

**Active Biotech
Interim Report
April-June 2002**

- **SAIK-MS Phase II trial in patients proceeding according to plan**
- **TTS Phase II cancer studies advancing according to plan – renal and pancreatic cancer patients now receiving treatment**
- **TASQ prostate cancer project – preparations ongoing for clinical trials in 2003**
- **Important milestone attained in the SLE project**
- **Loss after net financial items – SEK 68.1 million (- SEK 89.0 m), an improvement attributable to the focus on core operations.**

Swedish biotech company Active Biotech is a world leader in terms of the development of new drugs in tablet form for the treatment of MS. The company also develops new pharmaceuticals for use in the treatment of cancer (renal, lung and pancreas). At present, two of the lead projects are in Phase II clinical trials and the trials are proceeding according to plan.

In addition, the company has selected a number of candidate drugs that are currently being prepared for clinical development.

The research and development performed at Active Biotech focus on a wide range of indications, within autoimmune/inflammatory diseases and cancer. The research organisation has generated one candidate drug per year over the last three-year period.

Treatment of MS patients in Phase II ongoing

As part of a Phase II clinical trial, treatment of patients is currently ongoing at several clinics in the Netherlands, the UK, Russia and Sweden using the company's oral candidate drug for treating multiple sclerosis, MS. The recruitment of patients to the trial is proceeding as planned. A total of 180 patients are due to be included in the study during the year. The goal is to demonstrate the efficacy of SAIK-MS in treating MS. Both the degree of inflammation in the brain and functional parameters will be measured, and the recruitment of all patients is due to be completed during the autumn of 2002.

The study begins with a 4-week period during which no active treatment is given. After this, patients receive treatment for 24 weeks, either with 2 different doses of the active substance in tablet form or with placebo (without the active substance). The treatment period for each individual patient ends with an 8-week follow-up period.

The Phase I study for SAIK-MS was concluded during 2001 and demonstrated that MS patients tolerated the substance well. It also established the doses that the company is now using to treat patients during Phase II. (For more information, please visit our web site at www.activebiotech.com, News/Archive 20010424).

The total market for MS drugs was worth USD 2.3 billion in 2001 (UBS Warburg, Pharmaceuticals & Biotechnology, April 2001). In 2005, this market is expected to be worth USD 3.8 billion.

Background

At present, multiple sclerosis (MS) is an incurable disease that causes the body's own immune system to attack the myelin sheaths that surround the nerve fibres in the brain and elsewhere. This disrupts or breaks off nerve transmission, preventing sensory input from reaching the brain for processing and halting communication between the brain and the muscles of the body. MS may lead to a variety of symptoms, ranging from minor disability to severely incapacitating symptoms within a few short years. Initially, MS often progresses in flares that alternate with disease free intervals. The disease mainly affects young people and the average age at which it manifests is around 30. It is more common among women than men.

Active Biotech's unique MS candidate drug, SAIK-MS, is thought to have a unique mechanism of action and is expected to lead to an improvement in treatment results compared with the drugs currently in use. It also has the major advantage of being available in tablet form, unlike most current treatments that must be administered in the form of injections.

During a Phase II clinical trial, some 50- 200 patients are treated using one or several dose levels considered both safe and capable of producing the desired therapeutic effects. In order to increase our chances of being able to demonstrate statistically that the product is effective, the study also includes a group of patients who will receive inactive placebo treatment.

The clinical development programme for the TTS cancer project progresses

The clinical Phase II studies involving renal and pancreatic cancer patients are proceeding as planned. The studies are due to include 60 patients altogether and are being managed in co-operation with the Christie Hospital in Manchester in the UK. The Principal Investigator is Professor Robert Hawkins.

The start-up of a Phase I study of the next generation of TTS products is currently being prepared in collaboration with the Fox Chase Center cancer clinic in Philadelphia in the US.

Patients to all studies will be recruited and treated for a period of around 12 – 18 months.

According to the company's estimates, the market for drugs against lung-, renal- and pancreas cancer are currently worth USD 3.7 billion, USD 600 million and USD 500 million respectively.

