

Active Biotech AB Interim Report January - March 2011

- Laquinimod complete results from Allegro Phase III trial presented
- TASQ Active Biotech and Ipsen enter into a broad partnership for the codevelopment and commercialization of TASQ in uro-oncology
- ANYARA ongoing Phase III study expected to be concluded in 2012
- 57-57 orphan drug status granted
- ISI project proceeding according to plan
- RhuDex[™] preparations for continued clinical development in progress
- Net sales SEK 2.7 M (2.8)
- Operating loss SEK 70.9 M (loss: 51.0)
- Loss after tax SEK 69.3 (loss: 53.5)
- Loss per share for the period amounted to 1.02 (loss: 0.83)
- Private placement of SEK 375 M completed

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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 <u>multiple sclerosis</u> (MS). Active Biotech entered into an agreement with the Israeli pharmaceutical company <u>Teva Pharmaceutical Industries Ltd</u> (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. In December 2010, positive results from the Phase III ALLEGRO study was presented. Laquinimod met the primary endpoint of reducing annualized relapse rate and significantly slowed progression of disability. At present, the second of two global clinical Phase III trials is in progress, Bravo, which encompasses a total of 1,200 MS patients worldwide. Information regarding the ongoing clinical trials is available at www.clinicaltrials.gov.

- The second global clinical Phase III study, BRAVO, is currently under way and results are anticipated in the third quarter of 2011.
- Clinical Phase II trials for the treatment of Crohn's disease and Lupus are continuing according to plan.

TASQ – an antiangiogenic compound for the treatment of prostate cancer

The development of TASQ is principally focused on the treatment of <u>prostate cancer</u>. TASQ is an antiangiogenic compound, meaning that it cuts off the supply of nutrients to the tumor. Studies concluded that TASQ exhibits anti-tumor activity via inhibition of tumor angiogenesis. The upregulation of the antiangiogenic protein <u>thrombospondin-1</u> (TSP1) is a part of this mechanism. It was announced in December 2009 that the primary endpoint of the <u>Phase II clinical study</u>, to show a higher fraction of patients with no disease progression during the six-month period of treatment using TASO, had been attained.

- Enrollment of patents to a pivotal, global Phase III trial commenced in March 2011. The study is a global, randomized, double-blind, placebo-controlled Phase III trial in patients with metastatic castrate-resistant prostate cancer (CRPC). The aim of the study is to confirm TASQ's effect on the disease, with radiological progression-free survival (PFS) as the primary endpoint and survival as secondary endpoint. The planned study will include about 1,200 patients in more than 250 clinics.
- Updated data from the Phase II study of TASQ was presented at the 2011 Genitourinary Cancers Symposium scientific conference. The updated analysis confirmed an improved Progression Free Survival (PFS) from 3.3 months (placebo) to 7.6 months for those patients that were treated with TASQ (p=0.004). A more detailed analysis of various subgroups of patients showed a significant Progression Free Survival in most of these groups, especially among patients with bone or visceral metastatic disease in the lung or the liver. TASQ was generally well tolerated and the incidence of serious side effects was low.

ANYARA – a fusion protein for immunological treatment of renal cancer

ANYARA is a <u>TTS</u> (Tumor Targeting Superantigen) compound that makes the treatment of cancer tumor-specific. The development of ANYARA is mainly focused on <u>renal cell cancer</u>. Positive data was reported in connection with the <u>interim analysis in Phase II/III</u> 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 <u>Phase I</u> 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 <u>Phase III trials</u> 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 <u>orphan-drug status</u> by the EMA 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 evaluating the effect of ANYARA in combination with interferonalpha, compared with interferon-alpha alone, in patients with advanced renal cell cancer. The primary clinical efficacy parameter is survival and will be read after 384 registered events (deaths). It is expected that it will be possible to present the results in 2012.

57-57 — novel oral immunomodulatory compound for the treatment of systemic lupus erythematosus and systemic sclerosis/scleroderma

57-57 is a quinoline compound primarily intended for the treatment of <u>systemic lupus erythematosus</u> (SLE), a disease that causes inflammation and damage to connective tissue throughout the body, with serious secondary symptoms, such as kidney failure. Data from the completed <u>clinical Phase Ib trial</u> of 57-57 was presented at scientific conferences. 57-57 was well tolerated and the results indicate that treatment with 57-57 could influence pathways known to be important in SLE pathogenesis. A small-scale exploratory clinical study in SLE patients has been conducted in Sweden and Denmark. This study has recently been completed. In August 2011, the company also decided to initiate the development of 57-57 for the treatment of <u>Systemic Sclerosis</u>. This rare disease is classified as an orphan drug indication.

