

**Active Biotech AB
Interim report
January - June 2010**

- **Laquinimod** — Phase III trials proceeding as planned
- **TASQ** — final Phase II data presented at ASCO. Phase III preparations proceeding on schedule
- **ANYARA** — article published in *Journal of Immunotherapy*
- **57-57** — exploratory clinical trial under way. Development for treatment of orphan drug indication (systemic sclerosis/scleroderma) initiated
- **ISI** — project continuing according to plan
- **RhuDex[™]** — preclinical studies completed during the year
- **Net sales of SEK 6.1 M (5.2)**
- **Operating loss of SEK 102.4 M (loss: 118.5)**
- **Loss after tax SEK 108.3 M (loss: 118.6)**
- **Loss per share for the period amounted to SEK 1.67 (loss: 2.22)**
- **The company received approximately SEK 149 M from a directed share issue, cash and cash equivalents at the end of the period amounted to SEK 235 M**

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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 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.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.

– In April 2010, Teva presented new data that indicates laquinimod's ability to confer neuroprotective properties in addition to its anti-inflammatory effects. The trials were presented at the 62nd Annual Meeting of the American Academy of Neurology (AAN). The studies of the MS patients demonstrate that treatment with laquinimod results in a significant increase in the brain-derived neurotrophic factor (BDNF) in blood, a key protein responsible for the maintenance of mature neurons.

In addition, data from new animal models shows that following treatment with laquinimod there was significant reduction in the extent of demyelination, and more axonal preservation within spinal cord lesions. Furthermore, treatment with laquinimod inhibited the infiltration of inflammatory cells into the spinal cord and brain as well as causing a positive shift in specific white blood cells involved in MS pathology.

These new findings suggest laquinimod may have neuroprotective properties in addition to anti-inflammatory effects. Coupled with the Phase IIb study results, which demonstrated that oral laquinimod is effective and safe in MS patients, this data provides further insight into the contributing factors surrounding the favorable benefit-risk profile associated with this compound to date.

– The clinical Phase III program for the treatment of MS is continuing on schedule. The clinical Phase II trial for the treatment of Crohn's disease is also 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.

– Complete results from the randomized, placebo-controlled, double-blind clinical Phase II trial were presented at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago on June 7, 2010.

The primary endpoint, to show a difference in the number of patients with disease progression at six months, was, as previously reported, reached. Updated results showed that the fraction of patients with disease progression during the six month period was 31% for patients treated with TASQ compared with 66% for placebo-treated patients ($p < 0.0001$). The median progression-free survival was 7.6 months for the TASQ group, compared to 3.2 months for the placebo group ($p = 0.0009$). TASQ

treatment also had an effect on biomarkers relevant for prostate cancer progression and was generally well tolerated.

– Data relating to the mode of action of TASQ was presented in May 2010 in the scientific journal *Molecular Cancer*. Studies concluded that TASQ exhibits anti-tumor activity via inhibition of tumor angiogenesis. The up-regulation of the anti-angiogenic protein thrombospondin-1 (TSP1) is a part of this mechanism.

ANYARA – a fusion protein for immunological treatment of renal cancer

ANYARA is a [TTS](#) (Tumor Targeting Superantigen) 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 are fully enrolled since 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.

– In May 2010, the ANYARA project was published in the *Journal of Immunotherapy*. The results presented in the article show that tumor reactivity and therapeutic window were improved in ANYARA compared with earlier product candidates.

– 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 during 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 a 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

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 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 aimed at optimizing the clinical development program were completed during the year. Clinical trials are expected to be resumed in the first quarter of 2011.

Events after the end of the period

– Preparations for clinical Phase III development of TASQ against prostate cancer are in progress. Advisory meetings with regulatory bodies have been concluded. The company intends to submit an application for the initiation of a global, pivotal clinical trial – with progression-free survival (PFS) as the primary endpoint – in the third quarter of 2010. Final regulatory approval for the proposed trial is expected before the end of 2010, with studies set to commence in early 2011.

– The company has decided to initiate the development of the ABR-215757 compound for the treatment of systemic sclerosis/scleroderma. This rare disease is an orphan drug indication. The launch of an initial, explorative clinical study for the treatment of systemic sclerosis/scleroderma is expected to take place in the first six months of 2011.

Financial information

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

Net sales for the period amounted to SEK 6.1 M (5.2) and derived from service and rental revenues.

The operation's research and administration expenses totaled SEK 108.6 M (123.7). Research expenses amounted to SEK 96.8 M (114.1). The reduction in expenses 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 costs 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 appreciation of the SEK against the EUR and USD. Administration expenses amounted to SEK 11.8 M (9.6), the deviation refers to increased employment tax in relation to employees exercise of stock options during the period.

