

**Active Biotech
Interim report
January – September 2004**

- **TTS against lung cancer progressing according to plan**
- **All necessary permits obtained to commence patient study for the TASQ prostate-cancer project**
- **Phase I study with healthy volunteers has started for the SLE project**
- **Partnership with Teva implemented**
- **Net sales: SEK 68.2 M (0.2)**
- **Loss after net financial items: SEK 110.7 M (loss: 229.8)**
- **Loss per share for the period amounted to SEK 3.28 (loss: 9.79)**
- **Loss after tax: SEK 110.7 M (loss: 229.8)**

TTS project progressing to plan

The clinical Phase I dose-escalation study of TTS CD3 (Tumour Targeted Superantigens) is progressing according to plan. The study comprises patients with non-small cell lung cancer at the Fox Chase Center in Philadelphia, Pennsylvania, in the US and at the Radiumhospitalet hospital in Oslo, Norway. The study has been expanded to also document TTS CD3 in patients with renal cancer or pancreatic cancer. To date, the study has shown that TTS CD3 can be administered at 50-100 times higher doses than its predecessor TTS CD2 with maintained safety. The product's antigenicity has been lowered and the form of administration changed, making treatment simpler and more effective.

As part of the TTS project, pre-clinical data is also being compiled to study various kinds of treatments combining TTS with already established products. This data will be important in the design of future clinical studies.

The timing of the commencement of a controlled Phase II/III study depends on the length of the ongoing Phase I study. At the moment, such trials are planned to commence during 2005.

The market for the treatment of lung cancer is currently estimated at slightly more than USD 1 billion (source: Blomquist & Associates, February 1, 2003).

Background

Non-small cell lung cancer is one of the most common types of cancer. It is also the most fatal form of cancer. Non-small cell lung cancer accounts for about 80 percent of the total number of cases of lung cancer worldwide. In 2000, approximately one million people were afflicted by non-small cell lung cancer. In the same year, 880,000 people died of the disease. No adequate treatment methods are available. Surgery is the only form of treatment that can cure non-small cell lung cancer, although it is only effective for tumours that have not yet formed metastases. Cytostatic drugs such as cisplatin, carboplatin, vinorelbine, paclitaxel, docetaxel and gemcitabine are used with limited success for treating advanced disease.

Patient study planned for the TASQ prostate-cancer project

All the permits necessary for the commencement of a Phase Ib clinical study with prostate-cancer patients have now been obtained. The study will be started shortly and will be run in cooperation with Sahlgrenska Hospital in Gothenburg and the University Hospital in Lund.

A Phase I clinical study with healthy volunteers was concluded in February 2004. The study showed that the candidate drug TASQ can be administered orally, daily, and at dosage levels expected to be effective in the treatment of prostate cancer. In addition, an extensive pre-clinical safety documentation process was completed, making it possible to conduct clinical studies where the TASQ substance can be administered to patients during longer periods.

The global market for pharmaceuticals for the treatment of prostate cancer is currently estimated at approximately USD 3.1 billion annually (source: Blomquist & Associates, February 1, 2003).

Background

The purpose of the company's TASQ project is to develop a pharmaceutical that can be administered orally for the treatment of prostate cancer. Active Biotech is collaborating with Professor John T. Isaacs of Johns Hopkins University in Baltimore, Maryland, in the US, in this project. In various disease models, this candidate drug has shown favourable anti-angiogenesis effects, which means it is able to cut off nutrition to tumour cells, and has also shown a direct anti-tumour effect in pre-clinical models. Moreover, studies have also shown that the TASQ substance does not inhibit the enzyme systems (kinases) that are the target molecules for most of the current anti-angiogenesis compounds. This implies that the TASQ substance's mode of action differs from that of such drugs.

Prostate cancer is the most common form of cancer among men and accounts for almost one third of all cancers. The disease principally affects men in their 50s and older. Prostate cancer has varying degrees of severity. Despite a relatively good prognosis, prostate cancer is the second most common cause of death among men.

Clinical studies commenced for the 57-57 project for SLE

As announced, the company initiated a Phase I clinical trial with the candidate drug 57-57 for Systemic Lupus Erythematosus (SLE) in early November 2004.

The study is a dose-escalation study aimed at studying the safety of the ABR-215757 candidate drug in escalating doses in parallel groups of healthy volunteers. The study is being conducted at Karolinska University Hospital in Stockholm and is expected to finish during the first half of 2005.

The next step in the clinical development of 57-57 is a Phase I clinical trial to study how the substance is tolerated in the treatment of SLE patients.

SLE (Systemic Lupus Erythematosus) is a life-threatening, degenerative autoimmune disease for which current treatment alternatives are highly inadequate. The number of SLE patients in the US is estimated at not less than 500,000. Ninety percent of those affected are women.

