

**Active Biotech
Annual Account
for the Operating Year 2001**

- **SAIK-MS Phase II study to start as planned**
- **TTS Phase II studies:**
 - renal cancer study started and go-ahead given for start of pancreatic cancer study
- **Candidate drug selected for prostate cancer project**
- **Patent portfolio further strengthened by US patent approval for prostate cancer project**
- **Profit after financial items of SEK 34.8 million (SEK -419.4 million) for the full year - in line with forecast**

Clinical Phase II study of SAIK-MS to start as planned

Active Biotech has reached the final phase of preparations ahead of the start of a Phase II clinical trial for its SAIK-MS product. The goal of the study is to demonstrate the effect of SAIK-MS on multiple sclerosis. The study will measure both the degree of inflammation in the brain and functional parameters. The recruitment of all patients is due to be completed during the fall of 2002. More detailed information concerning the study design will be provided shortly.

The Phase I study of the product was completed during 2001 and demonstrated that MS patients tolerated the substance well. We will now be starting patient treatment in Phase II. (For more information, please visit our web site at www.activebiotech.com, News/Archive 20010424).

The total market for MS pharmaceuticals was worth USD 2.3 billion in 2001 (UBS Warburg Pharmaceuticals & Biotechnology, April 2001).

Background

Multiple sclerosis (MS) is currently an incurable disease, in the course of which the body's immune system attacks the myelin sheaths surrounding the nerves, including those in the brain. This disrupts nerve impulses or interrupts them completely so that sensory input fails to reach the brain for processing. This means that the brain can no longer communicate with the muscles in the body. MS can lead to anything from mild symptoms lasting for long periods to severe problems that entail serious handicaps within a couple of years. Initially, MS often follows an intermittent or episodic course, with periods of stability between the bouts. The disease mainly affects young people and the average age of patients when the disease manifests itself for the first time is around 30. More women than men suffer from multiple sclerosis, which is a chronic autoimmune disease.

Active Biotech's unique MS drug, SAIK-MS, is assumed to have a new active mechanism. The product is therefore expected to lead to better treatment results compared with currently available drugs. The product also has the major advantage of being administered in tablet form, as opposed to treatments that take the form of injections.

TTS Phase II clinical study started

In our cancer project known as TTS (Tumour Targeted Superantigens), a Phase II study with renal cancer began in December 2001. Permission to extend the study to cover pancreatic cancer has recently been received from the UK authorities. The study involves collaboration with the Christie Hospital in Manchester, England, with Professor Robert Hawkins as Principal Investigator.

A Phase II study on lung cancer is planned to begin in 2002.

In addition, a Phase I study of a new generation of TTS products is planned to start at the Fox Chase Center cancer clinic in Philadelphia, USA.

For all these studies, patients will be recruited and treated for a period of around 12–18 months.

The results of the first clinical Phase I trials confirm the company's assessment that TTS is a unique cancer treatment concept. Phase I trials on lung cancer were completed in 2001. The main purpose of these studies was to document the safety of the product. In addition, promising results were obtained as regards its effect, particularly with regard to stabilising the progress of the disease. (For more information, please visit our web site at www.activebiotech.com - News/Archive 20010626).

According to the company's calculations, the markets for lung, renal and pancreatic cancer are currently worth USD 3.7 billion, USD 600 million and USD 500 million respectively.

Background

TTS stands for "Tumour Targeted Superantigens". Superantigen is the term used to refer to a variety of substances that are among the most powerful known stimulators of the immune system, and particularly of T-cells, which are the human body's strongest tool for killing unwanted cells. By aiming a superantigen at the tumour cells via a tumour-specific antibody, Active Biotech has created a target-seeking product that recognises cancer cells and stimulates the body's own immune system to kill and remove these cells. Compared with other methods aimed at stimulating the immune system, the company believes that the TTS concept is unique. TTS technology can, in principle, be used to treat any tumour, but Active Biotech has chosen to focus its efforts on the treatment of lung, renal and pancreatic cancer.

