

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

- **SAIK-MS project advancing further**
- **TTS CD3 for lung cancer progressing according to plan**
- **New collaboration with Avidex Ltd.**
- **Phase I study for the SLE project planned to start during third quarter**
- **Patient study for prostate-cancer project TASQ to commence during the autumn of 2004**
- **Focus on clinical projects being implemented, negotiations in accordance with labour market legislation completed**
- **Loss after net financial items SEK 42.5 M (loss: 60.4)**
- **Loss per share for the period amounted to SEK 1.26 (loss: 4.72)**
- **Loss after tax SEK 42.5 M (loss: 60.4)**

SAIK-MS project advancing further

The final report for the Phase II study of laquinimod was presented at the 56th Annual Meeting of the American Academy of Neurology (AAN) in San Francisco on April 27. The conclusion of the report is that a daily oral dose of 0.3 mg of laquinimod is tolerated well and is effective in inhibiting harmful inflammations of the brain measured using magnetic resonance imaging (MRI) in relapsing multiple sclerosis (MS).

Contacts have been initiated with the US regulatory authority, the FDA, and the European registration authority, the EMEA, in preparation for the submission of an application for the initiation of further clinical trials both in the US (IND) and Europe.

As previously reported, treatment with 0.3 mg of laquinimod daily demonstrated a favourable safety profile in the recently completed Phase II study. To study safety at higher doses of laquinimod, an open Phase IIa study was initiated recently at the University Hospital in Lund, Sweden for the dosage interval 0.6 to 0.9 mg daily. The study will comprise 20 to 25 MS patients, who will receive treatment at these higher doses for 12 months. Since this is an open study, it will be possible to obtain information continually. In this way, this study will be valuable both for the long-term documentation of laquinimod and for the selection of doses in preparation for continued development

At the AAN conference in San Francisco Active Biotech also gave a poster presentation entitled “Laquinimod inhibits the development of murin experimental autoimmune encephalo-myelitis (EAE) in IFN- $\beta^{-/-}$ and wild-type mice.” The trials showed that laquinimod inhibited both the development of chronic EAE and pathological changes in the central nervous system. The studies also showed that SAIK-MS is able to slow the development of the disease in the absence of beta interferon, which indicates that SAIK-MS may have a broader field of use than beta interferon, which is currently available in the market.

The total market for MS pharmaceuticals amounted to USD 2.8 billion in 2002. In 2006, this market is expected to amount to USD 4.5 billion (source: SG Cowen, 2003).

Background

Multiple sclerosis is an incurable disease that results from the body's immune system attacking the myelin sheaths surrounding the nerve fibers 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.

Candidate drug TTS CD3 developing according to plan

The clinical Phase I dose-escalation study of candidate drug 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 able to confirm that TTS CD3 can be administered at considerably higher doses than its predecessor TTS CD2 with maintained safety. Among other aspects, the product's antigenicity is lower, meaning that treatment is expected to be simpler and more effective. In addition, it can be administered as a bolus injection (intravenous injection) instead of as an infusion (intravenous drop).

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 final report from the Phase IIa study on patients with advanced pancreatic cancer at a progressive phase treated with TTS CD2 was completed in March 2004 with promising results. The primary goal for the study was to determine the number of patients responding to treatment. Nineteen patients began treatment with TTS CD2 and after two months, five (26 percent) of the patients showed a stabilisation of the disease (SD). In four patients, the disease remained stable four months after having begun treatment with TTS. The median survival period was 148 days.

All patients in the study had previously received other treatments for their disease but had nonetheless continued to worsen. Eighteen patients (95 percent) had previously received chemotherapy and 17 patients (89 percent) had received chemotherapy with gemcitabin (Gemzar). The relatively high proportion of patients showing a stabilisation of the disease (SD) indicates that the TTS substances have biological activity against this severe tumour disease.

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

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. Almost one million people worldwide are afflicted by non-small cell lung cancer each year. No adequate treatment methods are available.

New collaboration with Avidex Ltd

Active Biotech has signed a collaboration agreement with Avidex, a private biotechnology company based in Oxford, UK, that has developed a new way of targeting cancer cells with its unique “monoclonal T Cell Receptors”. Many of the available targets for mTCRs are intracellular antigens and are hence not possible to be targeted by antibodies. The collaboration will combine the Active Biotech super-antigen with the Avidex mTCR as a fusion protein. If successful, this fusion protein could constitute a new generation of TTS products targeted to intracellular tumour antigens.

Patient study planned for prostate-cancer project TASQ

The protocol for the commencement of a Phase I/II clinical study with prostate-cancer patients is being developed. This study is planned to begin during the second half of 2004.

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 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 (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 proceeding according to plan

Currently, efforts within the SLE project 57-57 are focusing on preparation for the commencement of a Phase I clinical study with healthy volunteers planned to start during the third quarter of 2004.

