)**
- **Loss per share for the year was SEK 3.66 (loss: 4.47)**

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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 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. Information regarding the ongoing clinical trials is available at www.TevaClinicalTrials.com and www.clinicaltrials.gov.*

– In November 2008, Active Biotech’s partner Teva announced that patient enrolment for the clinical [Phase III Allegro study](#) had been completed. The aim of the Allegro study, which comprises more than 1,000 RRMS patients at 152 clinics throughout North America, Europe and Asia, is to evaluate the efficacy, safety and tolerability of laquinimod compared with placebo.

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. View the complete poster “**Effect on Interferon-inducible Gene Expression Signature by ABR-215757, a New Drug in Development for SLE**” on www.activebiotech.com.

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™ will be [further 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, in coordination with the MHRA, will compile a development plan for the further tests and expects these studies to be conducted in the first half of 2009.

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.

– In December 2008, results were presented where the effect of ANYARA was studied in combination with other established tumor therapies in experimental models of cancer. The results show that ANYARA can be effectively combined with other established tumor therapies such as docetaxel (Taxotere), bevacizumab (Avastin) and sunitinib (Sutent). ANYARA, combined with any of these products, had superior anti-tumor activity compared with single agent therapy. See the complete poster “**A fusion protein between a 5T4 binding antibody fragment and an engineered superantigen (ANYARA) is a targeted immunotherapy effective alone and in combination with other cancer therapies**” at www.activebiotech.com.

–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 with patient enrolment. At the end of the period, 407 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 [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.

– 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 target molecules 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, new chemical libraries of compounds were screened for binding to the target molecule.

EVENTS AFTER THE END OF THE PERIOD

57-57 – Phase II/III will not be initiated on a proprietary basis

Active Biotech has decided not to initiate a Phase II/III clinical development program for 57-57 on its own. A complete Phase II/III clinical development program has been prepared in cooperation with European and US regulatory bodies. Accordingly, the company will actively seek a partner for the continued implementation of the project during 2009.

A less extensive explorative clinical study in SLE patients will be performed during 2009/2010.

TASQ – safety profile evaluated by independent international expert group

An independent international expert group, a Data Safety Monitoring Board (DSMB), has evaluated the ongoing Clinical Phase II trial of TASQ, the prostate cancer project. The board has had access to the study's unblinded safety data and studied the side effect profile of TASQ. DSMB stated that after

analyzing long-term data concerning more than 50 patients that had been treated with TASQ, DSMB has recommended that the trial continue in accordance with the established protocol.

FINANCIAL INFORMATION

Comments on the Group results for the period January – December 2008

Net sales for the period amounted to SEK 53.5 M (12.1) and comprised a milestone payment of SEK 41.2 M from Teva Pharmaceutical Industries Ltd, service and rental revenues of SEK 10.6 M (8.8) and research grants of SEK 1.7 M (3.3) from Vinnova.

The operation's research and administration expenses totaled SEK 238.1 M (214.7), of which research costs amounted to SEK 207.4 M (189.7). The increase in costs was attributable to more comprehensive clinical trials at a later phase, primarily the Phase III trial for the ANYARA renal cancer project and the ongoing Phase II trial for the TASQ prostate cancer project. In addition, Active Biotech is conducting studies to explain the mode of action and target molecules that are behind the pharmacological effects of the quinoline compounds currently in clinical development.

Costs for Phase II trials with 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 184.6 M (loss: 202.7) was reported. The earnings improvement was attributable to increased revenues, which offset the increased costs for the more comprehensive clinical development program. Net financial income for the year totaled SEK 4.0 M (expense: 5.0), of which net interest expenses totaled SEK 3.4 M (expense: 5.0). Net financial items also include capital gains of SEK 7.4 M from the divestment of the minority holding in the UK research company, Isogenica Ltd, during the second quarter.

A loss of SEK 181.6 M (loss: 207.7) was reported after tax.

Cash flow, liquidity and financial position

At the end of the year, cash and cash equivalents amounted to SEK 138.7 M, compared to SEK 138.6 M at the end of 2007.

