

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

- **Partnership agreement for laquinimod (SAIK-MS) signed with Teva Pharmaceutical Industries**
- **TTS CD3 for lung cancer progressing according to plan**
- **Collaboration agreement signed with Strathmann Biotec for the production of TTS**
- **Patient study for TASQ prostate-cancer project to commence during the second half of the year**
- **Phase I study for the SLE project planned to start during the third quarter**
- **Net revenues SEK 30.4 M (0.1)**
- **Loss after net financial items SEK 77.4 M (loss: 139.3)**
- **Loss per share for the period amounted to SEK 2.29 (loss: 7.63)**
- **Loss after tax SEK 77.4 M (loss: 139.3)**

**Partnership agreement signed for laquinimod (SAIK-MS) project**

In June of this year, Active Biotech signed an agreement with Teva Pharmaceutical Industries Ltd. for the development and commercialisation of laquinimod; an immunomodulatory compound which has the potential to be an orally available disease modifying treatment for multiple sclerosis (MS).

The agreement gives Teva the global exclusive right to develop, register, produce and commercialise laquinimod. Active Biotech will retain the commercial rights for the future sale of the product in the Nordic and Baltic regions. Consequently, Teva will be responsible for future communications relating to this project.

Pending the approval discussed below, Teva will pay Active Biotech a sum of USD 5 M and will fund and conduct the continued clinical development of laquinimod. Teva will also make payments to Active Biotech upon the achievement of various milestones, which include sales targets. If all milestones are met, these payments will total USD 92 M. Active Biotech will also receive tiered double digit royalty payments from future sales of the product.

The agreement is currently being reviewed by the US Federal Trade Commission in accordance with the Hart-Scott-Rodino regulations. The review process is expected to be completed in the near future.

Teva Pharmaceutical Industries Ltd., headquartered in Israel ([www.tevapharm.com](http://www.tevapharm.com)), is one of the world's 20 largest pharmaceuticals companies. Teva is an MS specialist and a market leader. Teva's research focuses on development of new drugs for the treatment of diseases of the central nervous system. The company further develops, manufactures and markets generic pharmaceuticals and active pharmaceutical ingredients. Approximately 90 percent of Teva's sales are generated in North America and Europe.

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

#### *Background*

*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. In the case of MS, the immune defence system attacks the central nervous system. The CNS is built up of nerves coated in a substance called myelin. This substance is similar to the insulating material around electrical cables in that it surrounds and protects the nerve fibers. When the myelin or the nerve fibers are destroyed or damaged, the nerves can no longer send electrical impulses to and from the brain. This results in MS.*

*MS can lead to anything from minor symptoms for lengthy periods to severely incapacitating symptoms within a few years. Initially, MS progress in flares 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.*

#### **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, USA and at the Radiumhospitalet hospital in Oslo, Norway. The study has so far confirmed that TTS CD3 can be administered at considerably higher doses than its predecessor TTS CD2 with maintained safety. Furthermore, the product's antigenicity has been lowered and the form of administration changed, making treatment simpler and more effective.

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

The timing of the initiation 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. Almost one million people world-wide are afflicted by non-small cell lung cancer each year. No curative treatment is available.*

### **Collaboration agreement with Strathmann Biotec AG**

Active Biotech has signed an agreement with Strathmann Biotec AG in Germany. The agreement covers process development and production of TTS (Tumour Targeted Superantigens) for the treatment of non-small cell lung cancer.

The agreement with Strathmann Biotec enables Active Biotech to secure more cost-efficient development and production of clinical materials in the long term, and enables future production of commercial quantities.

The agreement is based on Strathmann Biotec and Active Biotech developing the product jointly, with Strathmann Biotec also assuming part of the financial risk. This means a reduction in Active Biotech's development costs for the project. In return, Strathmann Biotec is entitled to limited royalties based on Active Biotech's revenues from future milestone payments and sales. The potential maximum royalty payments to Strathmann amount to EUR 10 M.

### **Patient study for the TASQ prostate-cancer project**

The protocol for the commencement of a Phase I/II clinical study with prostate-cancer patients is under preparation. 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 at dosage levels expected to be effective in the treatment of prostate cancer. In addition, an extensive pre-clinical safety documentation process has been completed, making it possible to conduct studies where the TASQ substance can be administered to patients during prolonged 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 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.*

**SLE project 57-57 proceeding according to plan**

Currently, efforts within the SLE project 57-57 are focusing on preparation for the initiation 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. It is estimated that at least 500,000 individuals in the US suffer from SLE. 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.*

**Financial information**

**Comments on the Group’s results for the period January – June, 2004**

The Group’s net sales for the period amounted to SEK 30.4 M (0.1), of which SEK 30.3 M relates to the milestone payment from Chiron Corp. received when the travel vaccine Dukoral was approved for registration in Europe.

