

**Active Biotech AB
Year-end Report
January – December 2009**

- **Laquinimod — Phase III program proceeding according to plan**
- **57-57 — exploratory clinical trial in progress**
- **RhuDex[™] — additional preclinical studies to be conducted in 2010**
- **ANYARA — Phase III trials proceeding according to plan**
- **TASQ — primary endpoint met in clinical Phase II**
- **ISI — project proceeding according to plan**
- **Net sales of SEK 10.8 M (53.5)**
- **Operating loss of SEK 219.6 M (loss: 184.6)**
- **Loss after tax of SEK 224.0 M (loss: 181.6)**
- **Loss per share for the period amounted to SEK 3.81 (loss: 3.66)**

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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 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.*

[New data](#) was presented in September 2009 showing that laquinimod has both neuroprotective and anti-inflammatory properties. Results from several preclinical studies suggest that laquinimod reduces demyelination and induces axonal protection.

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. Teva completed patent enrolment for the first of two Phase III studies ([Allegro](#)) in November 2008 and the second ([Bravo](#)) in June 2009. 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. Fast Track designation can potentially facilitate development and expedite the review process. This may allow the drug to enter the market as soon as late 2011.

– The clinical Phase III program is proceeding according to plan.

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 but it 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, which showed that patients treated with TASQ developed few new bone metastases for example. In September 2009, the results from the Phase I trial of [TASQ](#) were published in the British Journal of Cancer. The results showed that long-term continuous oral administration of TASQ seems to be safe and that TASQ might delay disease progression.

– It was announced in December 2009 that the primary endpoint of the [Phase II clinical study](#), to show a lower fraction of patients with disease progression during the six-month period of treatment using TASQ, had been reached. The percentage of patients with disease progression during the six-month period was 43% for patients treated with TASQ compared with 67% for placebo treated patients. The median progression-free survival was 24.7 weeks for the TASQ group, compared to 12.9 weeks (p=0.0001) for the placebo group.

TASQ treatment also had a positive effect on several biomarkers relevant for prostate cancer progression and was generally well tolerated. The trial is a 2:1 random, placebo-controlled, double-blind study of 1 mg/day TASQ, compared with placebo. The study includes symptom-free patients with metastasized, hormone-resistant prostate cancer.

The top line data presented is based on the local review of disease progression and an additional central review is currently ongoing. Complete results from the trial, including additional details and data from the central review, will be presented at an upcoming scientific conference and in scientific publications.

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 cell 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 cell cancer and pancreatic cancer. The median survival of 26.2 months observed for patients with advanced renal cell cancer and treated with ANYARA is twice the expected length. In July 2009, the results from two Phase I studies of [ANYARA](#) were published in the *Journal of Clinical Oncology*, where ANYARA was studied both as a single agent (monotherapy) and in combination with an established tumor therapy – docetaxel (Taxotere®) – in patients with advanced cancer. The results showed that ANYARA was well tolerated both as monotherapy and in combination with docetaxel. Pivotal [Phase III trials](#) in patients with advanced renal cell cancer are currently under way. The [Phase III trials](#) were fully enrolled in June 2009. 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 cell cancer. Information concerning the ongoing clinical trial is available at www.activebiotech.com and www.clinicaltrials.gov.

– The ongoing Phase III study is progressing according to plan. The study is evaluating the effect of ANYARA in combination with interferon-alpha, compared with interferon-alpha alone, in patients with advanced renal cell cancer. The primary clinical efficacy parameter from this trial is overall survival and the current assessment is that the results will be presented in the first half of 2011.

57-57 – 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. Updated data from the completed clinical [Phase Ib trial](#) of 57-57 was presented in June 2009 at the 10th Annual Congress of the European League against Rheumatism (EULAR) – an international event for specialists in the field of rheumatology. The overall safety profile throughout the study was favorable. The new results strengthen previous data which indicated that treatment with 57-57 could normalize pathways known to be important in SLE pathogenesis. Read the entire poster A Phase I, Dose-Escalation Study to Evaluate the Tolerability of ABR-215757 in patients with Systemic Lupus Erythematosus (SLE) [here](#). A small-scale exploratory clinical study in SLE patients is being conducted in Sweden and Denmark. This study will include a maximum of 20 patients. Several parameters that correlate with the disease activity will be studied in detail. The study is expected to be concluded during 2010. For further information about the study, visit www.clinicaltrials.gov.

– The exploratory clinical study is proceeding according to plan.