Candidate drug selected for the prostate cancer project

Active Biotech collaborates with the Johns Hopkins University in Baltimore, USA, to develop a drug for use in treating prostate cancer.

The project has progressed to the stage where a candidate drug has now been selected. Clinical evaluation is planned to begin in 2003.

In January 2002, the company received US patent approval for the project. The patent protects the use of the substance and broadens the product protection that the company already has in this field. The patent covers method and product requirements, among other things, as well as the use of the substance in the treatment of breast and prostate cancer.

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

Background

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

Other projects

Other projects in Active Biotech's pre-clinical project portfolio are progressing as planned. One of the projects is aimed at selecting a candidate drug for an autoimmune disease indication by the end of the year. This product will come from the so-called Q competence platform. Another project is using the B competence platform to develop new substances for use in the treatment of inflammatory/autoimmune diseases. The company expects to be in a position to select candidate drugs during 2003.

Personnel

At the end of 2001, the number of employees amounted to 184 (337), whereof 49 PhD's. The decrease in number of employees is a consequence of the sale of the vaccine operations, SBL Vaccin.

Business development

Business development resources have been strengthened and collaborations on development and marketing have begun.

On January 1 2002, An van Es was appointed Vice President of Business Development. She will also be part of the company's management team. An van Es is a medical doctor with experience of several leading functions at companies such as Lilly, Pharmacia and Roche, in The Netherlands, Sweden, US and Switzerland. Her main focus has been on internal medicine and clinical development. Her latest position was that of President of a Swedish growth company in the biotech industry.

Financial information

The Group's financial results, cash flow and financial status for the period October-December 2001

Due to the change in the focus of operations, the comments on the company's financial status are only made on the basis of the pro forma adjusted financial results reported during the corresponding period the previous year, where relevant.

In Q4 2001, the Group reported income of SEK 0.1 million, compared with SEK 11.2 million for the corresponding period the previous year. SEK 10.0 million of the income for 2000 was income from contract research. All remuneration for contract research ceased at the end of 2000 after Active Biotech acquired the rights to the TTS project from Pharmacia.

Administration and research costs fell 5% compared with the corresponding period the previous year, totalling SEK 72.7 million (SEK 76.8 m). The research projects are proceeding as planned with a higher share of external clinical development costs for the SAIK-MS and TTS projects.

An amount of SEK -1.0 million is reported for the period for the loss from participations in associated companies, representing Active Biotech's 23.8-per cent ownership share in Isogenica Ltd, England. During 4Q 2000, Active Biotech contributed the Covalent Display Technology (CDT) project in a non-cash share issue to Isogenica Ltd., after which the operations were externally financed.

Net financial items for the period came to SEK 5.1 million (SEK 8.2 m). The decrease reflects lower capital gains from the management of financial investments over the period. The sale of the vaccine operations, however, led to a substantial injection of funds, which in turn led to a net interest income in Q4 of SEK 5.9 million (SEK 2.3 m).

The loss after financial items totalled SEK 69.4 million (SEK -50.0 m). The acquisition of the TTS project at the end of 2000, non-recurring income following the sale of the CDT project in Q4 2000, and a lower figure for net financial items for the current year all help to explain the development.

Tax expenses for the period came to SEK 1.8 million (SEK 0.1 m). The figure is attributable to an adjustment of taxation for the 1999 and 2000 financial years. The tax authorities' adjustments mainly relate to the right to deductions for input VAT. The company intends to appeal against the decision of the tax authorities.

Comments on the Group's financial results for the full year 2001 (non pro forma adjusted)

The Group's net sales totalled SEK 102.3 million (SEK 280.4 m). The decrease is largely attributable to the sale of SBL Vaccin on July 4, 2001. In addition, the previous year's net sales included an amount of SEK 40.0 million for contract research.