Research and administration costs for the period decreased by 17 percent compared with the year-earlier period to SEK 135.3 M (163.2). 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 half of 2004 included 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.

During the second quarter, an agreement was signed between Active Biotech and Pfizer Health AB concerning Pfizer’s obligation to manufacture commercial quantities of TTS substance. Pfizer’s obligation to produce has ceased and was offset by Active Biotech’s obligation to pay Pfizer additional compensation once a partnership agreement was signed for SAIK-MS. The positive net effect of the agreement amounted to USD 0.5 M, which was booked during the second quarter.

The operating loss decreased by SEK 58.2 M to a loss of SEK 104.9 M (loss: 163.1) as a result of higher revenues and lower costs.

Net financial income for the period amounted to SEK 28.2 M (25.4). The improved financial net is attributable to the first quarter, when a dividend from the Nectar interest hedge fund and a capital gain from the disposal of the investment in Nectar totalled SEK 26.9 M. Net interest income in the second quarter amounted to SEK 0.7 M (expense: 0.3).

Participation in the results of the associated UK company Isogenica Ltd amounted to a loss of SEK 0.7 M (loss: 1.5). The operation is progressing according to plan.

Loss after financial items amounted to SEK 77.4 M (loss: 139.3).

### **Liquidity and financial status**

Cash flow from current operations was negative in an amount of SEK 75.6 M (neg: 141.3). The improved cash flow is attributable to higher revenues and lower costs compared with the year-earlier period.

Investments in fixed assets – primarily laboratory equipment – during the period amounted to SEK 1.3 M (4.3). On June 30, 2004, the Group had no external debts, apart from a debt of SEK 7.0 M (6.2) to leasing companies.

The book value of the Group's short-term investments and liquid assets was SEK 149.4 M at the close of the period, compared with SEK 227.6 M at year-end 2003. Available liquidity per share amounted to SEK 4.43, compared with SEK 6.66 at the end of 2003.

### **Shareholders' equity**

Group shareholders' equity amounted to SEK 211.9 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 83.9 percent, compared with 83.8 percent at the end of 2003. The corresponding figures for the parent company Active Biotech AB were 30.9 percent and 28.5 percent, respectively.

### **Organisation**

The average number of employees at the end of the second quarter was 173 (181). Negotiations concerning the organisational changes announced in February with an increased focus on projects in or close to entering the clinical phase were concluded during the second quarter. Employees affected by the dismissals will leave the company gradually during the year. The new organisation will have a total of 87 employees and will become effective during the third quarter.

### **Outlook**

In June 2004, Active Biotech signed a development and commercialisation agreement with Teva Pharmaceutical Industries Ltd. for the SAIK-MS project for treatment of multiple sclerosis. The agreement entitles Active Biotech to an initial payment of USD 5 M, which is expected to be received during the third quarter of 2004 after approval by the US competition authorities. Operational co-operation will commence as soon as approval has been obtained.

Operations during the remainder of the year will continue to concentrate on the organisational shift towards clinical projects as decided during the spring and on concluding the Phase I study of TTS CD3 for non-small cell lung cancer that was initiated in 2003. In addition, Phase I patient studies are expected to commence during the second half of the year for the prostate-cancer project TASQ and the 57-57 project against SLE.

### **Forecast for full year 2004**

After accomplished business negotiations and decided organisational changes, the company's loss after financial items for the full year 2004 is estimated to a loss of SEK 175.0 M compared to a loss of SEK 307.0 M previous year.

### 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 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–September: November 5, 2004
- Year-end report 2004 February 17, 2005

Reports will be available at [www.activebiotech.com](http://www.activebiotech.com) from these dates.