Background

SLE - Systemic Lupus Erythematosus – is a disease of the connective tissues that can cause inflammation and damage to the connective tissue in any organ in the body. Progress and symptoms of the disease vary widely, depending on the organs affected. The disease primarily affects women of childbearing age. It progresses in “flare-ups” interspersed by relatively symptom-free periods. The autoimmune attacks affect many different organ systems, and the disease eventually leads to many patients experiencing serious secondary symptoms, such as kidney failure.

Partnership with Teva implemented

In June of this year, Active Biotech signed an agreement with Teva Pharmaceutical Industries Ltd. for the development and commercialisation of laquinimod; an immunomodulatory agent carrying the potential to develop an anti-retroviral drug in tablet form for the oral treatment of multiple sclerosis (MS). On August 24, the Federal Trade Commission approved the agreement, giving the go-ahead for the partnership.

The project has now been integrated into Teva’s research organisation, project teams have been appointed and the cooperation is well in progress.

On October 19, Active Biotech and Teva jointly arranged a Capital Market Meeting in Stockholm, at which Teva’s senior management gave a presentation of the company, its position in the MS market and its expectations for laquinimod.

Assuming continued successful development, the company assesses that laquinimod can be launched on the market in 2009, with a yearly sales potential exceeding USD 1 billion.

To view and listen to the entire presentation at the Capital Market Meeting, see www.activebiotech.com

The total market for MS drugs in 2003 amounted to USD 3.5 billion. This market is expected to exceed USD 6.5 billion in 2008 (source: SG Cowen, 2004).

Background

The Phase II study of laquinimod, presented in September 2003, shows that laquinimod, in a daily oral dose of 0.3 mg, is well tolerated and is effective in inhibiting the development of harmful inflammation in the brain measured using MRI in relapsing MS patients.

Teva has received a globally exclusive right to develop, register, produce and commercialise laquinimod. Active Biotech will retain commercial rights for the future sale of the product in the Nordic and Baltic regions. Teva will assume responsibility for future communications relating to the project. Teva has initially paid Active Biotech a sum of USD 5 M and will now implement and bear the cost of the continued clinical development of laquinimod. Teva will also make partial payments to Active Biotech as the project’s milestones – including sales targets – are met. If all milestones are met, the payments will total USD 92 M. Active Biotech will also receive two-figure royalty payments on a rising scale from future sales of the product in the market.

Multiple sclerosis is a chronic, progressive disease affecting the central nervous system and is the most commonly occurring neurological disease causing disability among young people. It is described as an autoimmune disease since it belongs to a large group of diseases that cause the body's immune defence system to attack healthy areas of the body as if they were foreign bodies. MS can lead to anything from minor symptoms for lengthy periods to severely incapacitating symptoms within a few years. Initially, MS comes in "flare-ups" with alternating periods of deterioration and stability. The disease mainly affects young people, and more women than men; the average age of onset of the disease is about 30.

Financial information

Comments on the Group's results for the period January – September 2004

Consolidated net sales for the period amounted to SEK 68.2 M (0.2), of which SEK 30.3 M pertains to a milestone payment from Chiron Corp. In addition, SEK 37.7 M pertains to the initial payment related to the partnership agreement with Teva Pharmaceutical Industries Ltd.

Research and administration costs for the period decreased by 12 percent compared with the year-earlier period to SEK 206.3 M (235.6). The reduction in costs is largely attributable to lower costs for the clinical development program with the Phase II trials for SAIK-MS and TTS CD2 being completed during the latter part of 2003. The first nine months of 2004 were burdened with costs for the ongoing Phase I study for TTS CD3 against lung cancer in the US and Norway and costs for starting up Phase I studies for the TASQ prostate-cancer project and 57-57 project against SLE.

Earnings for the period were burdened by a SEK 10.2 M provision for payroll expenses during the remaining period of notice for personnel who have left the company.

The operating loss decreased by SEK 117.1 M to a loss of SEK 138.0 M (loss: 255.1) as a result of higher revenues and lower costs.

Net financial income for the period amounted to SEK 28.9 M (27.6). The improved financial net is primarily attributable to the first quarter of 2004, when a dividend from the Nektar interest hedge fund and a capital gain from the disposal of this investment totalled SEK 26.9 M.

Participation in the results of the associated UK company Isogenica Ltd amounted to a loss of SEK 1.7 M (loss: 2.2). Operations in the associated company are progressing according to plan.

Loss after financial items amounted to SEK 110.7 M (loss: 229.8).

Liquidity and financial status

Cash flow from current operations before changes in working capital was negative in an amount of SEK 99.4 M (neg: 218.7). The improved cash flow is attributable to higher revenues and lower costs compared with the year-earlier period.

