

Active Biotech AB

Year-end report January – December 2013

Laquinimod

- Teva remains committed to the development of laquinimod (NERVENTRA®) for the treatment of multiple sclerosis (MS)
- On January 24, laquinimod received a negative opinion by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). The CHMP's opinion was based on the view that laquinimod's positive effect on reducing relapses did not outweigh the potential risks. Although the CHMP found that laquinimod has a positive effect on slowing disability in MS patients, this finding had no impact on the decision. In the risk assessment, the CHMP focused on findings in animal studies, performed in parallel with the pivotal clinical trials, relating to the potential risk of fetal damage and the potential increased risk of cancer. None of these effects have been observed in the comprehensive patient material, comprising 7,490 patient years in total, with some patients being exposed for more than seven years and tolerated treatment well.
- Teva has requested a re-examination of the CHMP's opinion.
- The ongoing pivotal Phase III study CONCERTO continues according to plan. Results are expected 2016.
- Teva plans to initiate clinical trials in primary progressive multiple sclerosis (PPMS).
- Analysis of data from the Phase III ALLEGRO study shows that laquinimod provides a beneficial impact on brain tissue damage. Laquinimod-treated patients accumulated significantly less brain tissue damage caused by neurodegeneration.
- Data presented at ECTRIMS shows that laquinimod reduces inflammation and has neuroprotective activity.
- At this time, Teva has decided to postpone further clinical development of laquinimod for the treatment of Crohn's disease until a clearer clinical strategy has been defined.

Tasquinimod

- Active Biotech received a milestone payment of EUR 12 M from Ipsen.
- Phase III 10TASQ10 study is proceeding as planned; the primary analysis of progression-free survival (PFS) and overall survival (OS) is expected in 2014.
- In February 2014, Ipsen launched a randomized, double-blind, placebo-controlled Phase III study of tasquinimod in chemo-naive CRPC patients in Asia.

ANYARA

- Detailed analysis provided further support for ANYARA's efficacy in a biomarker-defined sub-group of renal cell cancer patients. Results from the Phase II/III study was presented at the 2013 European Cancer Congress.
- The next step is a pivotal trial to treat a biomarker-defined group of renal cancer patients in second-line therapy, which will commence only when an out-licensing agreement has been reached with a partner.

Paquinimod (57-57)

- Evaluation of the clinical trial in systemic sclerosis demonstrated a favorable safety profile and effects on disease-related biomarkers.
- The next step in the development program is a Phase II study in systemic sclerosis, which will commence only when an out-licensing agreement has been reached with a partner.

