

Active Biotech AB Year-end Report January - December 2010

- **Laquinimod** — positive results presented from ALLEGRO Phase III trial
- **TASQ** — pivotal Phase III study initiated in the first quarter of 2011
- **ANYARA** — ongoing Phase III study expected to be concluded in 2012
- **57-57** — recommended Orphan Medicinal Product Status
- **ISI** — project proceeding according to plan
- **RhuDexTM** — preparations for continued clinical development in progress
- **Net sales SEK 11.4 M (10.8)**
- **Operating loss SEK 229.0 M (loss: 219.6)**
- **Loss after tax SEK 221.1 (loss: 224.0)**
- **Loss per share for the period amounted to 3.38 (loss: 3.81)**
- **Private placement of SEK 375 M completed after the end of the period**

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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, 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 trial is available at www.clinicaltrials.gov. [In February 2009, laquinimod received a Fast Track designation from the US Food and Drug Administration, FDA, which can potentially facilitate development and expedite the review process.](#)

- In October 2010, [data](#) that provided further evidence of the neuroprotective properties of laquinimod in experimental studies was presented at the 26th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Gothenburg, Sweden.
- In December 2010, positive [results from the two-year Phase III ALLEGRO study](#), which demonstrated that relapsing-remitting multiple sclerosis (RRMS) patients treated with 0.6 mg daily oral laquinimod experienced a statistically significant reduction in annualized relapse rate compared to placebo. Additional clinical endpoints, including significant reduction in disability progression, as measured by Expanded Disability Severity Scale (EDSS), were also achieved. The ALLEGRO study also confirmed laquinimod's highly favorable safety profile.
- 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 [prostate cancer](#). 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 up-regulation of the antiangiogenic protein [thrombospondin-1 \(TSP1\)](#) is a part of this mechanism. 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 Phase II trial were presented at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2010.

– Enrollment of patients to a pivotal, global Phase III trial will commence in the first quarter of 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 overall survival as the secondary endpoint. The planned study will include about 1,200 patients in more than 250 clinics. The total cost of the study is estimated at approximately EUR 80-100 M distributed over the period 2011-2015. It is anticipated that data relating to PFS will be ready to be presented in 2013 and the entire study is expected to have reached its conclusion in 2015. Partnership discussions are ongoing in parallel with the initiation of the Phase III trial.

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 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 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 [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. Data from the completed [clinical Phase Ib trial](#) 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 2010, the company also decided to initiate the development of 57-57 for the treatment of [Systemic Sclerosis/Scleroderma](#). This rare disease is classified as an orphan drug indication.

– In November 2010, the COMP (Committee for Orphan Medicinal Products) announced that it had adopted a positive opinion recommending the project 57-57 for designation as orphan medicinal product, for the indication Systemic Sclerosis (SSc), to the European Commission. 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 in 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 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 2011/2012.

– The project is proceeding according to plan.

RhuDexTM – 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 [January 27](#), 2011, Active Biotech announced that it completed a private placement of 2,500,000 new shares, providing the company with SEK 375 M before transaction costs.

The private placement, which was announced on January 26, 2011, allowed Active Biotech to place 2,500,000 new shares at a price of SEK 150 per share with international institutional investors and qualified investors in Sweden through an accelerated bookbuilding procedure.

The proceeds from the private placement are intended to be used to strengthen Active Biotech's R&D activities by enabling the company to fund development of its late-stage prostate cancer treatment candidate, TASQ, with potential partners, advancing existing projects further towards commercialization, bringing additional discovery projects into the clinic and for general corporate purposes.

Financial information

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

Net sales for the period amounted to SEK 11.4 M (10.8) and derived from service and rental revenues.

The operation's research and administration expenses totaled SEK 240.4 M (230.3). Research expenses amounted to SEK 217.3 M (212.0). The increase in expenses compared with the year-earlier period was entirely attributable to the cost for initiating Phase III trials of TASQ for the treatment of prostate cancer. The clinical Phase III trial, comprising 1,200 patients in more than 250 clinics in 40 countries, will commence patient enrollment during the first quarter 2011. During the second half of 2010, about SEK 45 M was expensed for the planning and launch of the Phase III trial. With the exception of 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, the cost of the ongoing Phase III trial for the ANYARA renal cancer project and the cost of the explorative study for the SLE project 57-57 were significantly lower than the cost level recorded in the corresponding period in the preceding year.

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

Costs for the period were positively impacted by the strengthening of the SEK in relation to the EUR and USD. Administration expenses amounted to SEK 23.1 M (18.3), the deviation is mainly attributable to increased costs for the employee stock option program.

The company recognized an operating loss of SEK 229.0 M (loss: 219.6). Net financial items totaled an expense of SEK 4.7 M (expense: 4.4). A loss of SEK 221.1 M (loss: 224.0) was recognized after tax.