Background

TTS stands for "Tumour Targeted Superantigens". The collective term "superantigens" refers to several different substances that include some of the most powerful known stimulators of the human immune system's T cells, which are the body's strongest weapon in the arsenal it uses to kill unwanted cells. By aiming the superantigen at tumour cells via a tumour-specific antibody, Active Biotech has created a unique product that will recognise cancer cells and stimulate the body's own immune system to attack and kill them. In principle, TTS technology can be used to treat several different types of cancer, although Active Biotech has chosen to focus development on the treatment of lung cancer, renal cancer and pancreatic cancer.

The prostate cancer project (TASQ)

In February 2002, the company selected a candidate drug (ABR-215050), for its TASQ prostate cancer project. The production of the candidate drug has been scaled up and activities are now ongoing in preparation for the initiation of a Phase I clinical trial. These activities include in-depth safety evaluation, manufacturing and compilation of clinical protocols. The company plans to start trials in humans during 2003.

According to the company's estimates, the market for drugs against prostate cancer is currently worth around USD 2.5 billion.

Background

Active Biotech collaborates with the Johns Hopkins University in Baltimore in the US with the aim to develop a drug for use in the treatment of prostate cancer. The company's candidate drug has demonstrated anti-angiogenetic properties, which means it has the ability to strangle the nutritional supply of the tumour cells. It also has demonstrated a direct anti-tumour effect in pre-clinical models.

Prostate cancer is the most common form of cancer among men and accounts for almost one third of all male cancers. The disease mainly affects men over 50 and its severity may vary considerably. Although the prognosis is relatively good, prostate cancer is still the cancer that causes most deaths among men. The relative 10-year survival rate is around 50 per cent.

Important milestone attained in the SLE project

In June 2002, the company selected a candidate drug (ABR-215757) for its SLE project. Preparations are currently ongoing for proceeding into the clinical phase. The plan is to be in a position to start clinical trials during 2003.

The indication for this project is SLE (Systemic Lupus Erythematosus), an autoimmune disease for which treatment options are currently highly limited. No new drug has been registered for this indication for 40 years and there may in time also be other indications that are interesting for this product.

This candidate drug (ABR-215757) has demonstrated efficacy in pre-clinical models of autoimmune diseases, including SLE. It has also demonstrated a favourable toxicological profile. The company considers that the project's patent protection is very strong, since this candidate drug (ABR-215757) is part of the extensive patent portfolio covering the company's Q-competence platform.

Background

SLE - Systemic Lupus Erythematosus – is a connective tissue disease that causes inflammation and damage in connective tissue throughout the body. The disease follows a highly variable course and symptoms depend on the organs affected. The disease affects approximately 1 in 20,000 individuals, mainly women of child-bearing age. It progresses in flares interspersed with relatively symptom-free intervals. The autoimmune attacks affect many different organ systems and the disease may therefore lead to serious secondary symptoms, such as renal failure. The current treatment for SLE comprises NSAID (non-steroidal anti-inflammatory drugs), corticosteroids, antimalarial drugs or cytotoxic drugs such as cyclophosphamide.

Other projects

Other projects included in Active Biotech's discovery- and pre-clinical project portfolio are proceeding as planned. They include, among others, the IMO-A (ImmunoMOdulation project A), which aims to determine the active mechanism behind substances within the Q-platform, as well as INDRA (Inhibition of NF- κ B Dependent Response Activity), which focuses on inflammatory bowel diseases.

The company Isogenica Ltd., UK, that was formed last year as a spin-off from Active Biotech's research portfolio and in which Active Biotech has a minority ownership, has initiated the operations signing a number of license- and research collaboration agreements. For further information, please visit the company's homepage www.isogenica.com.

Financial information

The Group's financial results, cash flow and financial status for the period April-June 2002. *In view of the sale of the vaccine operations on 4 July 2001, comments on the company's financial performance is only relevant on the basis of pro forma adjusted financial results for the corresponding period in the previous year.*

The Group's income in the second quarter this year totalled SEK 2.3 million (SEK 54.8 m), while the pro-forma adjusted figure for income in the previous year was SEK 0.9 million.