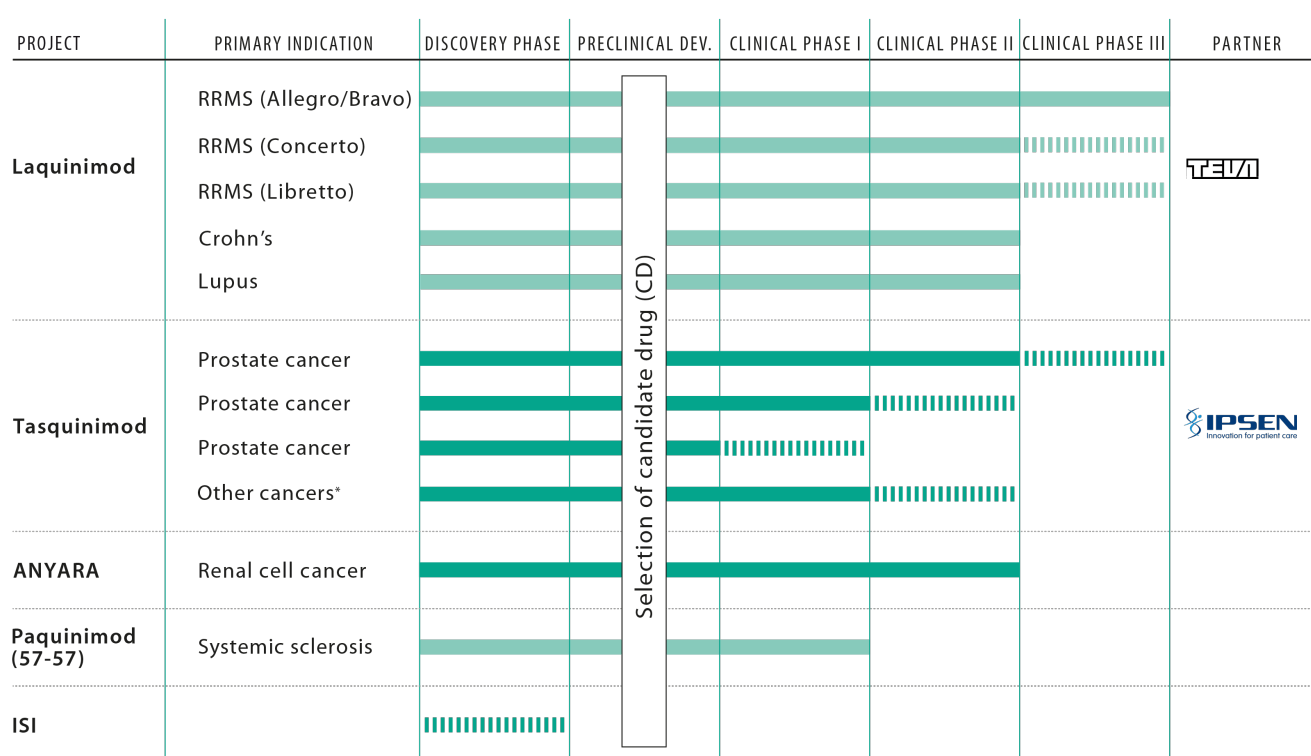
ISI

- Project proceeding according to plan.

Financial summary

| MSEK | Q4 | | Jan - Dec | |
|--------------------------|-------|------|-----------|--------|
| | 2013 | 2012 | 2013 | 2012 |
| Net sales | 4.0 | 91.5 | 116.0 | 227.9 |
| Operating profit/loss | -80.4 | 5.5 | -209.0 | -163.2 |
| Profit/loss after tax | -82.1 | 0.1 | -212.1 | -175.0 |
| Earnings per share (SEK) | -1.10 | 0.00 | -2.87 | -2.54 |

Project overview



*Hepatocellular, ovarian, renal & gastric cancer

■ Autoimmune/inflammatory ■ Cancer Striped = Ongoing

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Laquinimod – a novel oral immunomodulatory compound for the treatment of autoimmune diseases

Laquinimod (NERVENTRA®) is a quinoline compound under development for the treatment of such diseases as [multiple sclerosis \(MS\)](#). Active Biotech has an agreement with the Israeli company [Teva Pharmaceutical Industries Ltd](#) (June 2004) covering the development and commercialization of laquinimod. . [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 the 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 supported the direct effect of laquinimod in the central nervous system (CNS) and were in line with the results of the first laquinimod Phase III trial, ALLEGRO. In addition to the ongoing MS clinical trials, laquinimod has undergone clinical Phase II trials for the treatment of Crohn's disease and Lupus nephritis. The Phase III study CONCERTO is under way with the primary endpoint of time to confirmed disability progression. This study will also examine the impact of laquinimod on endpoints such as percentage change in brain volume and other clinical and MRI markers of disease activity.

– On [October 1](#), Active Biotech's partner Teva published data from a new Phase III exploratory analysis that shows that laquinimod may reduce brain damage caused by neurodegeneration. Based on this analysis, Teva plans to initiate a clinical trial in primary progressive multiple sclerosis (PPMS).

– On [October 4](#), Teva presented a pooled data analysis of the Phase III ALLEGRO and BRAVO studies, which shows that laquinimod can have an effect on both inflammation and the broader underlying mechanisms associated with disease progression in relapsing-remitting multiple sclerosis.

– On [November 4](#), it was announced that Active Biotech's partner Teva will initiate a further clinical trial, LIBRETTO, to evaluate the efficacy, safety and tolerability of two doses of oral laquinimod (0.6 and 1.2 mg/day), compared to interferon β -1a, in patients with relapsing remitting multiple sclerosis. The primary endpoint of the study is slowed progression of brain atrophy.

