

Active Biotech Year End Report January-December 2003

- **SAIK-MS (laquinimod) in preparation for Phase III clinical trials**
- **Focus on optimised candidate drug TTS CD3 for the treatment of non-small cell lung cancer**
- **Clinical Phase I study with healthy volunteers for the TASQ prostate-cancer project concluded**
- **SLE project 57-57 proceeding according to plan**
- **Future focus on clinical projects**
- **Consolidated sales amounted to SEK 0.3 M (3.8) for the full year, and to SEK 0.2 M (1.1) for the fourth quarter**
- **Loss after net financial items of SEK 307.0 M (loss: 308.3) for the full year, and a loss of SEK 77.2 M (loss: 92.6) for the fourth quarter**
- **Loss per share for the full year amounted to SEK 11.80 (loss: 23.38), and a loss of SEK 2.31 (loss: 6.56) for the fourth quarter**

SAIK-MS

During the autumn of 2003, SAIK-MS (laquinimod), intended for the oral treatment of multiple sclerosis (MS), demonstrated favourable results during Phase II clinical studies. Treatment over six months with 0.3 mg of laquinimod daily resulted in a 30-percent decrease in disease activity. Patients with disease activity at the start of the study showed a decrease of more than 40 percent. Decreased disease activity was also noted in patients receiving the lower dose of 0.1 mg per day. However, this decrease was not statistically significant. The study also confirmed laquinimod's advantageous safety profile.

During 2003, initial contacts were established with the US regulatory authority, the FDA, for the preparation of an application to commence clinical trials in the US (IND). A preparatory meeting will be held with the European registration authority, the EMEA, during the first quarter of 2004.

The protocol for Phase III clinical trials is being prepared before undergoing final evaluations with future partners.

The final report from the Phase II study of laquinimod has been accepted for presentation at the 56th Annual Meeting of the American Academy of Neurology (AAN), in San Francisco, California on April 27.

The total market for MS drugs in 2002 was valued at USD 2.8 billion. By 2006, the market value is expected to reach USD 4.5 billion (source: SG Cowen, 2003).

Background

Today, multiple sclerosis (MS) is an incurable disease that results from the body's immune system attacking the myelin sheaths surrounding the nerve fibres in the brain and elsewhere. Nerve impulses are disrupted or broken, preventing sensory inputs from reaching the brain and being perceived. The brain is no longer able to communicate with the body's muscles. 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 improvement. The disease mainly affects young people, and more women than men; the average age of onset of the disease is about 30.

Focus on optimised candidate drug TTS CD3

In parallel with the development of the candidate drug TTS CD2 (Tumour Targeted Superantigens), candidate drug TTS CD3 has been optimised with the objective to possess an enhanced anti-tumour activity with a very strong safety profile. This means that it can be administered in considerably higher doses, which in earlier clinical trials with TTS CD2 was shown to be of significance for the product's effect on tumour response.

A clinical Phase I dose-escalation study of TTS CD3 is currently in progress and involves patients with non-small cell lung cancer at the Fox Chase Cancer Center in Philadelphia, Pennsylvania in the US and at the Radiumhospitalet in Oslo, Norway. Already early in the study it has been possible to confirm that TTS CD3 can be administered at considerably higher doses than TTS CD2 with a retained level of safety. The product's antigenicity is lowered and treatment is therefore expected to be simpler and more effective. It can also be administered as a bolus injection (intravenous injection), rather than as an infusion (intravenous drip).

In December 2003, after having reached the objectives for TTS CD2 and CD3, Active Biotech decided to focus future product development on TTS CD3. The development of TTS CD3 will primarily be directed towards approval for the treatment of non-small cell lung cancer. Today, non-small cell lung cancer is primarily treated with chemotherapy and surgery. There is an extensive medical need for new treatment methods, since existing therapies do not provide satisfactory results and have major side effects.

The timing of the ongoing Phase I study will be decisive for the start of controlled Phase II/III trials but current estimates for the initiation of such trials would be during 2005.

The focus on CD3 means a more efficient development program with a more attractive product profile.

