

Active Biotech AB
Interim report
January – March 2010

- **Laquinimod — Teva extends its marketing and distribution rights for laquinimod**
- **TASQ — preparations for Phase III trials under way**
- **ANYARA — exploratory combination data presented**
- **57-57 — exploratory clinical trial in progress**
- **ISI — project proceeding according to plan**
- **RhuDex™ — preclinical studies in progress**
- **Net sales of SEK 2.8 M (2.2)**
- **Operating loss of SEK 51.0 M (loss: 63.7)**
- **Loss after tax of SEK 53.5 M (loss: 62.2)**
- **Loss per share for the period amounted to SEK 0.83 (loss: 1.21)**
- **After the end of the period a directed share issue raised approximately SEK 149 M for the company**

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This report is also available at www.activebiotech.com

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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.

[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 patient 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.

– Teva and Active Biotech announced on February 8 that they had amended the marketing and distribution agreement for laquinimod. 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 with the royalty rate set under the original licensing agreement for sales in the rest of the world.

– 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. 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 higher fraction of patients with no 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 with 12.9 weeks ($p=0.0001$) for the placebo group.

– Complete results from the Phase II trial, including additional details and data from the central review, will be presented at an upcoming scientific conference during the first half of 2010 and in scientific journals.

– Preparations for Phase III trials are under way.

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 and 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.

– 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 as in this experimental model.

– 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. 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 up to 20 patients. Several parameters that correlate with the disease activity will be studied in detail. The study is expected to be concluded in 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 in 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.

– Preclinical studies are currently in progress to optimize the clinical development program. Clinical trials are expected to be resumed at the end of 2010 or beginning of 2011.

Events after the end of the period

[Active Biotech raises SEK 149 M through a directed share issue](#)

On April 1, 2010, the Board of Directors – pursuant to the authorization given by the 2009 AGM – resolved to implement a directed share issue comprising 1,418,000 shares placed in funds managed by Sectoral Asset Management. The shares were issued at a subscription price of SEK 105 per share, corresponding to issue proceeds of approximately SEK 149 M (www.sectoral.com).

[New data suggest oral laquinimod may confer neuroprotection in addition to immunomodulation in the treatment of multiple sclerosis](#)

On April 15, 2010, Active Biotech and Teva presented data at the 62nd Annual Meeting of the American Academy of Neurology (AAN) demonstrating that laquinimod may have neuroprotective properties in addition to its anti-inflammatory effects.

Financial information

Comments on the Group's results for the period January – March 2010

Net sales for the period amounted to SEK 2.8 M (2.2) and derived from service and rental revenues.

The operation's research and administration expenses totaled SEK 53.7 M (65.9). Research costs amounted to SEK 49.1 M (61.5). The reduction in costs compared with the year-earlier period was attributable to lower costs in the ongoing Phase III trial for the ANYARA renal cancer project and relatively limited cost for the ongoing exploratory study in the SLE project 57-57. In addition to the clinical projects, Active Biotech is conducting the preclinical research project, ISI, aimed at utilizing the company's own research results that were generated around a target molecule for the Q compounds and their biological mode of action. Costs for the period were positively impacted by the strengthening of the SEK against the EUR and USD.

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 51.0 M (loss: 63.7) was recognized. Net financial expense for the period totaled SEK 2.5 M (income: 1.5). A loss of SEK 53.5 M (loss: 62.2) was recognized after tax.

Cash flow, liquidity and financial position

Cash and cash equivalents and short-term investments amounted to SEK 110.6 M at the end of the period, compared with SEK 156.0 M at the end of 2009.

Cash flow for the period amounted to a negative SEK 45.4 M (neg: 67.0), of which cash flow from operating activities was a negative SEK 50.5 M (neg: 65.1). Cash flow from financing activities totaled SEK 5.1 M (neg: 1.9), the latter of which was attributable to the exercise of employee stock options.

Investments

Investments in tangible fixed assets amounted to SEK 0.0 M (0.0).

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 (0.9).

Operating expenses during the period totaled SEK 4.9 M (4.7) and net financial items amounted to income of SEK 0.2 M (0.4). Loss after financial items amounted to SEK 3.7 M (loss: 3.4). No investments in fixed assets were made during the period.

Cash and cash equivalents, including short-term investments, totaled SEK 98.1 M at the end of the period, compared with SEK 144.2 M on January 1, 2010.

Share capital

Consolidated shareholders' equity at the end of the period amounted to SEK 142.0 M, compared with SEK 188.6 M at year-end 2009.

A total of 64,175,530 shares were outstanding at the end of the period. As a result of the share issue implemented in April and in the event of redemption of share warrants outstanding, the number of shares in Active Biotech could increase to a maximum of about 66.4 million.

At the end of the period, the equity/assets ratio for the Group was 32.0%, compared with 37.8% at year-end 2009. The corresponding figures for the Parent Company, Active Biotech AB, were 95.5% and 93.9%, respectively.

Organization

The average number of employees was 89 (90), with the average number of employees in the research and development operation accounting for 74 (73). At the end of the period, the Group had 88 employees (90).

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 2009 Annual Report.