Tasquinimod – an immunomodulatory, anti-metastatic substance for the treatment of prostate cancer

The development of tasquinimod is principally focused on the treatment of [prostate cancer](#). Tasquinimod is an immunomodulatory, anti-metastatic substance that indirectly affects the tumor's ability to grow and spread. It was announced in December 2009 that the primary endpoint of the [Phase II study](#), to reduce the fraction of patients with disease progression during the six-month period of treatment using tasquinimod, 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, tasquinimod. Under the terms of the agreement, Active Biotech granted Ipsen exclusive rights to commercialize tasquinimod worldwide, except for North and South America and Japan, where Active Biotech retains all commercial and marketing rights. Both companies will co-develop tasquinimod for the treatment of castrate-resistant prostate cancer (CRPC), with the possibility of developing tasquinimod in other cancer indications. In [December 2012](#), patient enrollment was successfully completed to the ongoing clinical Phase III trial for tasquinimod, with 1,245 randomized patients as planned in the clinical protocol. The primary analysis of progression free survival (PFS) for the Phase III study will be carried out in 2014, at the same time as the first interim overall survival (OS) analysis. In [October 2012](#), Ipsen initiated a proof-of-concept Phase II clinical trial to evaluate the clinical efficacy of tasquinimod used as maintenance therapy in patients with metastatic castrate-resistant prostate cancer (mCRPC) who have not progressed after a first-line docetaxel-based chemotherapy. In addition, Ipsen has initiated a [proof-of-concept Phase II clinical trial](#) with tasquinimod to evaluate the safety and efficacy of tasquinimod in advanced or metastatic hepatocellular, ovarian, renal cell and gastric carcinomas in patients whose condition has nonetheless deteriorated after standard therapies. Furthermore, an investigator-sponsored clinical Phase I trial ([CATCH](#)) is under way to determine the recommended dose of tasquinimod in combination with cabazitaxel in patients with mCRPC.

– On [October 9](#), Active Biotech announced that it had received EUR 12 M from its partner Ipsen relating to the Phase III 10TASQ10 study. The milestone payment was recorded as revenue in September 2013.

– In October 2013, the independent Data and Safety Monitoring Board (DSMB), which is monitoring the ongoing Phase III 10TASQ10 study, recommended that the trial continue in accordance with the protocol since no safety-related issues were noted.

– On [November 19](#), the results from the Phase II study in tasquinimod: “Long-term Survival and Biomarker Correlates of Tasquinimod Efficacy in a Multicenter Randomized Study of Men with Minimally Symptomatic Metastatic Castration-Resistant Prostate Cancer”, Armstrong et al, were published in the scientific journal *Clinical Cancer Research* (doi: 10.1158/1078-0432.CCR-13-1581).

– The ongoing clinical Phase III trial 10TASQ10 is a global, randomized, double-blind, placebo-controlled study of mCRPC patients. The aim of the study is to confirm tasquinimod’s efficacy on the disease, with radiological progression-free survival (PFS) as the primary endpoint and overall survival (OS) as the secondary endpoint. The study is proceeding according to plan and the primary analysis of progression-free survival and overall survival is expected in 2014.

– The other clinical studies with tasquinimod are proceeding according to schedule.

ANYARA – fusion protein for immunological treatment of renal cell cancer

ANYARA is a [TTS](#) (Tumor Targeted Superantigen) compound that makes cancer treatment 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. 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. Overall survival (OS) and progression-free survival (PFS) data from the ANYARA Phase II/III study in renal cell cancer was presented in June 2013. The study encompassed 513 patients and was designed to evaluate the efficacy of ANYARA (naptumomab estafenatox) in combination with interferon-alpha, compared with interferon-alpha alone, in patients with advanced renal cell cancer. The primary endpoint was improved overall survival, which was not achieved in the overall ITT population, but was attained in a biomarker-defined subgroup of 130 patients. In this subgroup, the median OS for the ANYARA vs. placebo treatment arm were 63.3 vs. 31.1 months (HR: 0.59; p=0.020), respectively. The median PFS were 13.7 (ANYARA) vs. 5.8 (placebo) months (HR: 0.62; p=0.016).