Operating costs excluding the cost of goods sold amounted to SEK 82.7 million (SEK 108.9 m), while the pro forma adjusted costs were SEK 62.2 million. The costs for initiating the SAIK-MS project's Phase II trial have been charged to the second quarter. This explains to a large extent the higher cost level compared with the same quarter previous year.

The operating loss amounted to – SEK 80.3 million (- SEK 97.8 m), while the pro forma adjusted loss was – SEK 61.3 million.

Net financial items for the period totalled SEK 13.8 million (SEK 8.8 m). The improvement is due to the capital gains made in asset management and to an improved net interest income/expenses item as a result of the sale of the vaccine operations in July, 2001.

The loss after financial items amounted to – SEK 68.1 million (- SEK 89.0 m), while the pro forma adjusted loss for the previous year amounted to – SEK 52.0 million.

Cash flow for the period totalled – SEK 60.4 million, compared with – SEK 106.8 million for the corresponding period the previous year. The positive trend is mainly due to a significant improvement in the profit/loss, as well as to lower investments and a positive change in the working capital as a result of the sale of the vaccine operations. At the end of the period, the Group had no external loans.

With the sale of the vaccine operations, the period's investments in tangible fixed assets fell to SEK 0.1 million (SEK 14.0 m) in the second quarter, while the pro forma adjusted figure was SEK 3.7 million.

Financial status

The Group's current investments and liquid assets at book-value at the end of the period came to SEK 458.9 million, compared with SEK 596.1 million at the end of the previous year.

Available liquidity per share came to SEK 40.80 per share compared with SEK 53.00 per share at the end of 2001.

Shareholders' equity

The Group's shareholders' equity at the end of the period totalled SEK 547.1 million, compared with SEK 678.8 million at the end of the previous year.

The Group's equity/assets ratio at the end of the period amounted to 91.8 %, compared with 90.8 % at the end of 2001. The corresponding figures for the parent company, Active Biotech AB, were 53.7 % and 55.6 % respectively.

Forecast

The operations in 2002 will focus on the launch and implementation of clinical Phase II trials under own auspices for the key projects, SAIK-MS and TTS. The clinical costs will thus be increasing in upcoming quarters as more and more patients are recruited. In parallel to these activities, discussions are being held with potential collaboration partners. The timing involved in licensing and partnership agreements for different projects cannot be specified at the moment, which is why no forecast can be made for 2002 as a whole.

Accounting and valuation principles

This interim report complies with the same principles as the latest annual report and adheres to the recommendations of the Swedish Financial Accounting Standards Council.

Due to its structure, which involves major costs for research and development, the company is not expected to be in a position to pay tax. The company's accumulated deficit deduction at the end of 2001 amounted to SEK 344.2 million including taxation for the 2001 financial year, which has still not been finalised.

Financial calendar

The interim report and preliminary year-end report for 2002 will be published on the following dates:

Q3, 1 July –30 September	8 November 2002
Q4, 1 October –31 December and full-year	13 February 2003

These reports will be available on the above dates at www.activebiotech.com under the heading News.

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Active Biotech 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 (clinical trials phase II) include orally administered small molecules with unique immunomodulatory properties that can be used to treat autoimmune and inflammatory diseases (SAIK), as well as a novel concept for use in cancer immunotherapy (TTS).