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.

The company recognized an operating loss of SEK 102.4 M (loss: 118.5). Net financial items totaled an expense of SEK 5.9 M (expense: 0.1). A loss of SEK 108.3 M (loss: 118.6) was recognized after tax.

Cash flow, liquidity and financial position

Cash and cash equivalents and short-term investments amounted to SEK 235.3 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 SEK 79.3 M (120.7), of which cash flow from operating activities was a negative SEK 93.9 M (neg: 123.3). Cash flow from financing activities totaled SEK 173.2 M as a result of the implementation of the directed share issue to Sectoral Asset Management during the period, which provided an injection of about SEK 149 M, and the exercise of employee stock options. In the corresponding period in 2009, positive cash flow from financing activities was reported in the amount of SEK 244.1 M, which was due to a rights issue that generated SEK 247.4 M.

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 1.8 M (1.8).

Operating expenses during the period totaled SEK 7.3 M (10.1) and net financial items amounted to income of SEK 0.5 M (0.4). Loss after financial items amounted to SEK 5.0 M (loss: 7.9). No investments in fixed assets were made during the period.

Cash and cash equivalents, including short-term investments, totaled SEK 222.5 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 257.2 M, compared with SEK 188.6 M at year-end 2009.

The total number of shares outstanding, following the directed issue to Sectoral Asset Management and the exercise of employee stock options, amounted to 65,952,164 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 66.4 million.

At the end of the period, the equity/assets ratio for the Group was 45.9%, compared with 37.8% at year-end 2009. The corresponding figures for the Parent Company, Active Biotech AB, were 97.7% 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 87 employees (90).

Employee stock options program

An Extraordinary General Meeting on December 8, 2003 resolved to implement a free employee stock options program comprising a total of 1,000,000 options for all employees of the company. The options program, combined with the hedging of future social-security costs and following the expiry of the series 1 options on May 31, 2009, comprised a total of 778,685 options. Of these, a total of

391,822 options, corresponding to 481,926 shares, were exercised during the January-June period, which increased the share capital by SEK 1.8 M and other capital contributions by SEK 26.2 M.

The number of options outstanding at the end of the period amounted to about 387,000 and the total number of shares can thus amount to about 66.4 million.

Capital Markets Day June 10, 2010

Management presented the company's project portfolio with emphasis on the TASQ projects positive Phase II results and the ongoing Phase III planning. The complete presentation is available on www.activebiotech.com.

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	April-June		January- June		Full Year
	2010	2009	2010	2009	2009
Net sales	3.4	3.0	6.1	5.2	10.8
Administrative expenses	-7.1	-5.2	-11.8	-9.6	-18.3
Research and development costs	-47.6	-52.6	-96.8	-114.1	-212.0
Operating loss	-51.4	-54.8	-102.4	-118.5	-219.6
Net financial items	-3.3	-1.6	-5.9	-0.1	-4.4
Loss after financial items	-54.8	-56.4	-108.3	-118.6	-224.0
Tax	-	-	-	-	-
Net loss for the period	-54.8	-56.4	-108.3	-118.6	-224.0
Comprehensive loss attributable to:					
Parent company shareholders	-54.8	-56.4	-108.3	-118.6	-224.0
Minority interest	-	-	-	-	-
Net loss for the period	-54.8	-56.4	-108.3	-118.6	-224.0
Other comprehensive income during the period					
Change in revaluation reserve	-0.3	-0.3	-0.7	-0.7	-1.3
Taxes attributable to other comprehensive income	0.1	0.1	0.2	0.2	0.3
Comprehensive loss for the period	-55.0	-56.6	-108.8	-119.1	-224.9
Comprehensive loss attributable to:					
Parent company shareholders	-55.0	-56.6	-108.8	-119.1	-224.9
Minority interest	-	-	-	-	-
Comprehensive loss for the period	-55.0	-56.6	-108.8	-119.1	-224.9
Depreciation/amortization included in the amount of	2.4	2.4	4.9	4.7	9.6
Investments in tangible fixed assets	-	-	-	-	0.1
Earnings per share before dilution (SEK)	-0.83	-1.02	-1.67	-2.22	-3.81
Earnings per share after dilution (SEK)	-0.83	-1.02	-1.67	-2.22	-3.81
Comprehensive loss per share before dilution (SEK)	-0.84	-1.02	-1.68	-2.23	-3.83
Comprehensive loss per share after dilution (SEK)	-0.84	-1.02	-1.68	-2.23	-3.83
Weighted number of outstanding common shares before dilution (000s)	65 764	55 465	64 944	53 365	58 753
Weighted number of outstanding common shares after dilution (000s)	65 764	55 465	64 944	53 365	58 753
Number of shares at close of the period (000s)	65 952	64 052	65 952	64 052	64 052
Outstanding warrants (000s)	387	782	387	782	779
- entitlement to number of shares after full exercise (000s)	476	962	476	962	958