– Active Biotech has discussed the continued development of ANYARA with the FDA and EMA, based on the results of the completed Phase II study in which ANYARA displayed a survival benefit in a subgroup of patients. A development plan has been designed on the basis of these meetings, the next step of which consists of a pivotal study to treat a biomarker-defined group of renal cell cancer patients in second-line therapy. In this study, ANYARA will be combined with a registered standard therapy and, accordingly, the next step in discussions with potential partners will have begun. The company will not commence the further clinical development of ANYARA on an independent basis.

Paquinimod (57-57) – novel oral immunomodulatory compound for the treatment of systemic sclerosis

Paquinimod is a quinoline compound primarily intended for the treatment of [systemic sclerosis](#). This rare disease is classified as an orphan drug indication. In February 2011, paquinimod was granted orphan medicinal product status in Europe for the indication systemic sclerosis. 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.

– Evaluation of the clinical trial in systemic sclerosis demonstrated a favorable safety profile and effects on disease-related biomarkers in line with paquinimod’s mode of action. The next step in clinical development is to verify these effects in a controlled Phase II study that can form the basis for a pivotal study in this patient group. Active Biotech has initiated discussions with potential partners for the continued clinical development of paquinimod. The company will not commence the further clinical development of paquinimod on an independent basis.

ISI (Inhibition of S100 interactions) – preclinical project based on the mode of action of quinoline compounds

Active Biotech is conducting a 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 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 showed 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.

– The project is proceeding according to plan. Efforts are centered on building up a patent portfolio around the compounds that interact with S100 proteins and the first patent applications have been filed. Selection of the first candidate drug is planned to take place during 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.

– MediGene is planning a clinical Phase IIa study in primary biliary cirrhosis (PBC), a chronic liver disease. This is being carried out to confirm the mode of action of RhuDex in autoimmune diseases and facilitate the continued development of the drug. The study is scheduled to commence in the first half of 2014. For more information and the latest news about RhuDex, see www.medigene.com.

Events after the end of the period

Laquinimod

Teva remain committed to the development of laquinimod (NERVENTRA®) for the treatment of multiple sclerosis (MS)

On January 24, laquinimod (Nerventra®) received a negative opinion by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA).

The CHMP's opinion was based on the view that laquinimod's positive effect on reducing relapses did not outweigh the potential risks. Although the CHMP found that laquinimod has a positive effect on slowing disability in MS patients this finding had no impact on the decision. In the risk assessment, the CHMP focused on findings in animal studies, performed in parallel with the pivotal clinical trials, relating to the potential risk of fetal damage and the potential increased risk of cancer. None of these effects have been observed in the comprehensive patient material, comprising 7,490 patient years in total, with some patients being exposed for more than seven years and tolerated the treatment well.

Teva has requested a re-examination of the CHMP's opinion a process that according to CHMP's regulations will take 120 days.

The ongoing pivotal Phase III study CONCERTO continues according to plan. Results are expected 2016.

At this time, Teva has decided to postpone further clinical development of laquinimod for the treatment of Crohn's disease until a clearer clinical strategy has been defined.

Tasquinimod

In February 2014, Ipsen launched a randomized, double-blind, placebo-controlled Phase III study of tasquinimod in chemo-naïve CRPC patients in Asia. For further information, visit www.clinicaltrials.gov.

Paquinimod

On [January 17](#), 2014, paquinimod (57-57), for the treatment of systemic sclerosis, was granted orphan-drug status by the US Food and Drug Administration (FDA). Orphan drug status in the US provides advantages such as market exclusivity for a period of seven years upon approval.

ANYARA

In [January 2014](#), the review article "Naptumomab Estafenatox: Targeted Immunotherapy with a Novel Immunotoxin", Eisen et al., was published in the scientific journal *Current Oncology Reports* (2014) 16:370 (doi: 10.1007/s11912-013-0370-0).

