

**Active Biotech AB
Year-end Report
January - December 2011**

- **Laquinimod** — a clinical trial is planned prior to filing an NDA in the US
- **TASQ** — an investigator-sponsored Phase I clinical trial launched
— enrolment of patients for Phase III trial proceeding according to plan
- **ANYARA** — Phase III trial continuing according to plan
- **57-57** — a clinical trial in systemic sclerosis/scleroderma initiated
- **ISI** — project is proceeding as planned
- **RhuDex[®]** — a Phase I clinical formulation study launched
- **Focusing of the operation; notice of termination of employment to 25 staff members**
- **Net sales SEK 234.6 M (11.4)**
- **Operating loss SEK 100.9 M (Loss: 229.0)**
- **Loss after tax SEK 94,5 M (Loss: 221.1)**
- **Loss per share for the period was SEK 1.38 (Loss: 3.38)**

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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 under development for the treatment of such diseases as [multiple sclerosis](#) (MS). Active Biotech has 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. In December 2010, positive results from the Phase III [ALLEGRO](#) study were presented. Laquinimod met the primary endpoint of reducing annualized relapse rate and significantly slowed progression of disability. On August 1, 2011, the initial results were announced from the second Phase III [BRAVO](#) study. The BRAVO findings support the direct effect of laquinimod in the central nervous system (CNS) and are in line with the results of the first laquinimod Phase III trial, ALLEGRO.

– [Phase III clinical and pre-clinical data](#) was featured in more than 20 scientific posters and presentations at the 5th Joint Triennial Congress of the European and Americas Committees for Treatment and Research in Multiple Sclerosis (ECTRIMS and ACTRIMS) in Amsterdam, the Netherlands, on October 19-22, 2011. The results collectively demonstrate that once-daily oral laquinimod modulates the pathological processes of multiple sclerosis to impact disease activity, disability progression and brain atrophy.

– In November 2011, Teva announced that, following discussions with the FDA, it had decided to carry out a further clinical study prior to filing an NDA in US. Teva intends to design the additional clinical study, which is required to support laquinimod's NDA, in cooperation with the FDA.

– The clinical Phase II trials for the treatment of Crohn's disease, Lupus nephritis and Lupus arthritis are continuing according to plan. The clinical Phase II study in Crohn's disease was fully enrolled in November 2011 and evaluation is under way.

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. It was announced in December 2009 that the primary endpoint of the [Phase II study](#), to show a higher fraction of patients with no disease progression during the six-month period of treatment using TASQ, had been attained. In April 2011, [Active Biotech and Ipsen](#) (Euronext: IPN; ADR: IPSEY) entered a broad partnership for the co-development and commercialization of Active Biotech's compound, 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 (CRPC), with the possibility of developing TASQ in other cancer indications.

– Enrolment of patients to a clinical Phase III trial is under way. The study is a global, randomized, double-blind, placebo-controlled Phase III trial in patients with metastatic 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 overall survival as the secondary endpoint. The study will include about 1,200 patients in more than 250 clinics. Enrolment is expected to be concluded by year-end 2012 and milestone payments from Ipsen to Active Biotech will be made on achievement of specific enrolment goals.

– In October 2011, an article was published in *The Prostate* demonstrating that TASQ has an inhibiting effect on metastasis; "[Inhibition of metastasis in a castration resistant prostate cancer model by the quinoline-3-carboxamide tasquinimod \(ABR-215050\)](#)", K Jennbacken, K Welén, A Olsson, B Axelsson, M Törnren, J-E Damber, T Leanderson.

ANYARA – 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 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 interferon-alpha, 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 the second half of 2012.

57-57 – novel oral immunomodulatory compound for the treatment of systemic sclerosis/scleroderma

57-57 is a quinoline compound primarily intended for the treatment of [systemic sclerosis/scleroderma](#). 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.

– In November 2011, the article “[Pharmacokinetics, tolerability, and preliminary efficacy of ABR-215757, a new quinoline-3-carboxamide derivative, in murine and human SLE](#)”, A Bengtsson, G Sturfelt, C Lood, L Rönnblom, R van Vollenhoven, B Axelsson, B Sparre, H Tuveesson, M Wallén-Öhman, T Leanderson, was published in the web edition of the *Arthritis & Rheumatism* journal.

– An explorative clinical study in systemic sclerosis/scleroderma was initiated and will include 10-20 patients. The primary endpoint of the study is safety, with the secondary endpoints including the effect on selected biomarkers.

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 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 and to select a candidate drug in 2013/2014.