ISI (Inhibition of S100 Interactions) – preclinical project based on the mode of action of quinoline compounds

Active Biotech is conducting a new research project aimed at utilizing 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 [results](#) of the target molecule for the Q compounds were published in *PLoS Biology* ([Volume 7, Issue 4, pp. 800-812](#)) in April 2009. The study shows that Q compounds bind to a molecule called S100A9, which is expressed in some white blood cells involved in the regulation of immune responses. Furthermore, it is shown that S100A9 interacts with two known pro-inflammatory receptors (Toll like receptor 4 (TLR4) and receptor of advanced glycation end products (RAGE)) and that this interaction is inhibited by Q compounds. The project aims at producing new, patentable chemical substances that interact with the target molecule of the Q compounds. The aim is to select a candidate drug during 2010.

– The project is proceeding according to plan.

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

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 AG](#), 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.

– After UK MHRA agreed to the continuation of the clinical development of RhuDex in October 2009, [MediGene announced](#) prior to the end of the year that further preclinical studies were to be conducted in 2010 to optimize the clinical program. Clinical trials are expected to be resumed at the end of 2010 or beginning of 2011.

Events after the end of the period

[Teva acquires marketing rights for laquinimod in the Nordic region and Baltic States](#)

Teva Pharmaceutical Industries and Active Biotech announced on February 8 that they had amended the marketing and distribution agreement for oral laquinimod, an investigational treatment for relapsing-remitting multiple sclerosis (RRMS). Under the new agreement, Teva extended its marketing and distribution rights to include the Nordic and Baltic regions, previously held by Active Biotech. Active Biotech will receive a higher royalty rate for sales in these territories compared to the royalty rate set under the original licensing agreement signed in 2004 for sales in the rest of the world.

[Exploratory data presented for Active Biotech's ANYARA project](#)

On February 10, Active Biotech presented results from exploratory preclinical studies at the Keystone Symposia "Molecular and Cellular Biology of Immune Escape in Cancer" held in Keystone, Colorado, USA, February 7-12. The complete poster "Combining tumor-targeted superantigens with anti-CTLA-4 results in synergistic anti-tumor effects in B16 tumor bearing mice" can be viewed at www.activebiotech.com. The results of the study demonstrate that TTS therapy can be further enhanced by specifically modulating the immune response in this experimental model.

Financial information

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

Net sales for the period amounted to SEK 10.8 M (53.5) and derived from service and rental revenues. The figure for the year-earlier period also included a milestone payment of SEK 41.2 M from Teva, service and rental revenues of SEK 10.6 M and research grants of SEK 1.7 M from Vinnova.

The operation's research and administration expenses totaled SEK 230.3 M (238.1). The decrease in costs was due to lower administration expenses. Research costs amounted to SEK 212.0 M (207.4). The increase in costs was 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 to the abovementioned clinical projects, Active Biotech is conducting a new preclinical research project, ISI, aimed at utilizing the company's own preclinical results that were generated around a target molecule for the Q compounds and their biological mode of action. Costs for the period were also negatively impacted by the weakening of the SEK against the EUR and USD in 2009, since approximately 47% of research costs consist of purchased research services that are primarily invoiced in foreign currency.

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

An operating loss of SEK 219.6 M (loss: 184.6) was reported. Net financial expense for the period totaled SEK 4.4 M (income: 4.0), with net financial income for the year-earlier period including a capital gain of SEK 7.4 M from the divestment of the minority holding in Isogenica Ltd. A loss of SEK 224.0 M (loss: 181.6) was reported after tax.

Cash flow, liquidity and financial position

Cash and cash equivalents and short-term investments amounted to SEK 156.0 M at the end of the period, compared with SEK 138.7 M at the end of 2008.

Accordingly, cash flow for the period amounted to SEK 17.3 M (0.1), of which cash flow from operating activities was a negative SEK 224.8 M (neg: 159.5). Cash flow from financing activities totaled SEK 242.1 M (152.6), with the current year including a rights issue that generated SEK 249.0 M and the corresponding period in 2008 including a rights issue that contributed SEK 153.9 M to the company.

Investments

Investments in tangible fixed assets amounted to SEK 0.1 M (2.9).

Dividend

The Board of Directors proposes that no dividend be paid for the fiscal year.

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 3.5 M (46.4).