Accordingly, cash flow for the year amounted to SEK 0.1 M (40.7), of which cash flow from operating activities was a negative SEK 159.5 M (neg: 186.7) and cash flow from investing activities was positive at SEK 7.0 M (0.2).

Cash flow from financing activities amounted to SEK 152.6 M (227.2), with the current-year figure including the proceeds from the rights issue of SEK 153.9 M implemented during the year. The 2007 fiscal year included the proceeds from the rights issue of SEK 234.4 M implemented that year.

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 year amounted to SEK 46.4 M (6.8).

Operating expenses during the year amounted to SEK 33.2 M (30.7) and net financial items to income of SEK 50.5 M (expense 4.1). Profit after financial items amounted to SEK 63.6 M (loss: 28.0). No investments in fixed assets were made during the period.

Cash and cash equivalents, including current investments, amounted to SEK 131.6 M at year-end, compared with SEK 122.9 M on January 1, 2008.

Share capital

Consolidated shareholders' equity at the end of the year amounted to SEK 163.6 M, compared with SEK 189.6 M at year-end 2007.

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 year, the equity/assets ratio for the Group was 34.6%, compared with 38.7% at year-end 2007. The corresponding figures for the Parent Company, Active Biotech AB, were 91.1% and 70.4%, respectively.

Organization

The average number of employees was 90 employees (89), of which the average number of employees in the research and development operation accounted for 73 (73). At year-end, 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 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 and 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 year, refer to a detailed account of these factors in the directors' report in the 2007 Annual Report.

Active Biotech – Group

Income statement, condensed SEK M	Oct-Dec		Jan-Dec	
	2008	2007	2008	2007
Net sales	44.6	3.4	53.5	12.1
Administration expenses	-6.5	-6.9	-30.7	-25.0
Research and development costs	-55.7	-51.4	-207.4	-189.7
Operating loss	-17.6	-54.9	-184.6	-202.7
Net financial items	-1.0	-1.1	4.0	-5.0
Loss after financial items	-18.6	-56.0	-180.6	-207.7
Tax	-1.0	0.3	-1.0	–
Net loss for the period	-19.6	-55.7	-181.6	-207.7
Attributable to:				
Parent Company shareholders	-19.6	-55.7	-181.6	-207.7
Minority interests	–	–	–	–
Depreciation/amortization included in an amount of	2.3	4.6	11.5	18.9
Investments in tangible fixed assets	0.2	0.1	2.9	0.1
Earnings per share before dilution (SEK)	-0.38	-1.18	-3.66	-4.47
Earnings per share after dilution (SEK)	-0.38	-1.18	-3.66	-4.47
Weighted number of outstanding common shares before dilution (000s)	51 242	47 300	49 605	46 427
Weighted number of outstanding common shares after dilution (000s)	51 242	47 300	49 605	46 427
Number of shares at close of the period, thousands	51 242	47 300	51 242	47 300
Number of shares at close of the period, including warrants (000s)	52 572	48 630	52 572	48 630
Condensed balance sheet			Dec 31	
SEK M			2 008	2 007
Tangible fixed assets			324.6	329.7
Financial fixed assets			0.0	2.5
Total fixed assets			324.6	332.2
Current receivables			9.7	18.8
Cash and cash equivalents			138.7	138.6
Total current assets			148.4	157.4
Total assets			472.9	489.5
Shareholders' equity			163.6	189.6
Long-term liabilities			251.7	250.6
Current liabilities			57.6	49.3
Total shareholders' equity and liabilities			472.9	489.5
Changes in shareholders equity, condensed				
Opening balance			189.6	60.4
Personnel options program			1.5	4.1
New share issue			153.9	234.4
Convertible issue			–	98.6
Revaluation reserve			1.0	–
Translation differences			-0.6	-0.2
Net loss for the period			-181.6	-207.7
Balance at close of period			163.6	189.6