Cash flow, liquidity and financial position

Cash and cash equivalents and short-term investments amounted to SEK 131.1 M at the end of the period, compared with SEK 156.0 M at the end of 2009. Following the private placement in January 2011, cash and cash equivalents amounted to about SEK 475 M, before issue expenses.

Cash flow for the period was negative in the amount of SEK 24.9 M (pos: 17.3), of which cash flow from operating activities was a negative SEK 196.3 M (neg: 224.8). Cash flow from financing activities totaled SEK 171.5 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 recognized in the amount of SEK 242.1 M, which was due to a rights issue that generated SEK 249.0 M.

Investments

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

Dividend

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

Comments on the Parent Company's earnings and financial position

To simplify the Group's legal structure and enhance the efficiency of its administration, the Parent Company Active Biotech AB and its wholly owned subsidiary Active Biotech Research AB were merged on December 23, 2010.

The Parent Company's net sales for the period amounted to SEK 23.2 M (3.5).

Operating expenses during the period totaled SEK 257.7 M (22.2) and net financial items amounted to income of SEK 1.7 M (2.3). Loss after financial items amounted to SEK 232.7 M (loss: 16.3).

Cash and cash equivalents, including short-term investments, totaled SEK 125.4 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 181.8 M, compared with SEK 188.6 M at year-end 2009. At year-end, a market valuation of the company's property was carried out, resulting in an increase of the Group's shareholders' equity by SEK 46.8 M, whereof 12.6 MSEK attributable to capitalization of the Group's loss carryforwards.

At December 31, 2010, the total number of shares outstanding amounted to 65,999,920. On January 26, 2011, Active Biotech completed a private placement of 2,500,000 new shares to international institutional investors and qualified investors in Sweden. 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 36.1%, compared with 37.8% at year-end 2009. The corresponding figures for the Parent Company, Active Biotech AB, were 81.3% and 93.9%, respectively.

Organization

The average number of employees was 87 (90), with the average number of employees in the research and development operation accounting for 71 (73). At the end of the period, the Group had 84 employees (89).

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 430,651 options, corresponding to 529,682 shares, were exercised during the January-December 2010 period, which increased the share capital by SEK 2.0 M and other capital contributions by SEK 28.7 M.

The number of options outstanding at the end of the period amounted to about 348,034 and the total number of shares can thus amount to about 68.9 million, following the private placement of 2.5 million shares implemented in January 2011.

Election Committee

In accordance with a decision made by the Annual General Meeting held on May 6, 2010, the Election Committee for Active Biotech shall comprise the representatives of the three largest shareholders on September 30 and the Board Chairman. For the 2011 Annual General Meeting, the Election Committee shall propose Board members and a Board Chairman, and fees to Board members and auditors. The following individuals were appointed representatives of the largest shareholders and, accordingly, are members of the Election Committee:

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

Under the leadership of the Board Chairman Mats Arnhög, the Election Committee shall prepare proposals for the Board of Directors that are to be presented to and decided upon at the Annual General Meeting on May 5, 2011.

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 the SEK 375 M, before issue expenses, that were raised in the private placement to Swedish and international investors on January 26, 2011, 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.

Consolidated profit and loss

SEK M	Oct. - Dec.		Jan. - Dec.	
	2010	2009	2010	2009
Net sales	2.9	3.0	11.4	10.8
Administrative expenses	-7.3	-4.8	-23.1	-18.3
Research and development costs	-74.9	-53.2	-217.3	-212.0
Operating loss	-79.3	-54.9	-229.0	-219.6
Net financial items	2.4	-3.9	-4.7	-4.4
Loss before tax	-76.8	-58.8	-233.6	-224.0
Tax	12.6	—	12.6	—
Net loss for the period	-64.3	-58.8	-221.1	-224.0
Comprehensive loss attributable to:				
Parent company shareholders	-64.3	-58.8	-221.1	-224.0
Non controlling interests	—	—	—	—
Net loss for the period	-64.3	-58.8	-221.1	-224.0
Comprehensive loss per share before dilution (SEK)	-0.97	-0.92	-3.38	-3.81
Comprehensive loss per share after dilution (SEK)	-0.97	-0.92	-3.38	-3.81