Investments in tangible fixed assets – primarily laboratory equipment – during the period amounted to SEK 1.3 M (5.2). On September 30, 2004, the Group had no external debts, apart from a debt of SEK 6.5 M (6.8) to leasing companies.

The book value of the Group's short-term investments and liquid assets was SEK 128.5 M at the close of the period, compared with SEK 227.6 M at year-end 2003. Available liquidity per share amounted to SEK 3.72, compared with SEK 6.66 at the end of 2003.

Share capital

Consolidated shareholders' equity amounted to SEK 178.7 M at the close of the period, compared with SEK 289.6 M at the end of the preceding year. The change is due to the negative earnings for the period.

The total number of outstanding shares on September 30, 2004 was 33,738,876, which was unchanged from the end of 2003.

At the close of the period, the Group had an equity/assets ratio of 78.6 percent, compared with 83.8 percent at the end of 2003. The corresponding figures for the parent company, Active Biotech AB, were 36.0 percent and 28.5 percent, respectively.

Organisation

On September 30, 2004, the Group had 133 (181) employees. In February 2004, the Group decided to focus its activities on projects in the clinical phase, resulting in significant staff cutbacks. The new organisation will comprise 87 employees. The reduction in the number of employees will take place gradually as employment contracts expire.

Outlook

In June 2004, Active Biotech signed a development and commercialisation agreement with Teva Pharmaceutical Industries Ltd. for laquinimod (SAIK-MS) for treatment of multiple sclerosis. The initial payment of USD 5 M was received in August and the cooperation is progressing according to plan.

Operations will continue to focus on implementing the Phase I dose-escalation study for TTS CD3 against non-small cell lung cancer and Phase I studies for the TASQ prostate-cancer project and the 57-57 project for SLE.

Forecast for full year 2004

The signing of the partnership agreement combined with the planned organisational changes will result in a significant reduction of the company's loss for the full year 2004. The forecast for the full year is for an operating loss not exceeding SEK 175 M (loss: 307) after financial items.

Parent company Active Biotech AB – Corporate reg. no. 556223-9227

The operations of the parent company, Active Biotech AB, comprise Groupwide administrative functions. Parent company net sales for the period amounted to SEK 70.6 M (2.6), of which SEK 30.3 M pertained to a milestone payment from Chiron Corp. and SEK 37.7 M to the initial payment from Teva Pharmaceutical Industries Ltd.

Operating expenses during the period amounted to SEK 24.4 M (expense: 43.8). The figure for 2003 includes an expense item arising from a lack of guarantee in connection with the sale of the Peltor AB subsidiary company in 1996. Net financial income for the period amounted to SEK 26.4 M (25.5). The parent company's gross investments in fixed assets during the period amounted to SEK 0.0 M (0.0). Liquid funds in the parent company at the end of the period amounted to SEK 125.4 M, compared with SEK 217.0 M on January 1, 2004.

Extraordinary General Meeting on November 8, 2004

The Board of Directors has decided to propose at an Extraordinary General Meeting that the company raises a convertible debenture loan in a nominal amount of SEK 149,950,560 through the issue of 3,748,764 convertible debentures.

MGA Holding AB, with shares corresponding to 28.9 percent of the share capital and votes, guarantees that the issue will be fully subscribed.

The Extraordinary General Meeting will be held on November 8, 2004 at 5 p.m. in the company's premises at Scheelevägen 22 in Lund.

Notification of the Board's decision and the invitation to attend the Extraordinary General Meeting can be read in full on the company website: www.activebiotech.com

Accounting and valuation principles

This interim report has been prepared in accordance with the Swedish Financial Accounting Standards Council's recommendations (RR20 Interim Reports). The accounting and valuation principles applied in the interim report remain unchanged from those applied in the 2003 Annual Report.

Because of the company's structure and considerable research and development costs, the company is currently not required to pay income taxes. The Group's accumulated tax loss carryforwards at the end of 2003 amounted to SEK 980 M, including the currently unconfirmed tax assessment for the fiscal year 2003.

In accordance with EU requirements for listed companies, Active Biotech will apply IFRS (International Financial Reporting Standards) in its consolidated accounts from 2005. Based on the company's current operations, the main differences will concern the reporting of pensions and other remuneration to employees, the reporting of "sale and leaseback agreements" pertaining to property and the reporting of financial instruments. The process of preparing for the introduction of the new accounting regulations is progressing according to plan.

The consequences of the change in accounting principles will be presented in a prospectus for convertible debentures published by the company in November 2004.

Future report dates

Year-end report 2004

17 February 2005

The report will be available at www.activebiotech.com from this date.

