

# The Active Biotech Group Interim Report January – March 2001

- Both key projects, SAIK-MS and TTS, are proceeding to Phase II clinical trials
- Increased focus on research projects in Lund
- Financing through partnerships, possible sale of operations and new share issue
- Operating loss of SEK –87.6 million for the period (SEK –51.5 million), adjusted pro forma year 2000 to SEK –67.8 million
- Vaccine sales of SEK 46.7 million (SEK 53.4 million)

Active Biotech plans to separate and further streamline its operations, investing heavily in the project portfolios while focusing on a partner strategy.

The operations of Active Biotech currently focus on the development of pharmaceuticals and vaccines.

In Lund, the company conducts pharmaceutical research and development and has very promising projects, particularly in the fields of MS and cancer.

The company's operations in Stockholm involve developing, manufacturing and marketing vaccines against diseases such as polio, cholera and tourist diarrhoea (ETEC).

The ongoing development of these operations requires a variety of strategies and skills, and the co-ordination gains to be made between the operations in Lund and Stockholm are therefore limited.

At today's meeting, the Board of Directors of Active Biotech decided that the operations should be streamlined and divided into two clearly defined subsidiaries, Active Biotech Research and SBL Vaccin, each with its own management team and separate organisation. A smaller Group-wide management team will be responsible for overall co-ordination of the Active Biotech Group.

The main focus of both units' strategies was approved. For both units, it involves explicit partner strategies. The company plans to allocate considerable resources and investments to the project platforms described below. The initiative is to be financed through partnership agreements and the possible sale of the SBL operations. The company will also start preparations for a potential new share issue.



#### **Active Biotech Research**

The general view is that the best way of promoting future value growth at the Active Biotech Group is through a broader, dynamic initiative focusing on the activities conducted at Active Biotech Research in Lund. On the basis of the decision made at today's Board meeting, operations will be reorganised into three platforms. The idea is to clarify the company's strategy and goals and facilitate the establishment of joint efforts the company has either already agreed or will be seeking in a variety of areas. One of the three platforms, the TTS platform, focuses on biologicals (biotechnology products), while the so-called Q and B platforms focus on the development of small molecules (low molecular weight chemicals).

### The Q Platform

The company's Q platform forms a basis for the development of pharmaceuticals used in the treatment of both inflammatory autoimmune diseases and cancer. The project that has made most progress in this platform area focuses on developing a drug in tablet form for use in treating multiple sclerosis, SAIK-MS.

Active Biotech announced at the end of April that the clinical goal of the Phase I study of SAIK-MS had been attained in a highly satisfactory manner.

The study was conducted in the form of a dose escalation study aimed at determining the highest dose that can safely be administered to MS patients. The study included 35 healthy volunteers and 11 MS patients, and the Maximum Tolerable Dose (MTD) was set at 1.2 mg/day, after patients showed uniform signs of inflammatory reactions to the higher dose of 2.4 mg/day. This means that the safety margin for SAIK-MS is good, since the estimated therapeutic dose level is 0.03-0.3 mg/day.

Discussions are being held with potential partners with the aim of initiating joint efforts centering on SAIK-MS. There is considerable interest in this project. Since development is still at a relatively early stage, it is important to find the right partner and the right form of cooperation so as to ensure optimal value growth. Alongside these discussions, a Phase II study is also being planned to ensure that the project work proceeds without losing momentum.

Within the framework of the Q platform activities, a co-operation agreement was reached on April 17, 2001 between Active Biotech and Dr. John T. Isaacs of the Johns Hopkins University in Baltimore (U.S.) with the aim of developing a product candidate for use in the treatment of prostate cancer.

Prostate cancer is the form of cancer with the highest mortality rate after lung cancer. At the early stages, when the disease is hormone-dependent, treatment usually involves orchiectomy or chemical castration. When the disease progresses and is no longer hormone-dependent, there are currently no effective treatment methods available.