The proceeds involved in the sale of SBL Vaccin AB to the UK vaccine company Powderject Pharmaceuticals Plc. comes to a maximum of USD 70 million, of which USD 50 million was received at the time of the signing of the agreement. Supplementary milestones of USD 10-20 million will be received when the travel vaccine Dukoral is registered in Europe and the tourist vaccine ETEC is registered in the USA. Depending on the sales outcome, these vaccine products may also generate royalties for Active Biotech of a maximum of USD 40 million.

The capital gains on the sale of SBL Vaccin came to SEK 341.7 million.

The Group's operating profit before financial items totalled SEK 17.1 million (SEK -509.4 m). This substantial improvement in profit is mainly attributable to capital gains of SEK 341.7 million. In addition, the previous year's figure includes one-off write-downs of SEK 270.7 million for capitalised research costs. Adjusted for items affecting comparability, the Group posted a loss of SEK 324.9 million (SEK -239.2 m).

The Group's cash flow

The Q4 cash flow came to SEK -49.8 million in comparison with SEK -68.7 million for the corresponding period the previous year. The positive trend is mainly attributable to lower capital spending and a positive trend for working capital.

The cash flow for the full year 2001 came to SEK 188.0 million (SEK -137.2 m), attributable in its entirety to the sale of SBL Vaccin.

At the end of the period, the Group had no external loans.

Due to the sale of the vaccine operations, investments in tangible fixed assets during the period fell to SEK 3.7 million (SEK 9.9 m) in Q4 and SEK 30.2 million (SEK 32.6 m) for the full year.

Financial status

The Group's current investments and liquid assets at the end of the period came to SEK 596.1 million, compared with SEK 408.0 million for the corresponding period the previous year.

Available liquidity per share totalled SEK 53.00 compared with SEK 38.94 at the end of 2000.

Shareholders' equity

The Group's shareholders' equity at the end of the period came to SEK 678.8 million compared with SEK 646.0 million at the end of the previous year.

The Group's equity/assets ratio at the end of the period was 90.8 %, which is a substantial improvement on the end of 2000, when it amounted to 74.3%. The corresponding figures for the Parent Company, Active Biotech AB, were 55.1 % at the end of the period and 59.5% at the end of 2000.

Forecast for 2002

During 2002, the operations will focus on the start-up and implementation of clinical Phase II trials held under the company's own auspices for the key SAIK-MS and TTS projects. Alongside these activities, discussions will be held with potential collaboration partners. The exact point at which licenses will be granted or partnership agreements signed for the various projects cannot be specified as yet, which is why no forecast for 2002 can be submitted.

Upcoming financial reports

Interim reports and the final accounts report for 2002 will be published on the following dates:

Interim report, January 1 - March 31	May 15, 2002
Interim report, April 1 – June 30	August 14, 2002
Interim report, July 1 - September 30	November 7, 2002
Interim report, October 1 – December 31 and full year	February 13, 2003

The reports will be available on these dates at www.activebiotech.com under the heading News.

Accounting and valuation principles

This report has been drawn up using the same principles as those applying in the latest annual report and pursuant to the recommendations of the Swedish Financial Accounting Standards Council.

Due to the company structure and its major research and development costs, the company is not in a position to pay tax. The company's accumulated loss carry-forward at the end of 2001 totals SEK 344 million, including taxation for the 2001 operating year that has not yet been approved.

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Active Biotech AB (Publ)

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Active Biotech AB is a biotech company focusing on pharmaceutical research and development. The company has a strong research portfolio that primarily focuses on autoimmune/inflammatory diseases and cancer. The main projects involve unique substances with immunomodulatory properties (SAIK), intended for use in the treatment of multiple sclerosis and other diseases, as well as a new concept for cancer treatment (TTS).