Condensed consolidated statement of comprehensive income SEK M	January -March		Full year
	2010	2009	2009
Net sales	2.8	2.2	10.8
Administrative expenses	-4.6	-4.4	-18.3
Research and development costs	-49.1	-61.5	-212.0
Operating loss	-51.0	-63.7	-219.6
Net financial items	-2.5	1.5	-4.4
Loss after financial items	-53.5	-62.2	-224.0
Tax	-	-	-
Net loss for the period	-53.5	-62.2	-224.0
Comprehensive loss attributable to:			
Parent company shareholders	-53.5	-62.2	-224.0
Minority interest	-	-	-
Net loss for the period	-53.5	-62.2	-224.0
Other comprehensive income during the period			
Change in revaluation reserve	-0.3	-0.3	-1.3
Taxes attributable to other comprehensive income	0.1	0.1	0.3
Comprehensive loss for the period	-53.8	-62.5	-224.9
Comprehensive loss attributable to:			
Parent company shareholders	-53.8	-62.5	-224.9
Minority interest	-	-	-
Comprehensive loss for the period	-53.8	-62.5	-224.9
Depreciation/amortization included in the amount of	2.4	2.4	9.6
Investments in tangible fixed assets	-	-	0.1
Earnings per share before dilution (SEK)	-0.83	-1.21	-3.81
Earnings per share after dilution (SEK)	-0.83	-1.21	-3.81
Comprehensive loss per share before dilution (SEK)	-0.84	-1.22	-3.83
Comprehensive loss per share after dilution (SEK)	-0.84	-1.22	-3.83
Weighted number of outstanding common shares before dilution (000s)	64 116	51 242	58 753
Weighted number of outstanding common shares after dilution (000s)	64 116	51 242	58 753
Number of shares at close of the period (000s)	64 176	51 242	64 052
Outstanding warrants (000s)	678	1 330	779
- entitlement to number of shares after full exercise (000s)	834	1 423	958

Consolidated balance sheet, condensed SEK M	March 31		Dec. 31
	2010	2009	2009
Tangible fixed assets	316.8	325.5	319.0
Financial fixed assets	0.0	0.0	0.0
Total fixed assets	316.8	325.5	319.0
Current receivables	16.1	13.2	23.5
Cash and cash equivalents	110.6	71.8	156.0
Total current assets	126.7	84.9	179.5
Total assets	443.4	410.4	498.5
Shareholders equity	142.0	101.2	188.6
Long-term liabilities	246.3	253.3	248.0
Current liabilities	55.1	55.9	61.9
Total shareholders equity and liabilities	443.4	410.4	498.5

Consolidated statement of changes in shareholders equity			
Opening balance	188.6	163.6	163.6
Transfer from revaluation reserve	0.2	0.2	1.0
New share issue	6.9	-0.2	249.0
Net loss for the period	-53.8	-62.5	-224.9
Balance at close of period	142.0	101.2	188.6

Condensed consolidated cash-flow statement SEK M	January- March		Full year
	2010	2009	2009
Loss after financial items	-53.5	-62.2	-224.0
Adjustment for non-cash items, etc.	2.4	2.4	9.6
Cash flow from operating activities before changes in working capital	-51.1	-59.9	-214.4
Changes in working capital	0.6	-5.2	-10.4
Cash flow from operating activities	-50.5	-65.1	-224.8
Investments in tangible fixed assets	-	-	-0.1
Cash flow from investing activities	-	-	-0.1
New share issue	6.9	-0.2	249.0
Loans raised/amortization of loan liabilities	-1.9	-1.7	-6.9
Cash flow from financing activities	5.1	-1.9	242.1
Cash flow for the period	-45.4	-67.0	17.3
Opening cash and cash equivalents	156.0	138.7	138.7
Closing cash and cash equivalents	110.6	71.8	156.0
		March 31	Dec. 31
Key figures	2010	2009	2009
Shareholders equity, SEK M	142.0	101.2	188.6
Equity per share, SEK	2.21	1.98	2.95
Equity/assets ratio in the Parent Company	95.5%	92.8%	93.9%
Equity/assets ratio in the Group	32.0%	24.7%	37.8%
Average number of annual employess	89	90	90

Active Biotech - parent company

Income statement, condensed SEK M	January- March		Full year
	2010	2009	2009
Net sales	0.9	0.9	3.5
Administration expenses	-4.9	-4.7	-22.2
Operating profit/loss	-4.0	-3.8	-18.7
<i>Profit/loss from financial items:</i>			
Interest income and similar income-statement items	0.2	0.4	2.3
Interest expense and similar income-statement items	0.0	0.0	0.0
Profit/loss after financial items	-3.7	-3.4	-16.3
Tax	-	-	-
Net profit/loss for the period	-3.7	-3.4	-16.3
		March 31	Dec. 31
Balance sheet, condensed SEK M	2010	2009	2009
Tangible fixed assets	0.4	0.4	0.4
Financial fixed assets	202.5	202.5	202.5
Total fixed assets	202.8	202.8	202.8
Current receivables	60.4	11.3	17.0
Short-term investments	50.0	-	50.0
Cash and bank balances	48.1	55.9	94.2
Total current assets	158.5	67.1	161.1
Total assets	361.3	269.9	363.9
Shareholders equity	345.0	250.5	341.8
Long-term liabilities	-	-	-
Current liabilities	16.3	19.4	22.1
Total equity and liabilities	361.3	269.9	363.9

Any errors in additions are attributable to rounding of figures.

Accounting policies and valuation principles

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

The Parent Company interim report was 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 2.3 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.

Annual General Meeting 2010

The Annual General Meeting will be held on May 6, 2010 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 (formerly VPC AB) on Thursday, April 29, 2010 and (b), notify the company of their intention to participate in the Meeting not later than 4:00 p.m. on Thursday, April 29, 2010. 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 29, 2010. 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, the Annual report and related documents are available in its entirety on the company's website www.activebiotech.com.

Financial calendar

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, April 22, 2010

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 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 April 22, 2010 at 8:30 a.m.

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