Active Biotech – Group

Income statement, condensed SEK M	July-Sept.		Jan.-Sept.		Full year
	2004	2003	2004	2003	2003
Net sales	37.8	0.1	68.2	0.2	0.3
Administrative expenses	-7.0	-6.7	-24.4	-24.2	-32.9
Research and development costs	-63.9	-65.7	-181.9	-211.4	-284.2
Items affecting comparability	–	-19.7	–	-19.7	-19.7
Operating loss	-33.1	-92.0	-138.0	-255.1	-336.4
Loss from shares in associated companies	-1.0	-0.6	-1.7	-2.2	-2.5
Net financial items	0.8	2.2	28.9	27.6	32.0
Loss after net financial items	-33.3	-90.5	-110.7	-229.8	-307.0
Tax	–	–	–	–	-0.6
Net loss for the period	-33.3	-90.5	-110.7	-229.8	-307.6
Depreciation/amortisation included in an amount of	3.3	3.7	10.2	11.9	15.5
Investments in fixed assets	0.0	0.9	1.3	5.2	5.6
Loss per share before dilution (SEK)	-0.99	-2.68	-3.28	-9.79	-11.80
Weighted number of ordinary shares before dilution (000s)	33,739	33,739	33,739	23,475	26,062
Weighted number of ordinary shares after dilution (000s)	33,739	33,739	33,739	23,475	26,062
Number of shares at close of period (000s)	33,739	33,739	33,739	33,739	33,739
Number of shares at close of period, including warrants (000s)	35,069	33,739	35,069	33,739	35,069
Balance sheet, condensed			30	Sept.	Dec. 31
SEK M			2004	2003	2003
Tangible fixed assets			41.4	53.5	50.3
Financial fixed assets			45.1	46.5	45.1
Total fixed assets			86.5	100.1	95.4
Current receivables			12.3	20.9	22.5
Short-term investments and liquid assets			128.5	288.1	227.6
Total current assets			140.8	309.0	250.0
Total assets			227.3	409.0	345.4
Shareholders' equity			178.7	367.3	289.6
Long-term liabilities			4.8	6.8	4.9
Current liabilities			43.8	35.0	50.9
Total liabilities and shareholders' equity			227.3	409.0	345.4
Changes in shareholders' equity, condensed					
Balance at start of period			289.6	380.3	380.3
New share issue			–	216.2	216.7
Translation differences			-0.1	0.6	0.2
Net loss for the period			-	-229.8	-307.6
Balance at end of period			178.7	367.3	289.6

Cash-flow statement, condensed	Jan.-Sept.		Full
	2004	2003	year
SEK M			2003
Loss after financial items	-110.7	-229.8	-307.0
Adjustments for items not included in cash flow, etc.	14.3	14.0	18.9
Tax paid	-2.9	-2.9	0.0
Cash flow from current operations before changes in working capital	-99.4	-218.7	-288.1
Changes in working capital	3.4	-10.6	-0.7
Cash flow from current operations	-95.9	-229.3	-288.8
Net investments in fixed assets	-1.7	-1.1	-1.1
Cash flow from investing activities	-1.7	-1.1	-1.1
New share issue	–	216.2	216.7
Loans raised/amortisation of borrowing	-1.4	-26.7	-28.2
Cash flow from financing activities	-1.4	189.5	188.5
Cash flow for the period	-99.1	-40.9	-101.4
Liquid funds, beginning of period	227.6	329.1	329.1
Exchange-rate differences in liquid funds	0.0	-0.1	-0.1
Liquid funds, end of period	128.5	288.1	227.6
		Sept. 30	Dec. 31
Key figures	2004	2003	2003
Shareholders' equity, SEK M	178.7	367.3	289.6
Shareholders' equity per share, SEK	5.30	10.89	8.58
Available liquid funds, SEK M	125.5	288.1	224.6
Available liquid funds per share, SEK	3.72	8.54	6.66
Equity/assets ratio of Parent Company, %	36.0%	43.7%	28.5%
Equity/assets ratio of Group, %	78.6%	89.8%	83.8%
Average number of annual employees	164	179	179

Any errors in addition are due to rounding-off of figures.

Lund, 5 November 2004
Active Biotech AB

Sven Andréasson
President & CEO

We have reviewed this interim report in accordance with the recommendation issued by FAR. A review is considerably limited in scope compared with an audit. Nothing has come to our attention that causes us to believe that the interim report does not comply with the requirements of the Annual Accounts Act.

Lund, 5 November 2004
KPMG Bohlins AB

Stefan Holmström, Authorised Public Accountant

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Active Biotech AB is a biotechnology company focusing on research and development of pharmaceuticals. Active Biotech has a strong R&D portfolio focusing primarily on autoimmune/inflammatory diseases and cancer. The main projects involve unique substances with immunomodulatory properties (SAIK-MS), intended for the treatment of diseases including multiple sclerosis, as well as a novel concept for the treatment of cancer (TTS).

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