Financial information

Comments on the Group's results for the period January – December 2013

Net sales amounted to SEK 116.0 M (227.9) and included a milestone payment from Ipsen amounting to SEK 104.1 M and SEK 11.9 M (15.2) in service and rental revenues. The year-earlier period included total milestone payments of SEK 212.8 M. Of this amount, Ipsen accounted for SEK 177.7 M, of which SEK 91.6 M was paid upon enrolment of half of the patients in the ongoing Phase III tasquinimod trial and SEK 86.1 was paid in December 2012 when the study was fully enrolled. In addition, SEK 35.1 M was received from Teva on submission of a marketing authorization application for laquinimod to the European Medicines Agency (EMA) in July 2012.

The operation's research and administration expenses amounted to SEK 325.0 M (391.1), of which research expenses amounted to SEK 308.0 M (375.3). The 18-percent decrease in expenses was attributable to planned lower costs for the ongoing clinical Phase III trial of tasquinimod for the treatment of prostate cancer. Under the partnership agreement with Ipsen, Active Biotech will receive clinical, regulatory and commercial milestone payments on fulfillment of defined goals. Provided that these milestones are met, the Phase III trial will be financed in full by Ipsen. The other research projects – the ANYARA renal cell cancer project, the explorative study for the 57-57 project and the preclinical research project ISI – only had a marginal impact on the cost development between the years. The out-licensed projects comprising laquinimod and RhuDex are financed by the relevant partners.

The operating loss for the period amounted to SEK 209.0 M (loss: 163.2). The decline in earnings of SEK 45.8 M compared with the year-earlier period was attributable to a SEK 108.7 M decrease in milestone payments in 2013, which was partially offset by an 18-percent (SEK 67.3 M) reduction in research costs due to the ongoing Phase III trial of tasquinimod being fully enrolled since December 2012 and the fact that the patients are in the therapy phase. Administration expenses totaled SEK 17.0 M (15.8). The net financial expense for the period amounted to SEK 5.3 M (expense: 8.7) and the loss after tax was SEK 212.1 M (loss: 175.0).

Comments on the Group's results for the period October – December 2013

The operating loss for the period amounted to SEK 80.4 M (profit: 5.5). The change in earnings compared with the year-earlier period is attributable to Ipsen's milestone payment totaling SEK 86.1 M received upon full enrollment of the Phase III study, which was recognized as income in the fourth quarter of 2012. In addition, service and rental revenues totaling SEK 4.0 M (5.4) were reported.

The operation's research and administration expenses amounted to SEK 84.4 M (86.0), of which research expenses amounted to SEK 80.0 M (81.3). The costs for the ongoing clinical Phase III tasquinimod trial in patients with prostate cancer are declining as planned. Administration expenses totaled SEK 4.4 M (4.7). The net financial expense for the period amounted to SEK 2.2 M (expense: 0.4) and the loss after tax was SEK 82.1 M (profit: 0.1).

Cash flow, liquidity and financial position, Group

Cash and cash equivalents at the end of the period amounted to SEK 376.2 M, compared with SEK 216.7 M at the end of 2012.

Cash flow for the period was SEK 159.5 M (neg: 248.5), of which cash flow from operating activities accounted for a negative SEK 102.3 M (neg: 240.4). Cash flow from financing activities totaled SEK 261.8 M (neg: 8.1), of which the directed share issue of 6,000,000 shares to Investor raised approximately SEK 270 M.

Investments

Investments in tangible fixed assets amounted to SEK 0.1 M (0.0).

Comments on the Parent Company's results and financial position for the period January – December 2013

Net sales for the period amounted to SEK 125.4 M (234.9) and operating expenses to SEK 356.4 M (422.7). The Parent Company's operating loss for the period was SEK 231.0 M (loss: 187.8). Net financial income amounted to SEK 3.7 M (2.5) and the loss after financial items was SEK 227.3 M (loss: 185.3). Cash and cash equivalents including short-term investments totalled SEK 370.5 M at the end of the period, compared with SEK 208.9 M on January 1, 2013.

Comments on the Parent Company's results and financial position for the period October – December 2013

Net sales for the period amounted to SEK 6.4 M (92.1) and operating expenses to SEK 92.4 M (93.8). The Parent Company's operating loss for the period was SEK 86.0 M (loss: 1.7). Net financial income amounted to SEK 0.5 M (2.6) and the expense after financial items was SEK 85.5 M (income: 0.9).