– In February 2011, the 57-57 project was granted orphan medicinal product status, for the indication Systemic Sclerosis (SSc). The EMA's "Orphan Medicinal Product Designation" is implemented to promote the development of drugs that may provide significant benefit to patients suffering from rare diseases identified as life-threatening or chronically debilitating. Under EMA guidelines, Orphan Medicinal Product Designation provides ten years of potential market exclusivity if the product candidate is approved for marketing in the European Union. Orphan status also permits EMA assistance in optimizing the candidate's clinical development through participation in designing the clinical protocol and preparing the marketing application. Additionally, a drug candidate designated by the EMA as an Orphan Medicinal Product may qualify for a reduction in regulatory fees as well as a European Union-funded research grant.

- Preparations are in progress for the launch of an explorative study in Systemic Sclerosis during 2011.

ISI (Inhibition of S100 interactions) – preclinical project based on the mechanism 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 with respect to a target molecule for the quinoline (Q) compounds and their biological mechanism 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 white blood cells involved in the regulation of immune responses. Furthermore, it is shown that S100A9 interacts with two known proinflammatory 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 and to select a candidate drug in 2011/2012.

- 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 concluded in which the RhuDex candidate drug was studied with respect to its safety, tolerability and pharmacokinetic properties in healthy volunteers. 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.

Events after the end of the period

- On April 12, the <u>results</u> from the two-year Phase III ALLEGRO study of laquinimod were presented. The data was presented as late-breaking research at the Annual Meeting of the American Academy of Neurology (AAN). In the ALLEGRO study, laquinimod showed a statistically significant 23 percent reduction in annualized relapse rate (p=0.0024), the primary endpoint, along with a significant 36 percent reduction in the risk of confirmed disability progression, as measured by Expanded Disability Status Scale (EDSS) (p=0.0122). Treatment with laquinimod was also associated with a significant reduction in brain tissue loss, as measured by a 33 percent reduction in progression of brain atrophy (p<0.0001). Laquinimod was safe and well-tolerated without immunosuppressive effects. The overall frequencies of adverse events, including incidence of infections, were comparable to those observed in the placebo group. The most commonly reported adverse events were headaches, nasopharyngitis and back pain. The incidence of liver enzyme elevation was higher in laquinimod treated patients; however, these elevations were transient, asymptomatic and reversible. No deaths were reported in laquinimod-treated patients.
- On April 18, Active Biotech and Ipsen (Euronext: IPN; ADR: IPSEY) announced that they had entered into a broad partnership to co-develop and commercialize Active Biotech's investigational compound Tasquinimod "TASQ". Under the terms of the agreement, Active Biotech granted Ipsen exclusive rights to commercialize TASQ worldwide, except for North and South America and Japan where Active Biotech retains all commercial and marketing rights. Both companies will co-develop TASQ for the treatment of castrate-resistant prostate cancer, with the possibility to develop TASQ in other cancer indications. Active Biotech is responsible for conducting and funding the Phase III pivotal clinical trial and will receive up to EUR 200 million consisting of an upfront payment of EUR 25 million and additional payments contingent upon achievement of clinical, regulatory and commercial milestones. In addition, Ipsen will pay Active Biotech progressive double-digit royalties on its net sales and will conduct and fund a European supportive study in prostate cancer patients out of its R&D budget. Any costs to develop TASQ in future other cancer indications will be shared.

Financial information

Comments on the Group's results for the January - March 2011 period

Net sales for the period amounted to SEK 2.7 M (2.8) and derived from service and rental revenues.

The operation's research and administration expenses totaled SEK 73.6 M (53.7). Research expenses amounted to SEK 67.0 M (49.1). The increase in expenses was entirely attributable to the cost for initiating Phase III trials of TASQ for the treatment of prostate cancer. At full recruitment, the clinical Phase III trial will comprise 1,200 patients in more 250 clinics in 40 countries.

With the exception of the preclinical research project, ISI, the costs for the ongoing Phase III trial for the ANYARA renal cancer project and costs for the explorative study for the SLE project 57-57 were significantly lower than the cost level recorded a year earlier.

The other two clinical-phase projects, laquinimod and RhuDex, are fully financed by the relevant partners.

Administration expenses amounted to SEK 6.6 M (4.6), with the deviation mainly attributable to increased costs for the employee stock option program.

The company recognized an operating loss of SEK 79.0 M (loss: 51.0). Net financial items totaled income of SEK 1.6 M (expense: 2.5). A loss of SEK 69.3 M (loss: 53.5) was recognized after tax.