The co-operation will involve the Johns Hopkins University using experimental models of prostate cancer to evaluate the effect of a series of substances developed by Active Biotech. A product candidate will be selected on the basis of this work. Active Biotech has submitted patent applications for the relevant substances and their use in the treatment of prostate cancer.



Other activities based on the Q platform aim to develop product candidates for use in treating other inflammatory/autoimmune diseases and to define molecules and mechanisms that interact with the Q substances to produce their biological effects.

#### The TTS Platform

The cancer project known as TTS (Tumor Targeted Superantigens) was previously conducted in the form of contract research on behalf of Pharmacia. At the end of 1999, all rights to the project were acquired with the aim of taking the project to the evaluation stage under the company's own auspices.

The TTS project was evaluated during 2000, and a Phase I clinical trial on a product candidate for use in the treatment of renal cancer and non small-cell lung cancer was completed. We are now awaiting the final report on the study, but the preliminary data looks promising. In addition, extensive development work is under way on the next generation of TTS products. Since TTS as a concept can be used against other forms of cancer, work is also under way to develop TTS products for other indications.

The company is now actively proceeding with the TTS project and is entering Phase II, and renewed efforts and investments are being devoted to it. Active Biotech intends to begin negotiations during the year with Pharmacia pursuant to the options agreement previously reached.

The upcoming clinical Phase II trials are being planned in co-operation with the Karolinska Hospital in Stockholm and Christie Hospital in Manchester and are expected to start during the second half of 2001.

#### The B Platform

In the B platform area in 2000, Active Biotech produced a new basis for the development of pharmaceuticals for use in the treatment of autoimmune/inflammatory diseases and cancer. One patent application has been submitted thus far in this platform area, and additional applications are being prepared.

The two most advanced subprojects in the B platform area aim to develop pharmaceutical candidates for use in the treatment of inflammatory bowel disease (IBD) and rheumatoid arthritis (RA). These two chronic diseases affect a large group of people in the West.

#### Other Projects

In addition to the above platforms, other projects are proceeding as planned.

### SBL Vaccin (SBL)

Compared to Active Biotech Research, the operations in Stockholm have reached a far higher level of maturity, with a number of products on the market or in late development phases (ETEC, Phase III). Ongoing efforts will focus on generating maximal sales of existing and upcoming products. The company will continue to develop its market position in the Nordic region and to broaden its international market penetration through close co-operation with major international companies with strong market organisations. Joint efforts have already been introduced in some markets, with Aventis Pasteur (international markets) and Aventis Pasteur MSD (the Nordic region).



Apart from the expenses involved in the current Phase III studies of a new vaccine against tourist diarrhoea (ETEC), SBL has no plans for any major investments in new projects or manufacturing plants. The company's expenses will mainly be attributable to product manufacturing, as well as marketing and sales in the Nordic region. Income from sales is expected to increase rapidly now that the SBL Cholera Vaccine and Dukoral are being launched in new markets, while cost increases will be limited.

The intent is for SBL to find joint efforts in areas other than those devoted solely to the marketing of existing products. Among other things, SBL intends to seek partners for the ETEC project and for the completion of the Phase III study, as well as for the international registration and launch of this product, which has a highly interesting market potential. Joint projects are also planned for the development of a paediatric indication for use in third-world countries. Further efforts in the ETEC project, however, await approval of SBL's application to change the definition of the goal of the study currently under way by U.S. FDA registration authorities.

# Diarrhoea Vaccines

The process involved in WHO registration of the SBL Cholera Vaccine has now reached the final phase and is expected to be completed during Q4 2001. One of the reasons for this registration is to allow UN organs to use the vaccine and to build up emergency stocks. Médecins sans Frontières (MSF) has already built up a small, contingency stock.

In a recent WHO publication, WHO renewed its recommendation of the SBL Cholera Vaccine as the only vaccine providing effective protection against cholera. The organisation emphasised that the SBL Cholera Vaccine is well tolerated and verifies the fact that the vaccine also provides good protection against ETEC infection.