Shareholders' equity

Consolidated shareholders' equity at the end of the period amounted to SEK 405.4 M, compared with SEK 339.9 M at year-end 2012. The number of shares outstanding at the end of the period totaled 74,923,582. At the end of the period, the equity/assets ratio for the Group was 52.8 percent, compared with 48.8 percent at year-end 2012. The corresponding figures for the Parent Company, Active Biotech AB, were 77.1 percent and 77.6 percent, respectively.

Organization

The average number of employees was 61 (76), of which the number of employees in the research and development organization accounted for 48 (62). At the end of the period, the Group had 59 employees.

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. Income from already signed agreements and existing cash and cash equivalents is expected to finance operations.

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 2012 Annual Report. Since the Group's operations are primarily conducted in the Parent Company, risks and uncertainties refer to both the Group and the Parent Company.

| Consolidated profit and loss | | Q4 | | Jan - Dec | |
|---|--------------|-------------|---------------|------------------|--|
| SEK M | 2013 | 2012 | 2013 | 2012 | |
| Net sales | 4,0 | 91,5 | 116,0 | 227,9 | |
| Administrative expenses | -4,4 | -4,7 | -17,0 | -15,8 | |
| Research and development costs | -80,0 | -81,3 | -308,0 | -375,3 | |
| Operating profit/loss | -80,4 | 5,5 | -209,0 | -163,2 | |
| Net financial items | -2,2 | -0,4 | -5,3 | -8,7 | |
| Profit/loss before tax | -82,6 | 5,1 | -214,3 | -172,0 | |
| Tax | 0,6 | -5,0 | 2,2 | -3,1 | |
| Net profit/loss for the period | -82,1 | 0,1 | -212,1 | -175,0 | |
| Comprehensive loss attributable to: | | | | | |
| Parent Company shareholders | -82,1 | 0,1 | -212,1 | -175,0 | |
| Non-controlling interests | - | - | - | - | |
| Net profit/loss for the period | -82,1 | 0,1 | -212,1 | -175,0 | |
| Comprehensive profit/loss per share before dilution (SEK) | -1,10 | 0,00 | -2,87 | -2,54 | |
| Comprehensive profit/loss per share after dilution (SEK) | -1,10 | 0,00 | -2,87 | -2,54 | |
| Statement of profit and loss and consolidated comprehensive income | | Q4 | | Jan - Dec | |
| SEK M | 2013 | 2012 | 2013 | 2012 | |
| Net profit/loss for the period | -82,1 | 0,1 | -212,1 | -175,0 | |
| Other comprehensive income | | | | | |
| Items that can not be reclassified into profit or loss | | | | | |
| Change in revaluation reserve | 1,8 | 1,8 | 7,2 | 7,2 | |
| Taxes attributable to other comprehensive income | -0,4 | 5,2 | -1,6 | 3,8 | |
| Total comprehensive profit/loss for the period | -80,7 | 7,1 | -206,5 | -164,1 | |
| Total other comprehensive profit/loss for the period attributable to: | | | | | |
| Parent Company shareholders | -80,7 | 7,1 | -206,5 | -164,1 | |
| Non-controlling interests | - | - | - | - | |
| Total comprehensive profit/loss for the period | -80,7 | 7,1 | -206,5 | -164,1 | |
| Depreciation/amortization included in the amount of | 3,2 | 3,2 | 12,9 | 12,9 | |
| Investments in tangible fixed assets | 0,0 | 0,0 | 0,1 | 0,0 | |
| Weighted number of outstanding common shares before dilution (000) | 74924 | 68924 | 73 954 | 68 924 | |
| Weighted number of outstanding common shares after dilution (000) | 74924 | 68924 | 73 954 | 68 924 | |
| Number of shares at close of the period (000s) | 74924 | 68924 | 74 924 | 68 924 | |
| Consolidated statement of financial position | | | | Dec 31 | |
| SEK M | | | 2013 | 2012 | |
| Tangible fixed assets | | | 381,0 | 381,5 | |
| Long-term receivables | | | 0,0 | 0,0 | |
| Total fixed assets | | | 381,0 | 381,5 | |
| Current receivables | | | 10,6 | 98,6 | |
| Cash and cash equivalents | | | 376,2 | 216,7 | |
| Total current assets | | | 386,8 | 315,2 | |
| Total assets | | | 767,8 | 696,7 | |
| Shareholders equity | | | 405,4 | 339,9 | |
| Long-term liabilities | | | 224,0 | 228,5 | |
| Current liabilities | | | 138,3 | 128,3 | |
| Total shareholders equity and liabilities | | | 767,8 | 696,7 | |