Cash flow, liquidity and financial position

Following the private placement in January 2011, cash and short-term investments amounted to SEK 411.3 M, compared with SEK 131.1 M at the end of 2010.

Cash flow for the period amounted to SEK 280.1 M (neg: 45.4), of which cash flow from operating activities was a negative SEK 84.9 M (neg: 50.5). Cash flow from financing activities totaled SEK 365.3 M (5.1) as a result of the implementation of the private placement to international institutional investors and qualified investors in Sweden, which provided an injection of about SEK 361 M after issue expenses.

Investments

Investments in tangible fixed assets amounted to SEK 0.2 M (0.0).

Comments on the Parent Company's earnings and financial position

To simplify and create more cost-effective management of the Group's structure, Active Biotech AB and its wholly owned subsidiary Active Biotech Research AB were merged as of December 23, 2010.

The Parent Company's net sales for the period amounted to SEK 5.6 M (0.9).

Operating expenses during the period totaled SEK 81.6 M (4.9) and net financial items amounted to income of SEK 1.1 M (0.2). Loss after financial items amounted to SEK 74.9 M (loss: 3.7).

Cash, including short-term investments, totaled SEK 405.4 M at the end of the period, compared with SEK 125.4 M on January 1, 2011.

Share capital

Consolidated shareholders' equity at the end of the period amounted to SEK 479.6 M, compared with SEK 181.8 M at year-end 2010.

At March 31, 2011, the total number of shares outstanding amounted to 68,582,691. In the event of redemption of share warrants outstanding, the number of shares in Active Biotech could increase to a maximum of about 68.9 million.

At the end of the period, the equity/assets ratio for the Group was 61.7%, compared with 36.1% at year-end 2010. The corresponding figures for the Parent Company, Active Biotech AB, were 92.6% and 81.3%, respectively.

Organization

The average number of employees was 81 (89), with the average number of employees in the research and development operation accounting for 66 (74). At the end of the period, the Group had 81 employees (88).

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 existing cash and cash equivalents and the EUR 25 M that was added to the company in connection with the signing of a partnership agreement with Ipsen Pharma S.A. after the close of the period will safeguard financing under 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 2010 Annual Report.

Consolidated profit and loss	Jan March		Full Year
SEK M	2011	2010	2010
Net sales	2.7	2.8	11.4
Administrative expenses	-6.6	-4.6	-23.1
Research and development costs	-67.0	-49.1	-217.3
Operating loss	-70.9	-51.0	-229.0
Net financial items	1.6	-2.5	-4.7
Loss before tax	-69.3	-53.5	-233.6
Tax	_	_	12.6
Net loss for the period	-69.3	-53.5	-221.1
Comprehensive loss attributable to:			
Parent company shareholders	-69.3	-53.5	-221.1
Non controlling interests	_	_	_
Net loss for the period	-69.3	-53.5	-221.1
Comprehensive loss per share before dilution (SEK)	-1.02	-0.83	-3.38
Comprehensive loss per share after dilution (SEK)	-1.02	-0.83	-3.38
Statement of consolidated comprehensive income			
Net loss for the period	-69.3	-53.5	-221.1
Other comprehensive income			
Change in revaluation reserve	-0.5	-0.3	46.4
Taxes attributable to other comprehensive income	0.1	0.1	-12.2
Total comprehensive loss for the period	-69.7	-53.8	-186.8
Total other comprehensive loss for the period attributable to:			
Parent company shareholders	-69.7	-53.8	-186.8
Non controlling interests	_	_	_
Total comprehensive loss for the period	-69.7	-53.8	-186.8
Depreciation/amortization included in the amount of	3.0	2.4	9.8
Investments in tangible fixed assets	0.2	-	0.1
Weighted number of outstanding common shares before dilution (000s)	67 693	64 116	65 465
Weighted number of outstanding common shares after dilution (000s)	67 693	64 116	65 465
Number of shares at close of the period (000s)	68 583	64 176	66 000
Outstanding warrants (000s)	280	678	348
- entitlement to number of shares after full exercise (000s)	345	834	428

