



**Active Biotech AB
Interim Report
January - September 2008**

- **Laquinimod — positive data presented from extension study**
- **57-57 — Clinical Phase II/III trial to commence in 2009**
- **RhuDex[®] — Additional preclinical tests under way**
- **ANYARA — Phase III study proceeding as planned**
- **TASQ — Phase II study proceeding as planned**
- **Net sales SEK 8.8 M (8.7)**
- **Operating loss SEK 167.0 M (loss: 147.8)**
- **Loss after tax SEK 162.0 M (loss: 152.0)**
- **Loss per share for the period amounted to SEK 3.30 (loss: 3.30)**

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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). 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 September, data was presented from the [extension study](#) following Phase IIb, which demonstrated a significant reduction in the mean number of gadolinium-enhancing (GdE) lesions in patients who switched from placebo to laquinimod and patients who continued with their initial laquinimod dose. In RRMS patients who switched from placebo to laquinimod, a 52% reduction in the mean number of GdE lesions was observed. The reduction was significant for both patients switching to high-dose and low-dose laquinimod. The proportion of patients with no new lesions during the treatment period, increased from 31% to 47% in the patient group that switched from placebo to active treatment. The results further reinforce Active Biotech's confidence in laquinimod's potential to treat multiple sclerosis.

- Active Biotech's partner Teva Pharmaceutical Industries Ltd announced that it will shortly commence a Phase II program for laquinimod in [Crohn's disease](#).

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 studies](#) indicates that 57-57 can prevent relapses and reduce steroid use in SLE patients. The Phase II/III program is planned to commence during 2009.

- The results from the concluded [Phase Ib trial](#), performed in Sweden and Russia, are currently being compiled. Preliminary data confirms the previously exhibited favorable safety profile, and demonstrates effects on markers for the disease.

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 Germany 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](#) achieved its objective. For further information and the latest news concerning RhuDex[®], visit www.medigene.com.

- Planning of the continued clinical development program is continuing.

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. Presently, pivotal [Phase III trials](#) in patients with advanced renal cancer are under way. The primary clinical efficacy

parameter from this study 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 study is available at www.activebiotech.com and www.clinicaltrials.gov.

- The ongoing, pivotal Phase III study 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, 330 patients were 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 enhances the quality of life of patients by delaying treatment with chemotherapy. 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 study](#) show that TASQ is well-tolerated and has a favorable safety profile. The preliminary data obtained to date is encouraging. 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 during the second half of 2009.

- At the UBS Global Life Sciences conference held in New York on September 23, the follow-up efficacy data from the Phase Ib study 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 conference.

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 which 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

[Further preclinical studies of RhuDex[®]](#)

RhuDex[®] will be examined in a further series of laboratory tests, under the auspices of the UK MHRA (Medicines and Healthcare products Regulatory Agency). These in-vitro studies will examine any potential detrimental interactions between RhuDex[®] and arteriosclerotic blood vessels. MediGene will work up a development plan for these tests and coordinate it with the MHRA, and expects these studies to be conducted in the first half of 2009.

[Presentation of new data concerning the SLE project 57-57](#)

At the American College of Rheumatology scientific meeting in October 2008, new data was presented from the Phase I study of 57-57. The new results demonstrate that treatment with 57-57 can influence signaling pathways that are central for the development of the SLE disease. View the entire poster “**Effect on Interferon-inducible Gene Expression Signature by ABR-215757, a New Drug in Development for SLE**” at www.activebiotech.com.

FINANCIAL INFORMATION

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

Net sales for the period amounted to SEK 8.8 M (8.7) and included service and rental revenues of SEK 7.1 M (6.2) as well as SEK 1.7 M (2.5) in research grants from Vinnova.

The operation's research and administration expenses totaled SEK 175.8 M (156.5), of which research costs amounted to SEK 151.7 M (138.4). The increase in costs is attributable to more comprehensive clinical trials at a later phase and primarily the Phase II/III trial for the ANYARA renal cancer project, the Phase II trial for the TASQ prostate cancer project and the concluded Phase I study for the SLE project 57-57. 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.

The Group's operating loss amounted to SEK 167.0 M (loss: 147.8). The earnings trend is attributable to the increased costs for the more comprehensive clinical development program and contractual expenses for the change of CEO during the quarter. Net financial income for the period totaled SEK 5.0 M (expense: 3.9), of which net interest expenses totaled SEK 2.4 M (expense: 3.9). Net financial items also include capital gains from the divestment of the minority holding in the UK research company Isogenica Ltd of SEK 7.4 M during the second quarter.

Loss after tax amounted to SEK 162.0 M (loss: 152.0).

Liquidity and financial position

At the end of the period, cash and cash equivalents amounted to SEK 160.6 M, compared with SEK 138.6 M at the end of 2007.