| Consolidated statement of changes in shareholders equity SEK M | Dec 31 | |
|---|--------------|--------------|
| | 2013 | 2012 |
| Opening balance | 339,9 | 502,0 |
| Transfer from revaluation reserve | 2,2 | 2,0 |
| New share issue | 269,8 | – |
| Net loss for the period | -206,5 | -164,1 |
| Balance at close of period | 405,4 | 339,9 |

| Condensed consolidated cash-flow statement SEK M | Jan - Dec | |
|--|---------------|---------------|
| | 2013 | 2012 |
| Loss after financial items | -214,3 | -172,0 |
| Adjustment for non-cash items, etc. | 12,9 | 12,9 |
| Cash flow from operating activities before changes in working capital | -201,4 | -159,1 |
| Changes in working capital | 99,1 | -81,3 |
| Cash flow from operating activities | -102,3 | -240,4 |
| Investments in tangible fixed assets | -0,1 | 0,0 |
| Cash flow from investing activities | -0,1 | 0,0 |
| New share issue | 269,8 | – |
| Loans raised/amortization of loan liabilities | -7,9 | -8,1 |
| Cash flow from financing activities | 261,8 | -8,1 |
| Cash flow for the period | 159,5 | -248,5 |
| Opening cash and cash equivalents | 216,7 | 465,2 |
| Closing cash and cash equivalents | 376,2 | 216,7 |

| Key figures | Dec 31 | |
|---|--------|-------|
| | 2013 | 2012 |
| Shareholders equity, SEK M | 405,4 | 339,9 |
| Equity per share, SEK | 5,41 | 4,93 |
| Equity/assets ratio in the Parent Company | 77,1% | 77,6% |
| Equity/assets ratio in the Group | 52,8% | 48,8% |
| Average number of annual employees | 61 | 76 |

| Consolidated profit and loss by quarter SEK M | 2010 | | | | 2011 | | | | 2012 | | | | 2013 | | | |
|--|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|---------------|--------------|--------------|------------|--------------|--------------|-------------|--------------|
| | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| Net sales | 2,8 | 3,4 | 2,3 | 2,9 | 2,7 | 226,1 | 2,6 | 3,3 | 2,6 | 94,0 | 39,8 | 91,5 | 2,4 | 2,5 | 107,0 | 4,0 |
| Administrative expenses | -4,6 | -7,1 | -4,0 | -7,3 | -5,3 | -4,4 | -3,2 | -4,0 | -3,8 | -4,2 | -3,2 | -4,7 | -4,2 | -4,6 | -3,8 | -4,4 |
| Research and development costs | -49,1 | -47,6 | -45,6 | -74,9 | -68,3 | -80,1 | -76,2 | -93,9 | -99,4 | -109,7 | -84,8 | -81,3 | -75,2 | -77,5 | -75,3 | -80,0 |
| Operating profit/loss | -51,0 | -51,4 | -47,3 | -79,3 | -70,9 | 141,5 | -76,8 | -94,7 | -100,7 | -19,9 | -48,2 | 5,5 | -77,0 | -79,5 | 27,9 | -80,4 |
| Net financial items | -2,5 | -3,3 | -1,2 | 2,4 | 1,6 | 4,3 | -2,8 | -5,7 | 1,0 | -5,3 | -4,1 | -0,4 | -1,6 | -2,2 | 0,8 | -2,2 |
| Profit/loss before tax | -53,5 | -54,8 | -48,5 | -76,8 | -69,3 | 145,8 | -79,6 | -100,4 | -99,6 | -25,1 | -52,3 | 5,1 | -78,6 | -81,7 | 28,7 | -82,6 |
| Tax | - | - | - | 12,6 | - | 1,2 | 0,6 | 7,2 | 0,6 | 0,6 | 0,6 | -5,0 | 0,6 | 0,6 | 0,6 | 0,6 |
| Net profit/loss for the period | -53,5 | -54,8 | -48,5 | -64,3 | -69,3 | 147,0 | -79,0 | -93,2 | -99,0 | -24,5 | -51,6 | 0,1 | -78,0 | -81,2 | 29,2 | -82,1 |