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Active Biotech Group

Income statement

	Apr.-June	Apr.-June	Jan.-June	Jan.-June	Last 12 months	Full year
SEK million	2002	2001	2002	2001	June 01-June 02	2001
Net sales	2.3	54.8	2.5	102.1	2.6	102.3
Cost of goods sold	0.1	-43.7	0.1	-76.6	0.2	-76.5
Gross income	2.3	11.1	2.6	25.5	2.8	25.8
Sales and marketing costs	-	-6.0	-	-12.7	-	-12.7
Administration costs	-9.0	-11.0	-17.2	-21.2	-38.2	-42.1
Research and development costs	-76.0	-93.3	-133.7	-177.0	-251.2	-294.6
Other income/expenses	2.3	1.4	1.5	-	0.3	-1.3
Items affecting comparability	-	-	-	-	0.3	0.3
Capital gains on the sale of subsidiaries	-	-	-	-	341.7	341.7
Operating profit/loss	-80.3	-97.8	-146.8	-185.4	55.6	17.1
Profit/loss from participations in associated companies	-1.6	-	-1.6	-	-	-1.0
Net financial items	13.8	8.8	16.4	9.8	25.3	18.7
Profit/loss after financial items	-68.1	-89.0	-132.0	-175.6	78.4	34.8
Tax on the profit/loss for the year	-	-0.1	-	-0.1	-1.7	-1.8
Profit/loss for the year	-68.1	-89.0	-132.0	-175.6	76.7	33.0
Depreciation included in the amount of	4.3	8.9	8.7	18.0	17.5	26.8
Investments in tangible fixed assets	0.1	14.0	0.4	25.9	4.7	30.2
Earnings per share	-6.05	-7.92	-11.74	-15.62	6.82	2.94
Number of shares, thousands	11 246	11 246	11 246	11 246	11 246	11 246

Income statement (excluding SBL Vaccin)

	Apr.-June	Apr.-June	Jan.-June	Jan.-June	Last 12 months	Full-year
SEK million	2002	2001	2002	2001	June 01-June 02	2001
Net sales	2.3	0.9	2.5	2.3	2.6	2.5
Cost of goods sold	0.1	0.1	0.1	0.1	0.2	0.2
Gross income	2.3	1.0	2.6	2.4	2.8	2.7
Sales and marketing costs	-	-	-	-	-	-
Administration costs	-9.0	-8.2	-17.2	-16.0	-38.2	-37.0
Research and development costs	-76.0	-54.4	-133.7	-113.7	-251.2	-231.3
Other income/expenses	2.3	0.4	1.5	0.4	0.3	-0.9
Items affecting comparability	-	-	-	-	0.3	0.3
Capital gains on the sale of subsidiaries	-	-	-	-	341.7	341.7
Operating profit/loss	-80.3	-61.3	-146.8	-126.9	55.7	75.5
Profit/loss from participations in associated companies	-1.6	-	-1.6	-	-	-1.0
Net financial items	13.8	9.3	16.4	10.5	25.3	19.4
Profit/loss after financial items	-68.1	-52.0	-132.0	-116.5	78.4	93.9
Tax on the profit/loss for the year	-	-0.1	-	-0.1	-1.7	-1.8
Profit/loss for the year	-68.1	-52.0	-132.0	-116.5	76.7	92.1
Depreciation included in the amount of	4.3	4.5	8.7	9.0	17.5	17.8
Investments in tangible fixed assets	0.1	3.7	0.4	5.1	4.9	9.6
Earnings per share	-6.05	-4.62	-11.74	-10.36	6.82	8.19
Number of shares, thousands	11 246	11 246	11 246	11 246	11 246	11 246

Balance sheet

SEK million	30 June 2002	30 June 2001	31 Dec. 2001
Intangible fixed assets	-	45.4	-
Tangible fixed assets	66.0	206.6	74.3
Financial fixed assets	49.5	53.8	52.0
Total fixed assets	115.5	305.7	126.3
Inventories	-	92.0	-
Current receivables	21.7	94.3	25.4
Current investments & liquid assets	458.9	212.8	596.1
Total current assets	480.6	399.0	621.5
Total assets	596.1	704.7	747.8
Shareholders' equity*	547.1	470.2	678.8
Allocations	9.1	35.8	9.1
Long-term liabilities	-	91.3	-
Current liabilities	39.9	107.5	59.9
Total shareholder's equity and liabilities	596.1	704.7	747.8

**Change in shareholders' equity*

Amount at the start of the period	678.8	646.0	646.0
Shareholders' dividends	-	-	-
Translation differences	0.3	-0.2	-0.3
Profit/loss for the period	-132.0	-175.6	33.0
Amount at the end of the period	547.1	470.2	678.8