Statement of consolidated comprehensive income

Net loss for the period	-64.3	-58.8	-221.1	-224.0
Other comprehensive income				
Change in revaluation reserve	47.4	-0.3	46.4	-1.3
Taxes attributable to other comprehensive income	-12.5	0.1	-12.2	0.3
Total comprehensive loss for the period	-29.3	-59.1	-186.8	-224.9
Total other comprehensive loss for the period attributable to:				
Parent company shareholders	-29.3	-59.1	-186.8	-224.9
Non controlling interests	—	—	—	—
Total comprehensive loss for the period	-29.3	-59.1	-186.8	-224.9
Depreciation/amortization included in the amount of	2.5	2.4	9.8	9.6
Investments in tangible fixed assets	0.1	—	0.1	0.1
Weighted number of outstanding common shares before dilution (000s)	65 992	64 052	65 465	58 753
Weighted number of outstanding common shares after dilution (000s)	65 992	64 052	65 465	58 753
Number of shares at close of the period (000s)	66 000	64 052	66 000	64 052
Outstanding warrants (000s)	348	779	348	779
- entitlement to number of shares after full exercise (000s)	428	958	428	958

Consolidated statement of financial position

SEK M	Dec. 31	
	2010	2009
Tangible fixed assets	358.5	319.0
Financial fixed assets	0.0	0.0
Total fixed assets	358.5	319.0
Current receivables	13.4	23.5
Short term investments	—	—
Cash and cash equivalents	131.1	156.0
Total current assets	144.6	179.5
Total assets	503.1	498.5
Shareholders equity	181.8	188.6
Long-term liabilities	241.7	248.0
Current liabilities	79.7	61.9
Total shareholders equity and liabilities	503.1	498.5

Consolidated statement of changes in shareholders equity

Opening balance	188.6	163.6
Transfer from revaluation reserve	1.0	1.0
New share issue	179.0	249.0
Net loss for the period	-186.8	-224.9
Balance at close of period	181.8	188.6

Condensed consolidated cash-flow statement

SEK M	Jan. - Dec.	
	2010	2009
Loss after financial items	-233.6	-224.0
Adjustment for non-cash items, etc.	9.8	9.6
Cash flow from operating activities before changes in working capital	-223.8	-214.4
Changes in working capital	27.5	-10.4
Cash flow from operating activities	-196.3	-224.8
Investments in tangible fixed assets	-0.1	-0.1
Investments in financial fixed assets	–	–
Cash flow from investing activities	-0.1	-0.1
New share issue	179.0	249.0
Loans raised/amortization of loan liabilities	-7.5	-6.9
Cash flow from financing activities	171.5	242.1
Cash flow for the period	-24.9	17.3
Opening cash and cash equivalents	156.0	138.7
Closing cash and cash equivalents	131.1	156.0

Key figures

	Dec. 31	
	2010	2009
Shareholders equity, SEK M	181.8	188.6
Equity per share, SEK	2.75	2.95
Equity/assets ratio in the Parent Company	81.3%	93.9%
Equity/assets ratio in the Group	36.1%	37.8%
Average number of annual employees	87	90

Active Biotech - parent company

Income statement, condensed SEK M	Oct. - Dec.		Jan. -Dec.	
	2010	2009	2010	2009
Net sales	3.0	0.9	23.2	3.5
Administration expenses	-8.9	-9.5	-24.2	-22.2
Research and development costs	-74.9	–	-233.5	–
Operating profit/loss	-80.9	-8.6	-234.4	-18.7
<i>Profit/loss from financial items:</i>				
Interest income and similar income-statement items	0.3	0.7	1.3	2.3
Interest expense and similar income-statement items	0.5	0.0	0.4	0.0
Profit/loss after financial items	-80.1	-7.9	-232.7	-16.3
Tax	–	–	–	–
Net profit/loss for the period	-80.1	-7.9	-232.7	-16.3

Balance sheet, condensed

SEK M	Dec. 31	
	2010	2009
Goodwill	161.5	–
Tangible fixed assets	1.0	0.4
Financial fixed assets	40.6	202.5
Total fixed assets	203.1	202.8
Current receivables	25.9	17.0
Short-term investments	–	50.0
Cash and bank balances	125.4	94.2
Total current assets	151.3	161.1
Total assets	354.4	363.9
Shareholders equity	288.1	341.8
Long-term liabilities	–	–
Current liabilities	66.3	22.1
Total equity and liabilities	354.4	363.9

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.

2011 Annual General Meeting

The Annual General Meeting will be held on May 5, 2011. A more detailed invitation to attend the Annual General Meeting will be issued closer to the date.

Financial calendar

Interim report, January-March 2011: April 28, 2011

Interim report, January-June 2011: August 11, 2011

Interim Report, January-September 2011: November 3, 2011

Year-end report 2011: February 16, 2012

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

Lund, February 10, 2011
Active Biotech AB (publ)

Tomas Leanderson
President and CEO

This interim report is unaudited.

About Active Biotech

Active Biotech AB (NASDAQ OMX NORDIC: ACTI) is a biotechnology company with focus on autoimmune/inflammatory diseases and cancer. Projects in or entering 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 Year-end Report in accordance with the Swedish Securities Market Act. This information was provided to the media for publication on February 10, 2011 at 8:30 a.m.

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