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

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Active Biotech – Group

Income statement, condensed SEK M	Apr – Jun		Jan – Jun		Full year
	2004	2003	2004	2003	2003
<b>Net sales</b>	<b>30.4</b>	<b>0.0</b>	<b>30.4</b>	<b>0.1</b>	<b>0.3</b>
Administrative expenses	-9.4	-10.1	-17.3	-17.5	-32.9
Research and development costs	-56.2	-67.8	-118.0	-145.7	-284.2
Items affecting comparability	–	–	–	–	-19.7
<b>Operating loss</b>	<b>-35.3</b>	<b>-77.9</b>	<b>-104.9</b>	<b>-163.1</b>	<b>-336.4</b>
Loss from shares in associated companies	-0.3	-0.8	-0.7	-1.5	-2.5
Net financial items	0.7	-0.3	28.2	25.4	32.0
<b>Loss after net financial items</b>	<b>-35.0</b>	<b>-78.9</b>	<b>-77.4</b>	<b>-139.3</b>	<b>-307.0</b>
Tax	–	–	–	–	-0.6
<b>Loss for the year</b>	<b>-35.0</b>	<b>-78.9</b>	<b>-77.4</b>	<b>-139.3</b>	<b>-307.6</b>
Depreciation/amortisation included in an amount of	3.4	4.1	6.9	8.2	15.5
Investments in fixed assets	0.9	1.1	1.3	4.3	5.6
Loss per share before dilution (SEK)	-1.04	-3.33	-2.29	-7.63	-11.80
Weighted number of ordinary shares before dilution (000s)	33,739	23,674	33,739	18,258	26,062
Weighted number of ordinary shares after dilution (000s)	33,739	23,674	33,739	18,258	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 SEK M	Jun 30		Dec 31
	2004	2003	2003
Tangible fixed assets	44.8	56.3	50.3
Financial fixed assets	46.3	46.4	45.1
<b>Total fixed assets</b>	<b>91.0</b>	<b>102.7</b>	<b>95.4</b>
Current receivables	12.0	19.9	22.5
Short-term investments and liquid assets	149.4	377.2	227.6
<b>Total current assets</b>	<b>161.4</b>	<b>397.1</b>	<b>250.0</b>
<b>Total assets</b>	<b>252.4</b>	<b>499.8</b>	<b>345.4</b>
Shareholders' equity	211.9	457.6	289.6
Long-term liabilities	5.3	6.2	4.9
Current liabilities	35.2	36.0	50.9
<b>Total liabilities and shareholders' equity</b>	<b>252.4</b>	<b>499.8</b>	<b>345.4</b>

Changes in shareholders' equity, condensed			
Total at start of period	289.6	380.3	380.3
New share issue	–	216.2	216.7
Translation differences	-0.3	0.4	0.2
Net loss for the period	-77.4	-139.3	-307.6
<b>Total at end of period</b>	<b>211.9</b>	<b>457.6</b>	<b>289.6</b>

Cash-flow statement, condensed SEK M	Jan – Jun		Full year
	2004	2003	2003
<b>Loss after financial items</b>	-77.4	-139.3	-307.0
Adjustments for items not included in cash flow, etc.	9.6	9.7	18.9
Tax paid	-1.9	-1.9	0.0
<b>Cash flow from current operations before changes in working capital</b>	<b>-69.7</b>	<b>-131.5</b>	<b>-288.1</b>
Changes in working capital	-5.8	-9.7	-0.7
<b>Cash flow from current operations</b>	<b>-75.6</b>	<b>-141.3</b>	<b>-288.8</b>
Net investments in fixed assets	-1.7	-0.1	-1.1
<b>Cash flow from investing activities</b>	<b>-1.7</b>	<b>-0.1</b>	<b>-1.1</b>
New share issue	–	216.2	216.7
Loans raised/amortisation of borrowing	-0.9	-26.7	-28.2
<b>Cash flow from financing activities</b>	<b>-0.9</b>	<b>189.5</b>	<b>188.5</b>
<b>Cash flow for the period</b>	<b>-78.3</b>	<b>48.2</b>	<b>-101.4</b>
<b>Liquid funds, beginning of period</b>	<b>227.6</b>	<b>329.1</b>	<b>329.1</b>
<b>Exchange-rate differences in liquid funds</b>	<b>0.1</b>	<b>-0.1</b>	<b>-0.1</b>
<b>Liquid funds, end of period</b>	<b>149.4</b>	<b>377.2</b>	<b>227.6</b>

Key figures	Jun 30		Dec 31
	2004	2003	2003
Shareholders' equity, SEK M	211.9	457.6	289.6
Shareholders' equity per share, SEK	6.28	13.56	8.58
Available liquid funds, SEK M	149.4	377.2	227.6
Available liquid funds per share, SEK	4.43	11.18	6.66
Equity/assets ratio of Parent Company, %	30.9	49.0	28.5
Equity/assets ratio of Group, %	83.9	91.5	83.8
Average number of annual employees	173	181	179