#### New Co-operation Agreements

On April 1, a new joint effort was entered into with Aventis Pasteur MSD on vaccines in the Swedish market.

Since April 1, SBL is also the Danish Statens Seruminstitut's (SSI) distributor in Sweden and Norway.

# **Financial Information**

#### Net Sales

The launch of the SBL Cholera Vaccine initiated last year and the changes to the agreements on agency and distribution operations in Sweden and Norway have had a major impact on the sales outcome during Q1 2001 compared with the previous year.



	Jan. – M	ar.		Sales (%)	( <b>%</b> )
Vaccine sales	2001	2000	Change (%)	2001	2000
Vaccines manufactured in-ho	use				
Dukoral	12,3	11,5	6%		
SBL Cholera Vaccine	0,0	6,9	neg		
Other products	2,6	3,6	-28%		
Total	14,9	22,0	-32%	32%	41%
Agency products	0,1	10,6	neg	0%	20%
Distribution orders	31,7	20,7	53%	68%	39%
<b>Total vaccine sales</b>	46,7	53,4	-13%	100.0%	100.0%
Income from contract research	0,0	10,0			
Other income	0,7	1,1			
Total net sales	47,4	64,5	-26%		

Sales of Dukoral in the Nordic market rose only 6 percent compared with the previous year as a result of distributors' stock adjustments. Sales to end customers in Sweden and Norway are continuing to perform well, reporting an increase of 17 and 38 percent respectively.

Aventis Pasteur is now preparing the launch of the SBL Cholera Vaccine in markets outside the EU/U.S. The registration process is proceeding and applications have been submitted in around 25 countries, with sales expected to start during the second half of the year. During the corresponding period the previous year, a single order totalling SEK 6.9 million was invoiced to Mozambique.

<u>Agency operations.</u> The windup of the GlaxoSmithKline partnership at the end of 2000 and the agreement with Aventis Pasteur MSD that came into force on April 1, 2001, led to a short-term decline in sales during Q1, when no invoicing was registered. Sales have begun very well for the Aventis Pasteur MSD travel-vaccination program.

Distribution orders are displaying excellent growth, with sales jumping 53 percent to SEK 31.7 million. The increase in sales is mainly attributable to volume growth for existing and new operations.

# **Group Financial Results**

The accounting principles used to report research expenses in the Group were harmonised at the end of the year. This has entailed booking all expenses related to the diarrhoea-vaccine projects as costs as they arise. In the corresponding period the previous year, the expenses involved in these projects were capitalised.

As a consequence of the take-over of all rights to the TTS project from Pharmacia, continued clinical development is being conducted in-house and previous agreements concerning contract research ceased to apply as of December 2000.



The operating loss before financial items totalled SEK –87.6 million (SEK –51.5 m), while the adjusted pro forma loss for the corresponding period the previous year was SEK –67.8 million. The change in the financial result can be attributed mainly to the fall in income from contract research in the TTS cancer project (SEK 10 million) after the Pharmacia agreement ceased at year end, as well as to higher research expenses as the prioritised projects proceed to new clinical phases according to plan.

The short-term decline in sales income during Q1 is attributable to the fact that Aventis Pasteur took over the international marketing of the SBL Cholera Vaccine and that the GlaxoSmithKline agency agreement ended on December 31, 2000. Despite this, the gross profit and the gross profit margin on vaccine sales improved, compared with the corresponding period the previous year.

Operating expenses, excluding the cost of goods sold, rose 13 percent to SEK 102 million (SEK 74 million). The adjusted pro forma figure is SEK 91 million. The difference is attributable to the continued positive performance of the prioritised research projects, SAIK-MS, TTS and ETEC, which have, as expected, led to increased costs, since SAIK-MS and TTS have now completed Phase I tests and the ETEC project is proceeding to Phase III.

Altogether, sales, administrative and other income/expenses have fallen marginally.