The final analysis, in December 2003, of tumour response in the Phase II study of patients with advanced renal cancer at a progressive stage, who were treated with TTS CD2, showed encouraging results.

After 2 and 4 months of TTS CD2 treatment, 68 percent and 40 percent of the patients showed stable disease (SD), respectively.

Of the total number of renal-cancer patients included in the study, 72 percent had previously received treatment with Interleukin-2, Interferon-alpha or chemotherapy, but continued to progress. The high frequency of patients with stable disease in the study indicates the efficacy of treatment. Furthermore, the TTS products possess a unique, immune-mediated mode of action with few and mild side effects.

One patient in the study showed a sustained partial response (PR) lasting more than 11 months. This patient received a relatively high dose compared to the other patients, a fact that emphasises the need for optimised dosing. This was previously noted in a separate TTS clinical study in patients with non-small cell lung cancer.

It is planned to present the final studies of the TTS CD2 pancreatic-cancer study during the first quarter of 2004.

Background:

Non small-cell lung cancer (NSCLC) is one of the most commonly occurring malignant diseases. It is also the form of cancer with the highest mortality rate. NSCLC affects close to a million people worldwide each year. There are no sufficiently effective treatment methods. The market for drugs used in the treatment of lung cancer are currently valued at slightly more than USD 1 billion (Source: Blomquist & Associates, February 1, 2003).

Phase I clinical study for the TASQ prostate-cancer project concluded

Within the TASQ project, the Phase I clinical study with healthy volunteers has now been concluded. The study has shown that the candidate drug TASQ can be administered orally, on a daily basis and at the dosage levels expected to be efficacious in the treatment of prostate cancer.

A study on the treatment of patients with prostate cancer is currently being planned in collaboration with the John Hopkins University Hospital in Baltimore, Maryland in the US. An IND application for permission to commence the study is being prepared and will be submitted to the FDA during the first half of 2004.

The anti-tumour and anti-angiogenesis effects of the TASQ substance were further documented. In addition, 6- and 12-month toxicity studies are being concluded, with reports currently being compiled.

Work is now in progress in order to compare the substance with competing compounds as well as studying how it functions in combination with other compounds. Since the mode of action of the TASQ substance is unique, a synergetic effect could hypothetically be achieved in combination with other anti-angiogenesis substances, such as VEGF inhibitors.

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, recently completed studies have also shown that the TASQ substance does not inhibit the enzyme systems (so-called kinases) that are the target molecules for most of the current anti-angiogenesis compounds. This implies that the TASQ substance's active mechanism 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.

SLE project 57-57 progressing according to plan

57-57, Active Biotech's candidate drug for the treatment of Systemic Lupus Erythematosus (SLE), has been shown to inhibit the disease in mice that spontaneously develop a condition similar to SLE. The results were presented at the American College of Rheumatology (ACR) conference on October 27, 2003.

Oral treatment with doses of 2 or 12 mg/kg of ABR-215757 per day resulted in a statistically significant decrease of kidney inflammation, measured as protein level and blood in the urine, compared to the control group. As a consequence, the survival of the animals treated with ABR-215757 was increased. A similar result was seen irregardless of whether the animals were treated at an early or late stage of the disease process. These results indicate that ABR-215757 could offer a new treatment alternative for SLE patients.

Favourable effects from 57-57 were also observed in experimental models for rheumatoid arthritis.

Work within this project is now focused on scaling-up production of the substance and the preparation of safety documentation. Phase I clinical trials are expected to commence during the first half of 2004.

SLE (Systemic Lupus Erythematosus) is a life-threatening, degenerative autoimmune disease for which very few treatment options are available at present. No new drug has been registered for the treatment of this indication in the past 40 years. It is estimated that at least 500 000 people in the US currently suffer from SLE. Nine out of ten 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.

Further strengthening of patent portfolio

Two priority applications related to the SAIK-MS, TASQ and 57-57 projects have been submitted. The patent applications refer to different compound compositions within this group of compounds. The patent applications would provide, subject to their approval, considerably reinforced patent protection with regard to both scope and period of applicability.