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Active Biotech Group

Income statement (including SBL Vaccin for the period January-June 2001)

SEK million	Oct-Dec 2001	Oct-Dec 2000	Full year 2001	Full year 2000
Net sales	0.1	90.2	102.3	280.4
Cost of goods sold	0.0	-55.4	-76.5	-179.9
Gross income	0.2	34.8	25.8	100.6
Sales and marketing costs		-8.8	-12.7	-28.1
Administration costs	-10.1	-12.5	-42.1	-64.4
Research and development costs	-62.6	-78.4	-294.6	-271.8
Other income/expenses	-1.2	2.6	-1.3	24.5
	-73.7	-62.4	-324.9	-239.2
Items affecting comparability	0.3	-267.0	0.3	-270.2
Capital gains on the sale of subsidiaries			341.7	
Operating profit/loss	-73.5	-329.4	17.1	-509.4
Profit/loss from participations in associated companies	-1.0		-1.0	
Net financial items	5.1	8.3	18.7	90.0
Profit/loss after financial items	-69.4	-321.0	34.8	-419.4
Tax on the profit/loss for the year	-1.8	0.1	-1.8	0.1
Profit/loss for the year	-71.2	-320.9	33.0	-419.3
Depreciation included to the amount of	4.2	10.8	26.8	38.3
Investments in tangible fixed assets	3.7	9.9	30.2	32.6
Earnings per share	-6.33	-28.53	2.94	-37.28
Number of shares (000s)	11 246	11 246	11 246	11 246

Income statement – proforma adjusted (excluding SBL Vaccin)

SEK million	Oct-Dec 2001	Oct-Dec 2000	Full year 2001	Full year 2000
Net sales	0.1	11.2	2.5	45.2
Cost of goods sold	0.1	0.1	0.2	0.1
Gross income	0.2	11.3	2.7	45.2
Sales and marketing costs	0.0	0.0		
Administration costs	-10.1	-10.8	-37.0	-54.9
Research and development costs	-62.6	-66.0	-231.3	-219.9
Other income/expenses	-1.2	7.2	-0.9	5.8
	-73.7	-58.2	-266.4	-223.7
Items affecting comparability	0.3		0.3	
Capital gains on the sale of subsidiaries			341.7	
Operating profit/loss	-73.5	-58.2	75.5	-223.7
Profit/loss from participations in associated companies	-1.0	0.0	-1.0	
Net financial items	5.1	8.2	19.4	91.6
Profit/loss after financial items	-69.4	-50.0	93.9	-132.1
Tax on the profit/loss for the year	-1.8	0.1	-1.8	0.1
Profit/loss for the year	-71.2	-49.9	92.1	-132.0
Depreciation included to the amount of	4.2	4.5	17.8	20.2
Investments in tangible fixed assets	3.7	0.5	9.6	7.0
Earnings per share	-6.33	-4.44	8.19	-11.74
Number of shares (000s)	11 246	11 246	11 246	11 246

Active Biotech Group

Balance sheet

SEK million	Dec 31 2001	Dec 31 2000
Intangible fixed assets	0.0	47.1
Tangible fixed assets	74.3	197.4
Financial fixed assets	52.0	53.3
Total fixed assets	126.3	297.9
Inventories	0.0	63.4
Current receivables	25.4	99.6
Current investments and liquid assets	596.1	408.0
Total current assets	621.5	571.0
Total assets	747.8	868.9
Shareholders' equity*	678.8	646.0
Allocations	9.1	35.8
Long-term liabilities	0.0	57.3
Current liabilities	59.9	129.8
Total equity and liabilities	747.8	868.9
<i>*Change in shareholders' equity</i>		
Amount at the start of the period	646.0	1 064.3
Shareholders' dividends		
Translation differences	-0.3	1.0
Profit/loss for the period	33.0	-419.3
Amount at the end of the period	678.8	646.0