SLE (Systemic Lupus Erythematosus) is a life-threatening, degenerative autoimmune disease for which current treatment alternatives are highly inadequate. No new pharmaceuticals have been registered for this indication in 40 years. It is estimated that at least 500,000 individuals in the US suffer from SLE. Nine out of ten 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.

Other projects

Patent applications have been submitted for the I-3D and Chemokines projects. These projects are close to entering the clinical phase with the objective to develop pharmaceuticals against autoimmune/inflammatory diseases.

Financial information

Comments on the Group’s results during the first quarter of 2004

The Group’s net sales for the period amounted to SEK 0.1 M (0.0).

Research and administration costs in operations decreased, as planned, by 18 percent to SEK 69.6 M (85.2).

The reduction in costs is 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 quarter was burdened with costs for the ongoing Phase I study for TTS CD3 for lung cancer in the US and Norway and costs for the start of the planned Phase I studies for the TASQ prostate-cancer project and 57-57 project against SLE.

As a consequence of the lower costs, the operating loss improved to SEK 69.6 M (loss: 85.3).

Net financial income for the period amounted to SEK 27.5 M (25.6). The improved financial net is attributable to a dividend of SEK 14.7 M from the interest hedge fund Nectar and the disposal of the investment in Nectar during the period, which resulted in a capital gain of SEK 12.2 M.

Participations in the results of the associated UK company Isogenica Ltd amounted to a loss of SEK 0.4 M (loss: 0.8). Operations developed favourably with a number of technology out-licensing agreements being implemented.

Loss after financial items amounted to SEK 42.5 M (loss: 60.4).

Liquidity and financial status

Cash flow for the period January to March was negative in the amount of SEK 14.6 M (neg.: 83.5). The considerable improvement in cash flow compared with 2003 is attributable to the improvement in earnings in the first quarter, the securing of an SEK 29.0 M overdraft facility and the amortisation of external loans amounting to SEK 26.7 M in the year-earlier period.

At the close of the period, the Group had an overdraft facility of SEK 29.0 M (0.0) and a debt to a leasing company of SEK 6.6 M (6.0). Investments in tangible assets, primarily laboratory equipment, during the period amounted to SEK 0.4 M (3.2).

The book value of the Group's short-term investments and liquid assets was SEK 213.0 M at the close of the period, compared with SEK 227.6 M at year-end 2003. Available liquidity per share amounted to SEK 6.31, compared with SEK 6.74 at the end of 2003.

Shareholders' equity

Group shareholders' equity amounted to SEK 246.8 M at the close of the period, compared with SEK 289.6 M at the end of the preceding year.

At the close of the period, the Group had an equity/assets ratio of 76.5 percent, compared with 83.8 percent at the end of 2002. The corresponding figures for the parent company Active Biotech AB were 33.4 percent and 28.5 percent, respectively.

Future prospects

Active Biotech's objective is to sign a partnership agreement for the SAIK-MS multiple sclerosis project before further clinical trials for this project commence. In addition, operations are being focused on the Phase I studies initiated during the year for the TTS CD3 candidate drug against non-small cell lung cancer and the commencement of Phase I studies for the TASQ prostate-cancer project and 57-57 project against SLE.

Partnership agreements in connection with the above-mentioned projects and products can significantly affect the company's financial position and earnings, and for that reason, no forecast for the full-year 2004 can be given.

Events after the closing date

On February 27, the company announced that operations would be focused on projects in, or close to entering, the clinical phase and that operations in earlier development phases would be discontinued. This change entailed 98 of the company's total of 176 employees being notified of termination. Negotiations in accordance with Swedish employment legislation between the company and the unions have now been concluded with the result that the employment of 89 individuals within the company will cease. The majority of those whose employment is to be terminated are currently involved in early research and development, although certain administrative and service positions are also affected by the decision. Expenses for those whose employment is being terminated will be paid gradually as termination periods expire and positions are phased out.

The arbitration procedure between PowderJect Pharmaceuticals plc and Active Biotech AB concerning disputes attributable to the 2001 agreement pertaining to the sale of SBL Vaccin AB was concluded on April 1, 2004. The parties agreed to a settlement with the following conditions:

PowderJect agreed to withdraw its demand of USD 20 M and to relinquish all rights regarding the disputed guarantees in the purchase agreement and Active Biotech agreed to reduce its demand regarding milestone payments for the approval of the Dukoral vaccine within the EU in 2001 to USD 4.5 M, which was paid immediately. Active Biotech agreed to relinquish all rights to further royalty and milestone payments and, consequently, all existing demands and disputed between the parties were settled.

Annual General Meeting

The Annual General Meeting held on April 21 authorised the Board to decide to issue at most 6,000,000 new shares, with or without preferential rights during the period extending until the next Annual General Meeting. This may take place on one or more occasions and at the then prevailing market price.

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, 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 M, including the currently unconfirmed tax assessment for the fiscal year.

Future report dates

- Interim report January - June: August 12, 2004
- Interim report January - September: November 5, 2004
- Year-end report 2004: February 17, 2005

Effective these dates, reports will be available at www.activebiotech.com.