– The project is proceeding according to plan. Efforts are centered on building up a strong patent portfolio around the compounds that interact with S100 proteins. When this goal has been achieved, a decision will be taken on a clinical development strategy and selection of the first CD (Candidate Drug) is planned for 2013/2014.

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.

– In October 2011, Active Biotech AB's collaboration partner MediGene AG announced that the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) granted the authorization of the planned clinical formulation study of RhuDex. The objective of the RapidFACTM trial (Rapid Formulation Development and Clinical Testing) is to determine an optimized formulation for chronic treatment. To read the complete press release, please see www.medigene.com.

Events after the end of the period

TASQ

In January 2012, a Phase I investigator-sponsored clinical trial was initiated under the leadership of Principal Investigator Dr. Andrew Armstrong at Duke University Hospital. The primary objective for the CATCH trial ([Cabazitaxel](#) (Jevtana) [And](#) [Tasquinimod](#) in Men with [Castration-Resistant Heavily](#) pre-treated Prostate Cancer) is to determine the recommended dose of TASQ in combination with cabazitaxel based on safety and tolerability in men with chemorefractory metastatic castration-resistant prostate cancer (CRPC). Secondary objectives include efficacy as measured by progression-free survival (PFS), and overall survival (OS). The study will include about 30 patients. For further information about the study, please see www.clinicaltrials.gov.

RhuDex

On [January 25](#), Active Biotech's partner MediGene AG announced the resumption of clinical development of its candidate drug RhuDex[®] through the initiation of a clinical formulation study. The trial objective is to develop an optimized oral formulation of the active substance suitable for the treatment of chronic diseases. The results of this formulation study are expected in mid-2012.

Organization

As the research projects progress to later development phases the project activities will increasingly be handled by strategic partners. A comprehensive overview of the organization has been performed to determine the optimal manner to satisfy the future needs of the projects. After out-licensing of the ANYARA, 57-57 and TASQ projects the operations will focus on carrying on the Phase III TASQ study and the development of the ISI platform. As a result of this focus, the company will provide notice of termination of employment to 25 staff members.

NASDAQ OMX Disciplinary Committee

On February 13, The Disciplinary Committee of NASDAQ OMX Stockholm announced that a warning had been issued to Active Biotech originating in two information events regarding the company's MS project laquinimod. For more detailed information, see www.nasdaqomx.com.

Financial information

Comments on the Group's results for full-year 2011

The operating loss for the period amounted to SEK 100.9 M (loss: 229.0), representing a year-on-year improvement of SEK 128.1 M.

Net sales for the period amounted to SEK 234.6 M (11.4) and included an upfront payment of SEK 223.2 M from Ipsen Pharma for the exclusive rights to commercialize TASQ worldwide, except for North and South America and Japan. Service and rental revenues amounted to SEK 11.4 M (11.4).

The operation's research and administration expenses amounted to SEK 335.5 M (240.4), of which research expenses amounted to SEK 318.6 M (217.3). The increase in expenses was entirely attributable to the cost for the ongoing Phase III trials of TASQ for the treatment of prostate cancer. At full enrolment, the clinical Phase III trial will comprise approximately 1,200 patients in more than 250 clinics in 40 countries. According to the partnership agreement with Ipsen Pharma, Active Biotech will receive clinical, regulatory and commercial milestone payments on fulfillment of defined goals. On condition that these milestones are met, the Phase III trial will be financed in full. The costs for the ongoing Phase III trial for the ANYARA renal cancer project, the explorative study for the 57-57 project and the preclinical research project ISI were lower than the cost level recorded in the corresponding year-earlier period. Previously out-licensed projects, laquinimod and RhuDex, are fully financed by the relevant partners.

Administration expenses amounted to SEK 16.9 M (23.1). Net financial items for the period were an expense of SEK 2.6 M (expense: 4.7) MSEK and the net loss was SEK 94.5 M (loss: 221.1).

Comments on the Group's earnings for the fourth quarter 2011

The fourth-quarter operating loss amounted to SEK 94.7 M (loss: 79.3). The earnings trend is attributable to costs for clinical Phase III studies related to TASQ.

Net sales amounted to SEK 3.3 M (2.9) and operating expenses to SEK 97.9 M (82.2). The increase in expenses is attributable in full to intensified activity in the TASQ clinical development program in prostate cancer. Net financial items for the period amounted to an expense of SEK 5.7 M (expense: 2.4) and the net loss was SEK 93.2 M (loss: 64.3).