Consolidated balance sheet, condensed

SEK M	June 30		Dec. 31
	2010	2009	2009
Tangible fixed assets	314.7	323.1	319.0
Financial fixed assets	0.0	0.0	0.0
Total fixed assets	314.7	323.1	319.0
Current receivables	9.8	21.7	23.5
Cash and cash equivalents	235.3	259.5	156.0
Total current assets	245.1	281.2	179.5
Total assets	559.8	604.3	498.5
Shareholders equity	257.2	294.4	188.6
Long-term liabilities	244.8	251.7	248.0
Current liabilities	57.8	58.2	61.9
Total shareholders equity and liabilities	559.8	604.3	498.5

Consolidated statement of changes in shareholders equity

Opening balance	188.6	163.6	163.6
Transfer from revaluation reserve	0.5	0.5	1.0
New share issue	176.9	249.4	249.0
Net loss for the period	-108.8	-119.1	-224.9
Balance at close of period	257.2	294.4	188.6

Condensed consolidated cash-flow statement

SEK M	January - June		Full year
	2010	2009	2009
Loss after financial items	-108.3	-118.6	-224.0
Adjustment for non-cash items, etc.	4.9	4.7	9.6
Cash flow from operating activities before changes in working capital	-103.4	-113.9	-214.4
Changes in working capital	9.5	-9.4	-10.4
Cash flow from operating activities	-93.9	-123.3	-224.8
Investments in tangible fixed assets	–	–	-0.1
Cash flow from investing activities	–	–	-0.1
New share issue	176.9	247.4	249.0
Loans raised/amortization of loan liabilities	-3.7	-3.4	-6.9
Cash flow from financing activities	173.2	244.1	242.1
Cash flow for the period	79.3	120.7	17.3
Opening cash and cash equivalents	156.0	138.7	138.7
Closing cash and cash equivalents	235.3	259.5	156.0

	June 30		Dec. 31
Key figures	2010	2009	2009
Shareholders equity, SEK M	257.2	294.4	188.6
Equity per share, SEK	3.90	4.60	2.95
Equity/assets ratio in the Parent Company	97.7%	94.4%	93.9%
Equity/assets ratio in the Group	45.9%	48.7%	37.8%
Average number of annual employess	89	90	90

Active Biotech - parent company

Income statement, condensed SEK M	April-June		January - June		Full Year
	2010	2009	2010	2009	2009
Net sales	0.9	0.9	1.8	1.8	3.5
Administration expenses	-2.4	-5.4	-7.3	-10.1	-22.2
Operating profit/loss	-1.5	-4.6	-5.5	-8.4	-18.7
<i>Profit/loss from financil items:</i>					
Interest income and similar income-statement items	0.2	0.1	0.5	0.4	2.3
Interest expense and similar income-statement items	0.0	–	0.0	0.0	0.0
Profit/loss after financial items	-1.3	-4.5	-5.0	-7.9	-16.3
Tax	–	–	–	–	–
Net profit/loss for the period	-1.3	-4.5	-5.0	-7.9	-16.3

Balance sheet, condensed SEK M	June 30		Dec. 31
	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	100.7	14.5	17.0
Short-term investments	–	–	50.0
Cash and bank balances	222.5	244.0	94.2
Total current assets	323.1	258.5	161.1
Total assets	525.9	461.3	363.9
Shareholders equity	513.6	435.6	341.8
Current liabilities	12.3	25.7	22.1
Total equity and liabilities	525.9	461.3	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 comply 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.

Financial calendar

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.

Board's assurance

The Board of Directors and the President assure that the interim report provides an accurate overview of the Parent Company's and the Group's operations, position and earnings as well as describes significant risks and uncertainties facing the companies that are included in the Group.

Lund, August 11, 2010

Mats Arnhög
Chairman

Klas Kärre
Board member

Tomas Nicolin
Board member

Magnhild Sandberg-Wollheim
Board member

Peter Sjöstrand
Board member

Peter Ström
Board member

Anette Sundstedt
*Employee rep/
Board member*

Karin Hallbeck
*Employee rep/
Board member*

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 a 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, and 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 August 11, 2010 at 8:30 a.m.

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