A patent application has also been submitted for the I-3D project, which seeks, with the help of structure-based pharmaceutical design, to develop a pharmaceutical against autoimmune/inflammatory diseases. This patent is for a new class of small molecules aimed at a known target molecule, intended primarily for the treatment of autoimmune diseases.

Financial information

Comments on Group results during the fourth quarter of 2003

The Group’s net sales during the period October-December amounted to SEK 0.2 M (1.1).

Operating costs for research and administration decreased from SEK 111.6 M to SEK 81.5 M. The cost reduction reflects decreased costs for the clinical development program, with the results of SAIK-MS and TTS CD2 against renal cancer being reported during the period. Also charged against earnings for 2002 was SEK 26.1 M for the take-back from Pharmacia of all commercial rights to SAIK-MS and TTS.

Operating income amounted to a loss of SEK 81.3 M (loss: 110.4).

Net financial items for the period amounted to income of SEK 4.4 M (18.9). The financial net is mainly attributable capital gains from asset management, with part of the Group’s holding in the fixed-income hedge fund Nektar and its remaining holdings of listed shares being sold during the period.

Participation in the results of the associated UK company Isogenica Ltd amounted to a loss of SEK 0.3 M (loss: 1.1), reflecting a positive trend for the company having secured a number of technology licensing agreements.

The operating loss after financial items was SEK 77.2 M (loss: 92.6).

Comments on Group results for full-year 2003

The Group’s net sales during the year amounted to SEK 0.3 M (3.8).

Operating costs for the full year amounted to SEK 336.8 M (345.2). Research and administration costs decreased from SEK 320.6 M to SEK 317.1 M as a consequence of the final reporting, during the fourth quarter, of the results from the Phase II studies for the key projects SAIK-MS and TTS CD2 against renal cancer. During the year, Phase I studies were initiated for TTS CD3 against lung cancer and TASQ against prostate cancer. The planning of the Phase I study for the 57-57 project against SLE is under way, with a view to commence the study during 2004.

SEK 19.7 M was charged against earnings for the current year for the lack of guarantees in connection with the divestment of Peltor Holding AB in 1996.

The operating loss for the year amounted to SEK 336.4 M (loss: 341.1).

Net financial items for the year amounted to income of SEK 32.0 M (35.8). The financial net is mainly attributable to dividends from the fixed-income hedge fund Nektar and capital gains from asset-management activities.

Active Biotech's participation in the earnings of the associated company Isogenica Ltd amounted to a loss of SEK 2.5 M (loss: 3.0). During the year, the company conducted a new share issue, to which Active Biotech subscribed for its ownership share.

The operating loss after financial items was SEK 307.0 M (loss: 308.3).

Liquidity and financial status

Cash flow for the fourth quarter was a negative SEK 60.5 M (negative: 54.0) and negative SEK 101.4 M (negative: 266.7) for the full year 2003. Cash flow from current operations was negative in the amount of SEK 288.8 M (negative: 291.7).

Investments in tangible assets during the fourth quarter, primarily instruments and laboratory equipment in research operations, amounted to SEK 5.6 M (3.6), of which SEK 5.5 M (3.2) was financed through financial leasing.

The preferential rights issue conducted during the year provided SEK 216.7 M in proceeds after transaction costs.

At the close of the period, the Group had no external bank loans, excluding liabilities to leasing companies amounting to SEK 6.7 M (2.7).

The book value of the Group's short-term investments and liquid assets was SEK 227.6 M at the close of the period, compared with SEK 329.1 M at year-end 2002. The market value of the financial investments exceeded book value by SEK 29.1 M at year-end.

Liquid funds amounted to SEK 6.74 per share, compared with SEK 29.27 per share at year-end 2002.

Shareholders' equity

Group shareholders' equity amounted to SEK 289.6 M at the close of the period, compared with SEK 380.3 M at the end of the preceding year.