The Group's net financial items fell from SEK 76.5 million in 2000 to SEK 1.0 million this year. This reflects realised profits made in the Zenit hedge fund during Q1 last year. The operating loss after net financial items totalled SEK –86.6 million (SEK 25.0 million), while the previous year's adjusted pro forma profit came to SEK 8.7 million.

#### **Financial Status**

The Group's equity/assets ratio on March 31, 2001, was 69.3 percent (74.3 percent on December 31, 2000). The company had no loans at the end of Q1.

Cash flow for Q1 came to SEK –89 million (SEK 37 million), which is explained by the financial result for the period, as well as investments in production facilities designed to meet future sales growth, and a positive change in operating capital.

The Group's liquid assets totalled SEK 319 million at the end of the reporting period (SEK 408 million on December 31, 2000). In addition, credit lines have been granted, but not utilised, in a total amount of SEK 30 million.

Shareholders' equity in the Group totalled SEK 547 million at the end of the reporting period (SEK 646 million on December 31, 2000).

The company currently has no plans to publish a forecast for the full year 2000, as it will be influenced by the outcome of ongoing business discussions.

## Accounting and Valuation Principles

This Interim Report has been drawn up pursuant to the same principles as those used in the latest Annual Report.



# **Upcoming Financial Information**

Q2 Interim Report August 8Q3 Interim Report November 6

- The preliminary yearend report for 2001 will be published on February 14, 2002.

Lund May 9, 2001 Active Biotech AB (publ)

Sven Andréasson President & CEO

The company's auditors have not reviewed this Interim Report.

Active Biotech is a biotechnology company focusing on research in and development of pharmaceuticals and vaccines. Our expertise lies in our in-depth knowledge of the human immune system. We have a high-quality project portfolio with significant value potential. Important products and projects include drugs for use in treating multiple sclerosis (SAIK) and cancer (TTS), as well as the cholera vaccine, SBL Cholera Vaccine and the tourist diarrhoea vaccines, Dukoral and ETEC. Active Biotech's net sales in 2000 totalled SEK 280 million.

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# Active Biotech Group

# **Income Statement**

MSEK	JanMar 2001	JanMar 2000	Last 12 months Apr.00- Mar. 01	Full Year 2000
Net sales	47,4	64,5	263,3	280,4
Cost of goods sold	-32,9	-41,7	-171,1	-179,9
Gross income	14,4	22,9	92,1	100,6
Sales & marketing costs	-6,7	-5,9	-28,9	-28,1
Administration costs	-10,3	-15,2	-59,4	-64,4
Research and development costs*	-83,7	-55,4	-300,1	-271,8
Other income/expenses	-1,4	2,3	20,7	24,5
	-87,6	-51,2	-275,6	-239,2
Items affecting comparability	0,0	-0,2	-270,0	-270,2
Operating profit/loss	-87,6	-51,5	-545,5	-509,4
Net financial situation	1,0	76,5	14,5	90,0
Profit/loss after financial items	-86,6	25,0	-531,0	-419,4
Tax on profit for the year	0,0	0,0	0,1	0,1
Profit/loss for the year	-86,6	25,0	-530,9	-419,3
Depreciation included in the amount of	9,1	10,0	37,4	38,3
* R&D expenses incl. historically capitalised expenses	-83,7	-71,8	-336,7	-324,8

# **Balance Sheet**

MSEK	Mar. 31, 2001	Mar. 31, 2000	Dec. 31, 2000	
Intangible fixed assets	46,3	299,3	47,1	
Tangible fixed assets	200,6	200,0	197,4	
Financial fixed assets	53,8	114,0	*	
			53,3	
Total fixed assets	300,6	613,3	297,9	
Inventories	97,9	68,6	63,4	
Current receivables	86,4	232,4	99,6	
Short-term investments & liquid funds	319,4	582,0	408,0	
Total current assets	503,7	883,0	571,0	
Total assets	804,3	1 496,3	868,9	
Equity*	557,6	1 089,4	646,0	
Allocations	35,8	32,5	35,8	
Long-term liabilities	57,2	141,0	57,3	
Current liabilities	153,7	233,5	129,8	
Total equity and liabilities	804,3	1 496,3	868,9	
*Change in shareholders equity				
Amount at the start of the period	646,0	1 064,3	1 064,3	
Shareholders' dividends	0,0	0,0	0,0	
Translation differences	-1,8	0,1	1,0	
Profit/loss for the period	-86,6	25,0	-419,3	
Amount at the end of the period	557,6	1 089,4	646,0	