Consolidated statement of financial position	March 31		Dec. 31
SEK M	2011	2010	2010
Tangible fixed assets	355.8	316.8	358.5
Financial fixed assets	0.0	0.0	0.0
Total fixed assets	355.8	316.8	358.5
Current receivables	9.6	16.1	13.4
Cash and cash equivalents	411.3	110.6	131.1
Total current assets	420.9	126.7	144.6
Total assets	776.7	443.4	503.1
Shareholders equity	479.6	142.0	181.8
Long-term liabilities	239.8	246.3	241.7
Current liabilities	57.3	55.1	79.7
Total shareholders equity and liabilities	776.7	443.4	503.1
Consolidated statement of changes in shareholders equity			
Opening balance	181.8	188.6	188.6
Transfer from revaluation reserve	0.4	0.2	1.0
New share issue	367.1	6.9	179.0
Net loss for the period	-69.7	-53.8	-186.8
Balance at close of period	479.6	142.0	181.8
Condensed consolidated cash-flow statement	Jan N	March	Full Year
SEK M	2011	2010	2010
Loss after financial items	-69.3	-53.5	-233.6
Adjustment for non-cash items, etc. Cash flow from operating activities	3.0	2.4	9.8
before changes in working capital	-66.4	-51.1	-223.9
before changes in working capital	-00.4	-31.1	-223.9
Changes in working capital	-18.5	0.6	27.5
Cash flow from operating activities	-84.9	-50.5	-196.3
Investments in tangible fixed assets	-0.2	_	-0.1
Investments in financial fixed assets	_	_	_
Cash flow from investing activities	-0.2	_	-0.1
New share issue	367.1	6.9	179.0
Loans raised/amortization of loan liabilities	-1.9	-1.9	-7.5
Cash flow from financing activities	365.3	5.1	171.5
Cash flow for the period	280.1	-45.4	-24.9
Opening cash and cash equivalents	131.1	156.0	156.0
Closing cash and cash equivalents	411.3	110.6	131.1
	March 31		Dec. 31
Key figures	2011	2010	2010
Shareholders equity, SEK M	479.6	142.0	181.8
Equity per share, SEK	6.99	2.21	2.75
Equity/assets ratio in the Parent Company	92.6%	95.5%	81.3%
Equity/assets ratio in the Group	61.7%	32.0%	36.1%
Average number of annual employees	81	89	87

Active Biotech - parent company

Income statement, condensed	Jan March		Full Year
SEK M	2011	2010	2010
Net sales	5.6	0.9	23.2
Administration expenses	-7.1	-4.9	-24.1
Research and development costs	-74.5	_	-233.5
Operating profit/loss	-76.0	-4.0	-234.4
Profit/loss from financial items:			
Interest income and similar income-statement items	1.6	0.2	1.7
Interest expense and similar income-statement items	-0.5	0.0	0.0
Profit/loss after financial items	-74.9	-3.7	-232.7
Tax	_	-	_
Net profit/loss for the period	-74.9	-3.7	-232.7
Statement of comprehensive income parent company			
Net loss for the period	-74.9	-3.7	-232.7
Other comprehensive income	_	_	_
Total comprehensive loss for the period	-74.9	-3.7	-232.7
Balance sheet, condensed	March 31		Dec 31
SEK M	2011	2010	2010
Goodwill	157.5		161.5
Tangible fixed assets	1.2	0.4	1.0
Financial fixed assets	40.6	202.5	40.6
Total fixed assets	199.2	202.8	203.1
Current receivables	22.2	60.4	25.9
Short-term investments	20.0	50.0	_
Cash and bank balances	385.4	48.1	125.4
Total current assets	427.6	158.5	151.3
Total assets	626.8	361.3	354.4
Shareholders equity	580.3	345.0	288.1
Long-term liabilities	_	=	_
Current liabilities	46.5	16.3	66.3
Total equity and liabilities	626.8	361.3	354.4

Any errors in additions are attributable to rounding of figures.

Accounting policies

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. 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 2011

The Annual General Meeting will be held on May 5, 2011. Shareholders who wish to participate in the Meeting must (i) be recorded in the register of shareholders maintained by Euroclear Sweden AB on Friday, April 29, 2011, and (ii), notify the Company of their intention to participate in the Meeting not later than 4 p.m. on Monday, May 2, 2011.

Shareholders who have trustee-registered their shares must temporarily re-register the shares in their own name with Euroclear to be entitled to participate in the Meeting. This registration must be completed not later than Friday, April 29, 2011. Accordingly, shareholders must inform the trustee of this request in ample time prior to this date.

Financial calendar

Interim report, January-June 2011: August 11, 2011 Interim Report, January-September 2012: November 3, 2011

Year-end report 2011: February 16, 2012

The reports will be available from these dates at <u>www.activebiotech.com</u>.

Lund, April 28, 2011 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, TASQ for prostate cancer and ANYARA for use in cancer targeted therapy, primarily of renal cell cancer. In addition, laquinimod is in Phase II development for Crohn's and Lupus. Further projects in clinical development comprise the two orally administered compounds, 57-57 for SLE and Systemic Sclerosis as well as RhuDexTM 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 28, 2011 at 8:30 a.m.