Operating expenses during the period totaled SEK 22.2 M (33.2) and net financial items amounted to income of SEK 2.3 M (50.5). Loss after financial items amounted to SEK 16.3 M (loss: 63.6). No investments in fixed assets were made during the period.

Cash and cash equivalents, including short-term investments, totaled SEK 144.2 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 188.6 M, compared with SEK 163.6 M at year-end 2008.

A total of 64,052,238 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 could increase to a maximum of about 65.0 million.

At the end of the period, the equity/assets ratio for the Group was 37.8%, compared with 34.6% at year-end 2008. The corresponding figures for the Parent Company, Active Biotech AB, were 93.9% and 91.1%, respectively.

Organization

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

Implemented rights issue

On May 7, 2009, the Annual General Meeting resolved to implement a guaranteed rights issue to strengthen the company's financial position and drive the development of the company's clinical project portfolio. The issue entitled 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 (15.4%), had undertaken to subscribe for the full amount of shares corresponding to their preferential rights. In addition, MGA Holding AB and Nordstjernan AB had undertaken, in the event the issue was not fully subscribed, to subscribe for any additional shares not subscribed with the support of preferential rights.

The issue was oversubscribed by 71% and contributed approximately SEK 249 M to the company after issue expenses.

Election Committee

In accordance with a decision made by the Annual General Meeting held on May 7, 2009, the Election Committee shall comprise the representatives of the three largest shareholders on September 30 and

the Board Chairman. For the 2010 Annual General Meeting, the Election Committee shall propose Board members and a Board Chairman, and fees to Board members and auditors. The following individuals were appointed representatives of the largest shareholders and, accordingly, are members of the Election Committee:

Johnny Sommarlund, MGA Holding
Tomas Billing, Nordstjernan
Peter Thelin, Brummer & Partners

Under the leadership of the Board Chairman Mats Arnhög, the Election Committee shall prepare proposals for the Board of Directors that are to be presented to and decided upon at the Annual General Meeting on May 6, 2010.

Outlook, including significant risks and uncertainties

A vital factor for Active Biotech's long-term 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 projects is expected to increase. The development of partnership agreements already signed and the addition of new agreements are assumed to have a significant impact on future revenues and cash balances. The Board of Directors is of the opinion that the present level of available liquidity 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, regulatory requirements, capital requirements, currencies and interest rates. Since no significant changes took place with regard to risks and uncertainties during the period, refer to the detailed account of these factors presented in the Directors' report in the 2008 Annual Report.

Condensed consolidated statement of comprehensive income SEK M	Oct - Dec		Jan - Dec	
	2009	2008	2009	2008
Net sales	3.0	44.6	10.8	53.5
Administrative expenses	-4.8	-6.5	-18.3	-30.7
Research and development costs	-53.2	-55.7	-212.0	-207.4
Operating loss	-54.9	-17.6	-219.6	-184.6
Net financial items	-3.9	-1.0	-4.4	4.0
Loss after financial items	-58.8	-18.6	-224.0	-180.6
Tax	-	-1.0	-	-1.0
Net loss for the period	-58.8	-19.6	-224.0	-181.6
Comprehensive loss attributable to:				
Parent company shareholders	-58.8	-19.6	-224.0	-181.6
Minority interest	-	-	-	-
Net loss for the period	-58.8	-19.6	-224.0	-181.6
Other comprehensive income during the period				
Change in revaluation reserve	-0.3	-0.3	-1.3	-1.3
Change in translation reserve	-	-	-	-0.6
Taxes attributable to other comprehensive income	0.1	1.1	0.3	1.3
Comprehensive loss for the period	-59.1	-18.8	-224.9	-182.2
Comprehensive loss attributable to:				
Parent company shareholders	-59.1	-18.8	-224.9	-182.2
Minority interest	-	-	-	-
Comprehensive loss for the period	-59.1	-18.8	-224.9	-182.2

Depreciation/amortization included in the amount of	2.4	2.3	9.6	11.5
Investments in tangible fixed assets	-	0.2	0.1	2.9
Earnings per share before dilution (SEK)	-0.92	-0.38	-3.81	-3.66
Earnings per share after dilution (SEK)	-0.92	-0.38	-3.81	-3.66
Comprehensive loss per share before dilution (SEK)	-0.92	-0.37	-3.83	-3.67
Comprehensive loss per share after dilution (SEK)	-0.92	-0.37	-3.83	-3.67
Weighted number of outstanding common shares before dilution (000s)	64 052	51 242	58 753	49 605
Weighted number of outstanding common shares after dilution (000s)	64 052	51 242	58 753	49 605
Number of shares at close of the period (000s)	64 052	51 242	64 052	51 242
Outstanding warrants (000s)	779	1 330	779	1 330
- entitlement to number of shares after full exercise (000s)	958	1 423	958	1 423