At the close of the period, the Group had an equity/asset ratio of 83.8 percent, compared with 81.3 percent at the end of 2002. The corresponding figures for the parent company Active Biotech AB were 28.5 percent and 36.1 percent, respectively.

Organisation – future focus on clinical projects

During 2003, the company reported positive results from clinical trials for the SAIK-MS project and the TTS cancer project. The TASQ prostate-cancer project is currently in Phase I clinical trials and the 57-57 SLE project is planned to enter Phase I clinical trials during 2004.

The successful clinical studies require that these projects receive further priority. This means that a review will be conducted with regard to the organisation and structure of the company. The intention is to reduce costs related to the project portfolio with a maintained priority on the clinical projects. This will generate a considerable reduction in the company's operating costs.

Other events

On April 10, 2003, the Annual General Meeting approved the preferential rights issue totalling SEK 225 M decided by the Board and the Board's proposal for a reduction in the par value of shares to SEK 10. The issue was completed during the second quarter and provided SEK 216.7 M in capital after transaction costs.

On June 12, 2003, Active Biotech received notification that arbitration proceedings had been initiated by PowderJect Pharmaceuticals Plc., on the basis of alleged incorrect assumptions in the transfer agreement pertaining to the sale of SBL Vaccin in July 2001. The claim amounts to a maximum of USD 20 M. Active Biotech considers the claim as groundless and arbitration is currently in progress.

On July 25, the CPMP committee of the European registration authority, the EMEA, gave a positive recommendation for the registration of the Dukoral travel vaccine. PowderJect Pharmaceuticals Plc. acquired SBL Vaccin AB from Active Biotech in 2001. According to the acquisition agreement, a supplemental purchase price of USD 10 M is to be paid to Active Biotech upon the approved registration of Dukoral in Europe before December 31, 2003. After that date, the milestone payment is reduced by 417 KUSD every month during 2004 to a minimum of USD 5 M. In addition, Active Biotech shall receive royalty payments for future annual sales in Europe in excess of USD 40 M.

At an Extra Ordinary General Meeting on December 8, 2003, it was decided to introduce an employee stock options program comprising 1,000,000 employee stock options to be distributed to all employees of Active Biotech. The stock options program, which, combined with the hedging of future social costs, comprises a total of 1,330,000 options, entails a maximum dilution of existing shareholders by 3.8 percent, of which 2.9 percent results from employee allocations.

The Extra Ordinary General Meeting also decided to amend the Articles of Association such that all shares shall be of the same class and carry the same voting rights, and such that the issue of Series A and B shares shall not be permitted.

Forecast

As a result of ongoing discussions with potential partners, which may affect the company's financial position and earnings, as well as the planned review of the organisation, no forecast for the 2004 full year can be given.

The Board proposes that no dividend be paid for 2003.

Accounting and valuation principles

This year-end report has been prepared in accordance with the Swedish Financial Accounting Standards Council's recommendation (RR20 Interim Report). The accounting and valuation principles used in this report are identical to those used in the 2002 annual report. The new recommendations have not affected the Group's accounting.

Because of the company's structure and considerable research and development costs, it is currently not required to pay income taxes. The parent company's accumulated tax loss carryforwards at the end of 2003 amounted to SEK 922.2 M, including the currently unconfirmed tax assessment for the fiscal year.

Future report dates 2004

The 2003 Annual Report will be available on the Group's website from the end of March.

Interim report January-March:	May 13
Interim report January-June:	August 12
Interim report January-September:	November 5

As of the above dates, reports will be available at www.activebiotech.com.

Annual General Meeting and Annual Report

The Annual General Meeting will be held on April 21, 2003 at Edison Park, Emdalavägen 18, Lund, Sweden. A more detailed invitation will be distributed closer to this date. The Annual Report will be available on the Group's website from the end of March and printed copies will be sent to those who request them.

Lund, February 12, 2004
Active Biotech AB

Sven Andréasson
President & CEO

This report is unaudited.