Cash-flow statement, condensed SEK M	Jan-Dec	
	2 008	2 007
Loss after financial items	-180.6	-207.7
Adjustment for non-cash items, etc.	5.4	23.5
Cash flow from operating activities before changes in working capital	-175.3	-184.2
Changes in working capital	15.8	-2.5
Cash flow from operating activities	-159.5	-186.7
Investment in tangible fixed assets	-2.9	-0.1
Investment in financial fixed assets	-	-
Decrease in financial fixed assets	9.8	0.3
Cash flow from investment activities	7.0	0.2
New share issue	153.9	234.4
Borrowing/repayment of loan liabilities	-1.2	-7.2
Cash flow from financing activities	152.6	227.2
Cash flow for the period	0.1	40.7
Opening cash and cash equivalents	138.6	97.9
Exchange-rate differences in cash and cash equivalents	-	0.0
Closing cash and cash equivalents	138.7	138.6
	Dec 31	
Key figures	2008	2007
Shareholders' equity, SEK M	163.6	189.6
Equity per share, SEK	3.19	4.01
Equity/assets ratio in the Parent Company	91.1%	70.4%
Equity/assets ratio in the Group	34.6%	38.7%
Average number of annual employees	90	89

Active Biotech – Parent Company

Condensed income statement SEK M	Oct-Dec		Jan-Dec	
	2008	2007	2008	2007
Net sales	42.1	1.7	46.4	6.8
Administration expenses	-6.8	-7.7	-33.2	-30.7
Operating profit/loss	35.3	-6.0	13.1	-23.9
<i>Profit/loss from financial items:</i>				
Profit/loss from participations in Group companies	37.6	-2.0	37.6	-8.0
Profit/loss from other securities and receivables classed as fixed assets	-	-	7.4	-
Interest income and similar income-statement items	1.4	1.3	5.5	6.3
Interest expense and similar income-statement items	0.0	0.0	0.0	-2.4
Profit/loss after financial items	74.4	-6.7	63.6	-28.0
Tax	-	-	-	-
Net profit/loss for the period	74.4	-6.7	63.6	-28.0
	Dec 31			
Condensed balance sheet SEK M	2008		2007	
Tangible fixed assets	0.4		0.4	
Financial fixed assets	202.5		231.9	
Total fixed assets	202.8		232.2	
Current receivables	10.3		66.8	
Short-term investments	-		99.5	
Cash and bank balances	131.6		23.4	
Total current assets	141.9		189.6	
Total assets	344.7		421.8	
Shareholders' equity	314.1		297.2	
Long-term liabilities	-		-	
Current liabilities	30.6		124.7	
Total equity and liabilities	344.7		421.8	

Any errors in additions are attributable to rounding of figures.

Accounting and valuation principles

Active Biotech prepares its consolidated accounts in accordance with International Financial Reporting Standards (IFRS). The interim report has been prepared in accordance with IAS 34, Interim Financial Reporting. The new or revised standards and statements of interpretation that came into effect from the 2008 fiscal year do not impact Active Biotech's financial statements. The same accounting principles were applied to this interim report as were applied in the 2007 Annual Report.

The Parent Company financial statements have been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2.1, Accounting for Legal Entities. The accounting principles are unchanged compared to those provided in the Annual Report for 2007.

Segment reporting

Active Biotech's operation comprises only one business segment, pharmaceutical development and, accordingly, the Group's income statement and balance sheet in their entirety comprise the primary segment.

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 and 2008 Annual Report

The 2009 Annual General Meeting will be held on May 7, 2009 at the company's premises on Scheelevägen 22, Lund, Sweden. A more detailed invitation to attend the Annual General Meeting will be issued closer to the time.

For the Annual General Meeting in May 2009, the election committee consists of Johnny Sommarlund, MGA Holding, Tomas Billing, Nordstjerman, Ulf Strömsten, Catella funds, and Mats Arnhög, Chairman of the Board. Individual shareholders that are not represented in the election committee can submit proposals to the election committee via the company by e-mail sent to susanne.jonsson@activebiotech.com.

Active Biotech's Annual Report for 2008 will be available on the company's website during the week beginning March 30, 2009 and be distributed by mail to the shareholders that have requested a copy.

Financial calendar

Interim Report January-March 2009: April 23, 2009

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, February 12, 2009

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 February 12, 2009 at 8:30 a.m.

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