Consolidated balance sheet, condensed

SEK M	Dec 31	
	2009	2008
Tangible fixed assets	319.0	324.6
Financial fixed assets	0.0	0.0
Total fixed assets	319.0	324.6
Current receivables	23.5	9.7
Cash and cash equivalents	156.0	138.7
Total current assets	179.5	148.4
Total assets	498.5	472.9
Shareholders equity	188.6	163.6
Long-term liabilities	248.0	251.7
Current liabilities	61.9	57.6
Total shareholders equity and liabilities	498.5	472.9

Consolidated statement of changes in shareholders equity

Opening balance	163.6	189.6
Personnel options program	-	1.5
Transfer from revaluation reserve	1.0	0.9
New share issue	249.0	153.9
Net loss for the period	-224.9	-182.2
Balance at close of period	188.6	163.6

Condensed consolidated cash-flow statement

SEK M	Jan - Dec	
	2009	2008
Loss after financial items	-224.0	-180.6
Adjustment for non-cash items, etc.	9.6	5.4
Cash flow from operating activities before changes in working capital	-214.4	-175.3
Changes in working capital	-10.4	15.8
Cash flow from operating activities	-224.8	-159.5
Investments in tangible fixed assets	-0.1	-2.9
Investments in financial fixed assets	-	-
Decrease in financial fixed assets	-	9.8
Cash flow from investing activities	-0.1	7.0
New share issue	249.0	153.9
Loans raised/amortization of loan liabilities	-6.9	-1.2
Cash flow from financing activities	242.1	152.6
Cash flow for the period	17.3	0.1
Opening cash and cash equivalents	138.7	138.6
Closing cash and cash equivalents	156.0	138.7

Key figures	Dec 31	
	2009	2008
Shareholders equity, SEK M	188.6	163.6
Equity per share, SEK	2.95	3.19
Equity/assets ratio in the Parent Company	93.9%	91.1%
Equity/assets ratio in the Group	37.8%	34.6%
Average number of annual employess	90	90

Parent Company, income statement, condensed SEK M	Oct - Dec		Jan - Dec	
	2009	2008	2009	2008
Net sales	0.9	42.1	3.5	46.4
Administration expenses	-9.5	-6.8	-22.2	-33.2
Operating profit/loss	-8.6	35.3	-18.7	13.1
<i>Profit/loss from financial items:</i>				
Profit/loss from participations in Group companies	-	37.6	-	37.6
Profit/loss from other securities and receivables classed as fixed assets	-	-	-	7.4
Interest income and similar income-statement items	0.7	1.4	2.3	5.5
Interest expense and similar income-statement items	0.0	0.0	0.0	0.0
Profit/loss after financial items	-7.9	74.4	-16.3	63.6
Tax	-	-	-	-
Net profit/loss for the period	-7.9	74.4	-16.3	63.6

Parent Company, balance sheet, condensed SEK M	Dec 31	
	2009	2008
Tangible fixed assets	0.4	0.4
Financial fixed assets	202.5	202.5
Total fixed assets	202.8	202.8
Current receivables	17.0	10.3
Short-term investments	50.0	-
Cash and bank balances	94.2	131.6
Total current assets	161.1	141.9
Total assets	363.9	344.7
Shareholders equity	341.8	314.1
Long-term liabilities	-	-
Current liabilities	22.1	30.6
Total equity and liabilities	363.9	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 recognized 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 stipulations in 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 in 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.

2010 Annual General Meeting

The 2010 Annual General Meeting will be held on May 6, 2010 at the company's premises on Scheelevägen 22 in Lund. A more detailed invitation to attend the Annual General Meeting will be issued closer to the time.

Financial calendar

Interim Report January – March 2010: April 22, 2010

Interim Report January – June 2010: August 11, 2010

Interim Report January – September 2010: October 27, 2010

Year-end Report 2010: February 10, 2011

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

Lund, February 11, 2010
Active Biotech AB (publ)

Tomas Leanderson
President and CEO

This Year-end 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 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 interim report in accordance with the Swedish Securities Market Act. This information was provided to the media for publication on February 11, 2010 at 8:30 a.m.

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