Cash flow statement

SEK million	Jan.-June 2002	Jan.-June 2001	Full year 2001
Profit/loss after financial items	-132.0	-175.6	34.8
Adjustments for items not included in the cash flow, etc.	11.9	16.9	-315.2
Tax paid	-0.2	0.0	-1.5
Cash flow from ongoing operations before changes in working capital	-120.3	-158.7	-281.9
Changes in working capital	-15.5	-45.2	-72.7
Cash flow from ongoing operations	-135.8	-203.9	-354.6
Net investments in fixed assets	-1.2	-25.6	508.6
Cash flow from investment activities	-1.2	-25.6	508.6
Loans raised/repayment of loans	-	34.1	34.0
Cash flow from financing activities	0.0	34.1	34.0
Cash flow for the period	-137.0	-195.4	188.0
Liquid assets at year-start	596.1	408.0	408.0
Exchange rate difference in liquid assets	-0.2	0.2	0.1
Liquid assets at the end of the period	458.9	212.8	596.1

KEY FIGURES

	30 June 2002	30 June 2001	Full year 2001
Shareholders' equity, SEK million	547.1	470.2	678.8
Equity per share, SEK	48.65	41.81	60.36
Available liquidity, SEK million	459	243	596
Available liquidity per share	40.80	21.59	53.00
Parent company equity/assets ratio, %	53.7%	54.0%	55.6%
Group equity/assets ratio, %	91.8%	66.7%	90.8%
Average number of year-round employees	185	337	186

Income statement – pro forma 2001 – 1999

(The Active Biotech Group excluding SBL Vaccin)

SEK million	1999	2000				Full year
	Full year	Q1	Q2	Q3	Q4	
Net sales	81.1	11.3	11.9	10.7	11.2	45.2
Cost of goods sold	-2.0	-0.2	0.0	0.1	0.1	0.1
Gross income	79.1	11.1	12.0	10.9	11.3	45.2
Sales and marketing costs	-3.4	-0.1	0.0	0.1	-	-
Administration costs	-59.1	-13.2	-20.4	-10.5	-10.8	-54.9
Research and development costs	-232.1	-49.9	-57.5	-46.4	-66.0	-219.9
Other income/expenses	.1	-	-	-1.4	7.2	5.8
	-215.3	-52.1	-66.0	-47.4	-58.2	-223.7
Items affecting comparability	15.0	-	-	-	-	-
Capital gains on the sale of subsidiaries		-	-	-	-	-
Operating profit/loss	-200.3	-52.1	-66.0	-47.4	-58.2	-223.7
Profit/loss from participations in associated companies		-	-	-	-	-
Net financial items	57.7	77.3	-8.6	14.7	8.2	91.6
Profit/loss after financial items	-142.6	25.2	-74.6	-32.7	-50.0	-132.1
Tax on profit/loss for the year		-	-	-	0.1	0.1
Profit/loss for the year	-142.6	25.2	-74.6	-32.7	-49.9	-132.0
		2001				
SEK million		Q1	Q2	Q3	Q4	Full year
Net sales		1.4	0.9	0.0	0.1	2.5
Cost of goods sold		0.1	0.1	0.1	0.1	0.2
Gross income		1.5	1.0	0.1	0.2	2.7
Sales and marketing costs		-	-	-	-	-
Administration costs		-7.8	-8.2	-10.8	-10.1	-37.0
Research and development costs		-59.3	-54.4	-54.9	-62.6	-231.3
Other income/expenses		0.0	0.4	-0.1	-1.2	-0.9
		-65.7	-61.3	-65.8	-73.7	-266.4
Items affecting comparability		-	-	-	0.3	0.3
Capital gains on the sale of subsidiaries		-	-	341.7	-	341.7
Operating profit/loss		-65.7	-61.3	275.9	-73.5	75.5
Profit/loss from participations in associated companies		-	-	-	-1.0	-1.0
Net financial items		1.1	9.3	3.8	5.1	19.4
Profit/loss after financial items		-64.5	-52.0	279.8	-69.4	93.9
Tax on profit/loss for the year		-	-0.1	0.1	-1.8	-1.8
Profit/loss for the year		-64.5	-52.0	279.8	-71.2	92.1