Lund, May 13, 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 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 (SAIK-MS), as well as a novel concept for use in cancer immunotherapy (TTS).

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Active Biotech - Group

| Income statement, condensed | Jan - Mar | | Full year |
|--|------------------|--------------|------------------|
| SEK M | 2004 | 2003 | 2003 |
| Net sales | 0.1 | 0.0 | 0.3 |
| Administrative expenses | -7.9 | -7.3 | -32.9 |
| Research and development costs | -61.7 | -77.9 | -284.2 |
| Items affecting comparability | - | - | -19.7 |
| Operating loss | -69.6 | -85.3 | -336.4 |
| Loss from shares in associated companies | -0.4 | -0.8 | -2.5 |
| Net financial items | 27.5 | 25.6 | 32.0 |
| Loss after net financial items | -42.5 | -60.4 | -307.0 |
| Tax | - | - | -0.6 |
| Loss for the year | -42.5 | -60.4 | -307.6 |
| Depreciation/amortisation included in an amount of | 3.5 | 4.1 | 15.5 |
| Investments in fixed assets | 0.4 | 3.2 | 5.6 |
| Loss per share before dilution (SEK) | -1.26 | -4.72 | -11.80 |
| Weighted number of ordinary shares before dilution (000s) | 33 739 | 12 783 | 26 062 |
| Weighted number of ordinary shares after dilution (000s) | 33 739 | 12 783 | 26 062 |
| Number of shares at close of period (000s) | 33 739 | 11 246 | 33 739 |
| Number of shares at close of period, including warrants (000s) | 35 069 | 11 246 | 35 069 |
| Balance sheet, condensed | March 31, | | Dec. 31, |
| SEK M | 2004 | 2003 | 2003 |
| Tangible fixed assets | 47.3 | 59.7 | 50.3 |
| Financial fixed assets | 44.9 | 47.2 | 45.1 |
| Total fixed assets | 92.2 | 106.9 | 95.4 |
| Current receivables | 17.4 | 18.1 | 22.5 |
| Short-term investments and liquid assets | 213.0 | 245.6 | 227.6 |
| Total current assets | 230.4 | 263.7 | 250.0 |
| Total assets | 322.6 | 370.6 | 345.4 |
| Shareholders' equity | 246.8 | 319.2 | 289.6 |
| Long-term liabilities | 4.9 | 6.0 | 4.9 |
| Current liabilities | 71.0 | 45.4 | 50.9 |
| Total liabilities and shareholders' equity | 322.6 | 370.6 | 345.4 |
| Changes in shareholders' equity, condensed | | | |
| Total at start of period | 289.6 | 380.3 | 380.3 |
| New share issue | - | -1.0 | 216.7 |
| Translation differences | -0.3 | 0.3 | 0.2 |
| Net loss for the period | -42.5 | -60.4 | -307.6 |
| Total at end of period | 246.8 | 319.2 | 289.6 |

| Cash-flow statement, condensed SEK M | Jan - Mar | | Full year |
|--|------------------|--------------|----------------|
| | 2004 | 2003 | 2003 |
| Loss after financial items | -42.5 | -60.4 | -307.0 |
| Adjustments for items not included in cash flow, etc. | 4.4 | 5.1 | 18.9 |
| Tax paid | -1.0 | -1.0 | 0.0 |
| Cash flow from current operations before Changes in working capital | -39.0 | -56.2 | -288.1 |
| Changes in working capital | -4.6 | 0.5 | -0.7 |
| Cash flow from current operations | -43.6 | -55.8 | -288.8 |
| Net investments in fixed assets | 0.0 | 0.0 | -1.1 |
| Cash flow from investing activities | 0.0 | 0.0 | -1.1 |
| New share issue | – | -1.0 | 216.7 |
| Loans raised/amortisation of borrowing | 29.0 | -26.7 | -28.2 |
| Cash flow from financing activities | 29.0 | -27.7 | 188.5 |
| Cash flow for the period | -14.6 | -83.5 | -101.4 |
| Liquid funds, beginning of period | 227.6 | 329.1 | 329.1 |
| Exchange-rate differences in liquid funds | 0.1 | -0.1 | -0.1 |
| Liquid funds, end of period | 213.0 | 245.6 | 227.6 |
| | March 31, | | Dec 31, |
| Key figures | 2004 | 2003 | 2003 |
| Shareholders' equity, SEK M | 246.8 | 319.2 | 289.6 |
| Shareholders' equity per share, SEK | 7.31 | 28.38 | 8.58 |
| Available liquid funds, SEK M | 213.0 | 245.6 | 227.6 |
| Available liquid funds per share, SEK | 6.31 | 21.84 | 6.74 |
| Equity/assets ratio of Parent Company, % | 33.4 | 38.0 | 28.5 |
| Equity/assets ratio of Group, % | 76.5 | 86.1 | 83.8 |
| Average number of annual employees | 176 | 181 | 179 |