The consolidated cash flow for the period amounted to SEK 21.9 M (85.1), of which cash flow from operating activities amounted to negative SEK 139.0 M (neg: 143.7).

Cash flow from financing activities amounted to SEK 153.8 M (228.5), since the current period includes the proceeds from the implemented preferential rights issue totaling SEK 153.7 M. The corresponding period in 2007 included the proceeds from the implemented preferential rights issue totaling SEK 234.4 M.

Parent Company Active Biotech AB

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 4.3 M (5.1).

Operating expenses during the period totaled SEK 26.5 M (23.0) and net financial income amounted to SEK 11.5 M (expense 3.4). Loss after financial items amounted to SEK 10.7 M (loss: 21.3). No investments in fixed assets were made during the period.

Cash and cash equivalents, including current investments, amounted to SEK 142.1 M at the end of the period, compared with SEK 163.5 M on January 1, 2008.

Share capital

Consolidated shareholders' equity at the end of the period amounted to SEK 182.0 M, compared with SEK 189.6 M at year-end 2007.

A total of 51,241,791 shares were outstanding at the end of the period. 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 shares.

At the end of the period, the equity/assets ratio for the Group was 36.5%, compared with 38.7% at year-end 2007. The corresponding figures for the Parent Company, Active Biotech AB, were 66.6% and 70.4%, respectively.

Organization

At the end of the period, the Group had 89 employees (89), of which the number of employees in the research and development operation amounted to 73 (73).

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 will have a significant impact on revenues and cash balances. The Board of Directors has determined that the present level of available liquidity and the expected revenues as specified above will provide sufficient financial resources to finance the company's operations.

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, and there are a number of factors that 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 this period, refer to a detailed account of these in the directors' report in the 2007 annual report.

Active Biotech - Group

Income statement, condensed SEK M	July-Sept		Jan-Sept		Full-year 2007
	2008	2007	2008	2007	
Net sales	3.0	2.8	8.8	8.7	12.1
Administration expenses	-11.9	-5.2	-24.1	-18.1	-25.0
Research and development costs	-53.3	-37.0	-151.7	-138.4	-189.7
Operating loss	-62.3	-39.3	-167.0	-147.8	-202.7
Net financial items	-0.5	-0.3	5.0	-3.9	-5.0
Loss after financial items	-62.7	-39.7	-162.0	-151.7	-207.7
Tax	-	-0.3	-	-0.3	-
Loss for the year	-62.7	-39.9	-162.0	-152.0	-207.7
Attributable to:					
Parent Company's shareholders	-62.7	-39.9	-162.0	-152.0	-207.7
Minority interests	-	-	-	-	-
Depreciation/amortization included in an amount of	2.3	4.7	9.1	14.3	18.9
Investment in tangible fixed assets	1.0	-	2.6	0.0	0.1
Earnings per share before dilution (SEK)	-1.22	-0.84	-3.30	-3.30	-4.47
Earnings per share after dilution (SEK)	-1.22	-0.84	-3.30	-3.30	-4.47
Weighted number of common shares before dilution (000s)	51 242	47 300	49 055	46 133	46 427
Weighted number of common shares after dilution (000s)	51 242	47 300	49 055	46 133	46 427
Number of shares at close of period (000s)	51 242	47 300	51 242	47 300	47 300
Number of shares at close of period, including warrants (000s)	52 572	48 630	52 572	48 630	48 630
Balance sheet, condensed			Sept. 30		Dec. 31
SEK M			2008	2007	2007
Tangible fixed assets			324.7	334.1	329.7
Financial assets			-	2.5	2.5
Total fixed assets			324.7	336.5	332.2
Current receivables			13.1	14.4	18.8
Cash and cash equivalents			160.6	183.0	138.6
Total current assets			173.7	197.4	157.4
Total assets			498.3	533.9	489.5
Shareholder's equity			182.0	244.7	189.6
Long-term liabilities			251.4	251.6	250.6
Current liabilities			64.9	37.6	49.3
Total shareholders' equity and liabilities			498.3	533.9	489.5
Changes in shareholders' equity, condensed					
Opening balance			189.6	60.4	60.4
Personnel options program			1.5	3.2	4.1
New share issue			153.7	234.4	234.4
Convertible issue			-	98.6	98.6
Tax attributable to items reported directly against shareholders' equity			-	0.3	-
Translation differences			-0.6	-0.2	-0.2
Net loss for the period			-162.0	-152.0	-207.7
Balance at close of period			182.0	244.7	189.6