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Active Biotech AB is a biotechnology company focusing on research in and development of pharmaceuticals. Active Biotech has a strong R&D portfolio and pipeline products with focus primarily on autoimmune/ inflammatory diseases and cancer. Most advanced projects include orally administered small molecules with unique immunomodulatory properties that can be used to treat autoimmune and inflammatory diseases, as well as a novel concept for use in cancer immunotherapy.

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The Active Biotech Group

Income statement in summary

MSEK	Oct-Dec		Jan-Dec	
	2003	2002	2003	2002
Net sales	0.2	1.1	0.3	3.8
Cost of goods sold	0.0	0.1	0.0	0.2
Gross Profit	0.2	1.2	0.3	4.0
Administrative expenses	-8.7	-9.8	-32.9	-35.4
Research and development costs	-72.8	-75.7	-284.2	-285.2
Items affecting comparability - income	0.0	0.4	0.0	2.7
Items affecting comparability - expenses	0.0	-26.5	-19.7	-27.3
Operating loss	-81.3	-110.4	-336.4	-341.1
Loss from share in associated companies	-0.3	-1.1	-2.5	-3.0
Net financial items	4.4	18.9	32.0	35.8
Loss after financial items	-77.2	-92.6	-307.0	-308.3
Tax on profit for the period	-0.6	8.8	-0.6	9.4
Net loss for the period	-77.8	-83.9	-307.6	-298.9
Depreciation incl. in an amount of	3.6	4.7	15.5	17.6
Investments in fixed assets	0.4	3.2	5.6	3.6
Loss per share before dilution (SEK)*	-2.31	-6.56	-11.80	-23.38
Weighted no of shares bef. dilution, -000	33 739	12 783	26 062	12 783
Weighted no of shares after dilution, -000	34 071	12 783	26 146	12 783
Average number of shares, -000	33 739	11 246	33 739	11 246
Number of shares at close of period, -000	35 069	11 246	35 069	11 246

* Earnings per share after dilution are not reported since the warrants issued entail no dilution of earnings per share because exercise would result in an improvement in the reported earnings per share.

Balance sheet in summary

MSEK	December 31	
	2003	2002
Tangible fixed assets	50.3	60.2
Financial fixed assets	45.1	47.9
Total fixed assets	95.4	108.1
Current receivables	22.5	30.3
Short-term investments and liquid assets	227.6	329.1
Total current assets	250.0	359.4
Total assets	345.4	467.5
Shareholders equity	289.6	380.3
Long-term liabilities	4.9	2.7
Current liabilities	50.9	84.6
Total liabilities and shareholders' equity	345.4	467.5

Changes in shareholders' equity in summary	31 December	
	2003	2002
Total at start of period	380.3	678.8
New share issue	216.7	-
Translation differences	0.2	0.4
Net loss for the period	-307.6	-298.9
Total at end of period	289.6	380.3

Cash flow statement in summary MSEK	Jan-Dec	
	2003	2002
Loss after financial items	-307.0	-308.3
Adjustments for items not included in cash flow etc.	18.9	23.5
Tax paid	0.0	-0.9
Cash flow from current operations before		
Changes in working capital	-288.1	-285.7
Changes in working capital	-0.7	-6.0
Cash flow from current operations	-288.8	-291.7
Net investments in fixed assets	-1.1	-1.2
Cash flow from investing activities	-1.1	-1.2
New share issue	216.7	-
Loans raised/amortisation of borrowing	-28.2	26.2
Cash flow from financing activities	188.5	26.2
Cash flow for the period	-101.4	-266.7
Liquid funds, beginning of period	329.1	596.1
Exchange-rate differences in liquid funds	-0.1	-0.2
Liquid funds, end of period	227.6	329.1

KEY FIGURES	December 31	
	2003	2002
Shareholders' equity, MSEK	289.6	380.3
Shareholders' equity per share, SEK	8.58	33.81
Available liquid funds, MSEK	227.6	329.1
Available liquid funds per share, SEK	6.74	29.27
Equity/assets ratio of parent company, %	28.5%	36.1%
Equity/assets ratio of Group, %	83.8%	81.3%
Average number of annual employees	179	183