| Active Biotech Parent Company - Income Statement, condensed | | Q4 | | Jan - Dec | |
|--|--|--------------|-------------|------------------|---------------|
| SEK M | | 2013 | 2012 | 2013 | 2012 |
| Net sales | | 6,4 | 92,1 | 125,4 | 234,9 |
| Administration expenses | | -8,8 | -9,0 | -34,2 | -33,1 |
| Research and development costs | | -83,6 | -84,8 | -322,2 | -389,6 |
| Operating profit/loss | | -86,0 | -1,7 | -231,0 | -187,8 |
| <i>Profit/loss from financial items:</i> | | | | | |
| Interest income and similar income-statement items | | 1,3 | 1,1 | 5,2 | 6,7 |
| Interest expense and similar income-statement items | | -0,8 | 1,5 | -1,5 | -4,2 |
| Profit/loss after financial items | | -85,5 | 0,9 | -227,3 | -185,3 |
| Tax | | - | - | - | - |
| Net profit/loss for the period | | -85,5 | 0,9 | -227,3 | -185,3 |
| Statement of comprehensive income parent company | | | | | |
| Net profit/loss for the period | | -85,5 | 0,9 | -227,3 | -185,3 |
| Other comprehensive income | | - | - | - | - |
| Total comprehensive profit/loss for the period | | -85,5 | 0,9 | -227,3 | -185,3 |

| Active Biotech Parent Company - Balance sheet, condensed | | Dec 31 | |
|---|--|---------------|--------------|
| SEK M | | 2013 | 2012 |
| Goodwill | | 113,0 | 129,2 |
| Tangible fixed assets | | 0,6 | 0,8 |
| Financial fixed assets | | 40,6 | 40,6 |
| Total fixed assets | | 154,2 | 170,5 |
| Current receivables | | 21,9 | 108,9 |
| Short-term investments | | 264,3 | 189,5 |
| Cash and bank balances | | 106,2 | 19,4 |
| Total current assets | | 392,4 | 317,8 |
| Total assets | | 546,6 | 488,3 |
| Shareholders equity | | 421,6 | 379,1 |
| Current liabilities | | 125,0 | 109,2 |
| Total equity and liabilities | | 546,6 | 488,3 |

Any errors in additions are attributable to rounding of figures.

Note 1: Accounting policies

The interim report of the Group 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 and accounting estimates and assumptions were applied to this interim report as were used in the preparation of the most recent annual report.

Note 2: Fair value of financial instruments

| | Dec 31 2013 | Dec 31 2012 |
|-------------------------------------|--------------------|--------------------|
| MSEK | Level 2 | Level 2 |
| Short term investments | 264.3 | 169.5 |
| Short-term liabilities, derivatives | 4.3 | 8.9 |

Fair value regarding financial assets and liabilities essentially corresponds to the carrying amount in the balance sheet. The fair-value measurement of financial assets and liabilities has been conducted according to level 2 as defined in IFRS 7.27 A, with the exception of cash and cash equivalents, which is measured according to level 1. For more information, refer to Note 16 in the 2012 Annual Report. No significant changes have occurred in relation to the measurement made at December 31.

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 reports 2014: April 24, August 7 and November 5

Year-end report 2014: February 11, 2015

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

Lund, February 13, 2014

Active Biotech AB (publ)

Tomas Leanderson

President and CEO

***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 (NERVENTRA®), an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, tasquinimod for prostate cancer and ANYARA primarily for the treatment of renal cell cancer. In addition, laquinimod Phase II clinical trials in Crohn's and Lupus has been concluded. The company also has one additional project in clinical development, the orally administered compound paquinimod (57-57) for systemic sclerosis. 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 13, 2014 at 8:30 a.m.