Cash-flow statement, condensed SEK M	Jan-Sept		Full-year 2007
	2008	2007	
Loss after financial items	-162.0	-151.7	-207.7
Adjustments for items not included in the cash flow etc.	2.6	17.3	23.5
Cash flow from operating activities before changes in working capital	-159.4	-134.4	-184.2
Changes in working capital	20.4	-9.3	-2.5
Cash flow from operating activities	-139.0	-143.7	-186.7
Investments in tangible fixed assets	-2.6	0.0	-0.1
Investments in financial assets	-	-	-
Decrease in financial assets	9.8	0.3	0.3
Cash flow from investing activities	7.2	0.3	0.2
New share issue	153.7	234.4	234.4
Borrowings/repayment of debt	0.1	-5.9	-7.2
Cash flow from financing activities	153.8	228.5	227.2
Cash flow for the period	21.9	85.1	40.7
Cash and cash equivalents, beginning of the period	138.6	97.9	97.9
Exchange-rate differences in cash and cash equivalents	-	0.0	0.0
Cash and cash equivalents, end of the period	160.6	183.0	138.6
	Sept. 30		Dec. 31
Key figures	2008	2007	2007
Shareholders' equity (SEK M)	182.0	244.7	189.6
Shareholders' equity per share (SEK)	3.55	5.17	4.01
Equity/assets ratio in Parent Company	66.6%	73.8%	70.4%
Equity/assets ratio in Group	36.5%	45.8%	38.7%
Average number of employees	89	89	89

Active Biotech - Parent Company

Income Statement, condensed SEK M	July-Sept		Jan-Sept		Full Year 2007
	2008	2007	2008	2007	
Net Sales	0.9	1.7	4.3	5.1	6.8
Administration expenses	-12.2	-6.3	-26.5	-23.0	-30.7
Operating loss	-11.3	-4.6	-22.2	-17.9	-23.9
<i>Profit/loss from financial items:</i>					
Loss from participations in Group companies	-	-6.0	-	-6.0	-8.0
Profit from other securities and receivables that are fixed assets	-	-	7.4	-	-
Interest income and similar items	2.1	1.6	4.1	5.0	6.3
Interest expenses and similar items	0.0	0.0	0.0	-2.4	-2.4
Loss after financial items	-9.2	-9.0	-10.7	-21.3	-28.0
Tax	-	-	-	-	-
Loss for the year	-9.2	-9.0	-10.7	-21.3	-28.0
Balance sheet, condensed			Sept. 30		Dec. 31
SEK M			2008	2007	2007
Tangible fixed assets			0.4	0.4	0.4
Financial assets			229.4	231.9	231.9
Total fixed assets			229.8	232.2	232.2
Current receivables			69.2	69.0	66.8
Current investments			75.0	99.7	99.5
Cash and bank balances			67.1	63.8	23.4
Total current assets			211.3	232.5	189.6
Total assets			441.0	464.7	421.8
Shareholders' equity			293.6	343.2	297.2
Long-term liabilities			-	-	-
Current liabilities			147.5	121.5	124.7
Total shareholders' equity and liabilities			441.0	464.7	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, 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

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.

Financial calendar

Year-end Report 2008: February 12, 2009
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.

Active Biotech AB (publ)

The Board and the President hereby give their assurance that this interim report for the period January 1, 2008 – September 30, 2008 provides a true and fair overview of the Parent Company's and the Group's operations, position and earnings, and describes key risks and uncertainty factors facing the Parent Company and the companies that are part of the Group.

Lund, November 14, 2008

Mats Arnhög <i>Chairman of the Board</i>	Klas Kärre <i>Board member</i>	Magnhild Sandberg-Wollheim <i>Board member</i>	Peter Sjöstrand <i>Board member</i>
Peter Ström <i>Board member</i>	Anette Sundstedt <i>Employee representative/ Board member</i>	Karin Hallbeck <i>Employee representative/ Board member</i>	

Tomas Leanderson
President and CEO

Review report

Introduction

We have conducted a review of the interim report for Active Biotech AB (Corp. Reg. No. 556223-9227) on September 30, 2008 and the nine-month period leading up to this date. The Board of Directors and the President are responsible for preparing and presenting this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Focus and scope of the review

We have conducted our review in accordance with the Standard on Review Engagements SÖG 2410, *Review of Interim Financial Information 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 has a different direction and is substantially more limited in scope than an audit conducted in accordance with Standards of Auditing in Sweden, RS, and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that, in all material respects, the accompanying interim report for the Group has not been prepared in accordance with IAS 34 and the Annual Accounts Act and the interim report for the Parent Company has not been prepared in accordance with the Annual Accounts Act.

Stockholm, November 14, 2008

KPMG AB
Stefan Holmström
Authorized Public Accountant

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 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 press release in accordance with the Swedish Securities Market Act. This information was provided to the media for publication on November 14, 2008, at 8:30 a.m.

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