Cash flow, liquidity and financial position

Cash and cash equivalents at the end of the period amounted to SEK 465.2 M, compared with SEK 131.1 M at the end of 2010.

Cash flow for the period amounted to SEK 334.0 M (neg: 24.9), of which cash flow from operating activities was negative in the amount of SEK 47.0 M (neg: 196.3). Cash flow from financing activities amounted to SEK 381.5 M (171.5), as a result of the implementation during the period of the private placement to international institutional investors and qualified investors in Sweden and the exercise of employee stock options, which provided an injection of SEK 389.6 M in total after issue expenses.

Investments

Investments in tangible fixed assets amounted to SEK 0.5 M (0.1).

Dividend

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

Comments on the Parent Company's earnings and financial position

The Parent Company's operating loss for the period was SEK 125.1 M (loss: 234.4), net sales for the period amounted to SEK 244.3 M (23.2) and operating expenses totaled SEK 369.4 M (257.7).

Net financial items amounted to income of SEK 11.8 M (1.7) and the loss after financial items was SEK 113.3 M (loss: 232.7).

Cash and cash equivalents, including short-term investments, totaled SEK 456.6 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 502.0 M, compared with SEK 181.8 M at year-end 2010. At year-end, a market valuation of the company's property was carried out; the market value was assessed to SEK 375.0 M, an increase of SEK 25.0 M compared to the valuation at year-end 2010. The increased market value resulted in an increase of the Group's shareholders' equity by SEK 25.0 M. At December 31, 2011, the total number of shares outstanding amounted to 68,923,582.

At the end of the period, the equity/assets ratio for the Group was 58.5 percent, compared with 36.1 percent at year-end 2010. The corresponding figures for the Parent Company, Active Biotech AB, were 84.7 percent and 81.3 percent, respectively.

Organization

The average number of employees was 80 (87), with the average number of employees in the research and development operation accounting for 67 (71). At the end of the period, the Group had 79 employees (83).

Election Committee

In accordance with a decision made by the Annual General Meeting held on May 5, 2011, the Election Committee for Active Biotech shall comprise the representatives of the three largest shareholders on September 30, 2011 and the Board Chairman. For the 2012 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
Eggert Mörling, East Bay AB

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 10, 2012.

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, income from already signed and expected partnership agreements 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 SEK M	Oct - Dec.		Jan. - Dec.	
	2011	2010	2011	2010
Net sales	3.3	2.9	234.6	11.4
Administrative expenses	-4.0	-7.3	-16.9	-23.1
Research and development costs	-93.9	-74.9	-318.6	-217.3
Operating profit/loss	-94.7	-79.3	-100.9	-229.0
Net financial items	-5.7	2.4	-2.6	-4.7
Profit/loss before tax	-100.4	-76.8	-103.5	-233.6
Tax	7.2	12.6	9.0	12.6
Net profit/loss for the period	-93.2	-64.3	-94.5	-221.1
Comprehensive loss attributable to:				
Parent company shareholders	-93.2	-64.3	-94.5	-221.1
Non controlling interests	-	-	-	-
Net profit/loss for the period	-93.2	-64.3	-94.5	-221.1
Comprehensive profit/loss per share before dilution (SEK)	-1.35	-0.97	-1.38	-3.38
Comprehensive profit/loss per share after dilution (SEK)	-1.35	-0.97	-1.38	-3.38

Statement of consolidated comprehensive income

Net profit/loss for the period	-93.2	-64.3	-94.5	-221.1
Other comprehensive income				
Change in revaluation reserve	26.8	47.4	32.2	46.4
Taxes attributable to other comprehensive income	-7.0	-12.5	-8.5	-12.2
Total comprehensive profit/loss for the period	-73.5	-29.3	-70.8	-186.8
Total other comprehensive profit/loss for the period attributable to:				
Parent company shareholders	-73.5	-29.3	-70.8	-186.8
Non controlling interests	-	-	-	-
Total comprehensive profit/loss for the period	-73.5	-29.3	-70.8	-186.8
Depreciation/amortization included in the amount of	3.0	2.5	12.0	9.8
Investments in tangible fixed assets	0.1	0.1	0.5	0.1
Weighted number of outstanding common shares before dilution (000s)	68 924	65 992	68 597	65 465
Weighted number of outstanding common shares after dilution (000s)	68 924	65 992	68 597	65 465
Number of shares at close of the period (000s)	68 924	66 000	68 924	66 000
Outstanding warrants (000s)	-	348	-	348
- entitlement to number of shares after full exercise (000s)	-	428	-	428