## Active Biotech Group

Cash Flow Statement MSEK	JanMar. 2001	JanMar. 2000	Full year 2000
Profit/loss after financial items	-86,6	25,0	-419,4
Adjustments for items not included in cash flow, etc.	6,7	9,5	314,2
Tax paid	0,0	-0,3	-0,5
Cash flow from ongoing operations before change			
in working capital	-79,9	34,2	-105,7
Changes in working capital	2,6	17,2	65,5
Cash flow from ongoing operations	-77,3	51,4	-40,2
Net investment in fixed assets	-11,3	-39,0	-46,9
Cash flow from investment activity	-11,3	-39,0	-46,9
Loans raised/loan amortisation	0,0	24,5	-50,0
Cash flow from financing activity	0,0	24,5	-50,0
Cash flow for the period Liquid funds, opening balance	-88,6 408,0	36,9 545,1	-137,2 545,1
Liquid funds, closing balance	319,4	582,0	408,0

KEY FIGURES	Mar. 30, 2001	Mar. 30, 2000	Whole year 2000	
Equity per share, SEK	49,58	96,87	57,44	
Available liquidity, MSEK	349	662	680	
Parent company equity/assets ratio, %	58,0	64,7	64,5	
Group equity/assets ratio, %	69,3	72,8	74,3	
Investments in tangible assets	11,9	7,8	32,6	
Average number of employees	338	341	337	
Earnings per share, SEK	-7,70	2,23	-37,28	
Number of shares (000)	11 246	11 246	11 246	



A ctive Biotech Group
Incomes Statement per quarter, "adjusted pro forma, with capitalised research expenses distributed per quarter"

| Pro forma | Pro |

	Pro forma					Pro forma	
	Full year	Pro forma	Pro forma	Pro forma	Pro forma	Full year	
MSEK	1999	Q1/2000	Q2/2000	Q3/2000	Q4/2000	2000	Q1/2001
Net sales	267,3	64,5	59,6	66,1	90,2	280,4	47,4
Cost of goods sold	-147,9	-41,7	-39,8	-43,0	-55,4	-179,9	-32,9
Gross profit	119,5	22,9	19,8	23,1	34,8	100,6	14,4
Sales costs	-23,8	-5,9	-7,7	-5,8	-8,8	-28,1	-6,7
Administration costs	-74,7	-15,2	-23,8	-12,9	-12,5	-64,4	-10,3
Research and development costs	-270,7	-55,4	-62,9	-75,1	-78,4	-271,8	-83,7
Historically capitalised research expenses	-68,6	-16,4	-16,5	-1,9	-18,3	-53,0	
Other income/expenses	-2,2	2,3	0,4	19,1	2,6	24,5	-1,4
	-320,5	-67,6	-90,6	-53,4	-80,7	-292,2	-87,6
Items affecting comparability	139,6	-0,2	-0,1	-3,0	3,3	0,0	
Operating profit/loss	-181,0	-67,8	-90,6	-56,3	-77,4	-292,2	-87,6
Net financial items	54,7	76,5	-9,4	14,6	8,3	90,0	1,0
Profit/loss after financial items	-126,2	8,7	-100,0	-41,7	-69,0	-202,2	-86,6
Tax on profit for the year	-4,5	0,0	0,0	0,0	0,1	0,1	0,0
Profit/loss for the year	-130,7	8,7	-100,0	-41,7	-68,9	-202,1	-86,6