Active Biotech Group

Cash flow statement

SEK million	Oct-Dec 2001	Oct-Dec 2000	Full year 2001	Full year 2000
Profit/loss after financial items	-69.4	-321.0	34.8	-419.4
Adjustments for items not included in cash flow, etc.	5.1	284.9	-315.2	314.2
Tax paid	-1.3	1.7	-1.5	-0.5
Cash flow from ongoing operations before changes in working capital	-65.6	-34.3	-281.9	-105.7
Changes in working capital	19.3	1.3	-72.7	65.5
Cash flow from ongoing operations	-46.3	-33.1	-354.6	-40.2
Net investment in fixed assets	-3.5	-26.0	508.6 ¹⁾	-46.9
Cash flow from investment activities	-3.5	-26.0	508.6	-46.9
Loans raised/repayment of loans	0.0	-9.7	34.0	-50.0
Cash flow from financing activities	0.0	-9.7	34.0	-50.0
Cash flow for the period	-49.8	-68.7	188.0	-137.2
Liquid assets at the start of the period	646.0	476.7	408.0	545.1
Exchange rate difference in liquid assets	-0.1	0.0	0.1	0.0
Liquid assets at the end of the period	596.1	408.0	596.1	408.0

1) SEK 538.1 million relates to the sale of SBL Vaccin.

KEY FIGURES	Full year 2001	Full year 2000
Equity per share, SEK	60.4	57.4
Available liquidity, MSEK	596	438
Available liquidity per share	53.00	38.94
Parent Company equity/assets ratio, %	55.1	59.5
Group equity/assets ratio, %	90.8	74.3
Average number of year-round employees (2001 excl. SBL Vaccin)	184	337

Active Biotech Group

Income statement 1999 - 2001 - "proforma adjusted"

SEK million	Full year 1999	2000				Full year 2000	2001				Full year 2001
		1Q	2Q	3Q	4Q		1Q	2Q	3Q	4Q	
Net sales	81.1	11.3	11.9	10.7	11.2	45.2	1.4	0.9	0.0	0.1	2.5
Cost of goods sold	-2.0	-0.2	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2
Gross income	79.1	11.1	12.0	10.9	11.3	45.2	1.5	1.0	0.1	0.2	2.7
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	-7.8	-8.2	-10.8	-10.1	-37.0
Research and development costs	-232.1	-49.9	-57.5	-46.4	-66.0	-219.9	-59.3	-54.4	-54.9	-62.6	-231.3
Other income/expenses	0.1	0.0	0.0	-1.4	7.2	5.8	0.0	0.4	-0.1	-1.2	-0.9
	-215.3	-52.1	-66.0	-47.4	-58.2	-223.7	-65.7	-61.3	-65.8	-73.7	-266.4
Items affecting comparability	15.0									0.3	0.3
Capital gains on the sale of subsidiaries									341.7		341.7
Operating profit/loss	-200.3	-52.1	-66.0	-47.4	-58.2	-223.7	-65.7	-61.3	275.9	-73.5	75.5
Profit/loss from participations in associated companies										-1.0	-1.0
Net financial items	57.7	77.3	-8.6	14.7	8.2	91.6	1.1	9.3	3.8	5.1	19.4
Profit/loss after financial items	-142.6	25.2	-74.6	-32.7	-50.0	-132.1	-64.5	-52.0	279.8	-69.4	93.9
Tax on the profit/loss for the year					0.1	0.1		-0.1	0.1	-1.8	-1.8
Profit/loss for the year	-142.6	25.2	-74.6	-32.7	-49.9	-132.0	-64.5	-52.0	279.8	-71.2	92.1
Depreciation included to the amount of	22.9	6.0	5.1	4.7	4.5	20.2	4.6	4.5	4.6	4.2	17.8

Principles for proforma adjustments

1. The subsidiary SBL Vaccin was reported as an external company between 1999 and 2001. The debiting of administrative services between the Parent Company and SBL Vaccin has been reported as external services to the amount of around SEK 1.8 million per year in the pro forma income statement.
2. The net financial items in the pro forma income statement have not been adjusted for a fictitious return on an alternative investment of the purchase sum for acquiring SBL Vaccin.
3. In fiscal terms, the sale of SBL Vaccin is neutral in the proforma income statement since other companies within the Group have utilised Group contributions from the Parent Company.