Consolidated statement of financial position

SEK M	Dec. 31	
	2011	2010
Tangible fixed assets	382.7	358.5
Long term receivables	0.0	0.0
Total fixed assets	382.7	358.5
Current receivables	10.7	13.4
Cash and cash equivalents	465.2	131.1
Total current assets	475.9	144.6
Total assets	858.5	503.1
Shareholders equity	502.0	181.8
Long-term liabilities	234.8	241.7
Current liabilities	121.7	79.7
Total shareholders equity and liabilities	858.5	503.1

Consolidated statement of changes in shareholders equity

Opening balance	181.8	188.6
Transfer from revaluation reserve	1.5	1.0
New share issue	389.6	179.0
Net loss for the period	-70.8	-186.8
Balance at close of period	502.0	181.8

Condensed consolidated cash-flow statement

SEK M	Jan. - Dec.	
	2011	2010
Loss after financial items	-103.5	-233.6
Adjustment for non-cash items, etc.	12.0	9.8
Cash flow from operating activities before changes in working capital	-91.6	-223.9
Changes in working capital	44.6	27.5
Cash flow from operating activities	-47.0	-196.3
Investments in tangible fixed assets	-0.5	-0.1
Cash flow from investing activities	-0.5	-0.1
New share issue	389.6	179.0
Loans raised/amortization of loan liabilities	-8.1	-7.5
Cash flow from financing activities	381.5	171.5
Cash flow for the period	334.0	-24.9
Opening cash and cash equivalents	131.1	156.0
Closing cash and cash equivalents	465.2	131.1

Key figures	Dec. 31	
	2011	2010
Shareholders equity, SEK M	502.0	181.8
Equity per share, SEK	7.28	2.75
Equity/assets ratio in the Parent Company	84.7%	81.3%
Equity/assets ratio in the Group	58.5%	36.1%
Average number of annual employees	80	87

Active Biotech - parent company

SEK M	Oct. - Dec.		Jan. - Dec.	
	2011	2010	2011	2010
Net sales	5.4	3.0	244.3	23.2
Administration expenses	-8.5	-8.9	-25.8	-24.2
Research and development costs	-97.5	-74.9	-343.6	-233.5
Operating profit/loss	-100.7	-80.9	-125.1	-234.4
<i>Profit/loss from financial items:</i>				
Interest income and similar income-statement items	-5.3	0.7	11.8	1.7
Interest expense and similar income-statement items	2.3	0.0	0.0	0.0
Profit/loss after financial items	-103.6	-80.1	-113.3	-232.7
Tax	-	-	-	-
Net profit/loss for the period	-103.6	-80.1	-113.3	-232.7
Statement of comprehensive income parent company				
Net profit/loss for the period	-103.6	-80.1	-113.3	-232.7
Other comprehensive income	-	-	-	-
Total comprehensive profit/loss for the period	-103.6	-80.1	-113.3	-232.7

Balance sheet, condensed

SEK M	Dec. 31	
	2011	2010
Goodwill	145.3	161.5
Tangible fixed assets	1.3	1.0
Financial fixed assets	40.6	40.6
Total fixed assets	187.2	203.1
Current receivables	22.6	25.9
Short-term investments	20.0	-
Cash and bank balances	436.6	125.4
Total current assets	479.2	151.3
Total assets	666.4	354.4
Shareholders equity	564.3	288.1
Current liabilities	102.0	66.3
Total equity and liabilities	666.4	354.4

Any errors in additions are attributable to rounding of figures

Accounting policies

This interim report has been prepared in accordance with IAS 34, Interim Financial Reporting and applicable parts of the Annual Accounts Act. The interim report of the Parent Company has been prepared in accordance with Chapter 9 of the Annual Accounts Act. For the Group and the parent company the same accounting policies as well as accounting estimates and assumptions have been used in this interim report as were used to prepare 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 2012

The Annual General Meeting will be held on May 10, 2012. A more detailed invitation to attend the Annual General Meeting will be issued closer to the date.

Financial calendar

Interim Report, January – March 2012: April 26, 2012

Interim Report, January – June 2012: August 10, 2012

Interim Report, January – September 2012: November 9, 2012

Year-end Report 2012: February 14, 2013

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

Lund, February 16, 2012
Active Biotech AB (publ)

Tomas Leanderson
President and CEO

This interim report is unaudited.

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 primarily for the treatment 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 Systemic Sclerosis as well as 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 16, 2012 at 8:30 a.m.