

**Active Biotech Group  
Half Year Report  
January – June 1999**

- **SmithKline Beecham gives top priority to the ETEC-vaccine**
  - **completes Phase III trials in a new project organisation**
- **Investing in increased production capacity for the ETEC-vaccine**
- **The cholera vaccine – international breakthrough following WHO recommendation**
- **SAIK-MS in Phase I – great market potential**
- **Focusing and integration provide savings of approx. 75 MSEK a year**
- **Pre-tax profit –74.9 MSEK, 20 MSEK better than plan**
- **Shareholders' equity per share 93 SEK and available liquid funds per share 64 SEK**
- **Group equity/assets ratio 75 %**
- **Available liquid funds 721 MSEK**

**SMITHKLINE BEECHAM GIVES TOP PRIORITY TO ETEC**

The partner SmithKline Beecham (SB), the world's largest vaccine company, gives top priority to the ETEC-vaccine and contributes resources in a new project organisation for completion of Phase III trials in Guatemala/Mexico. The estimated launch on the first selected market in SB's marketing plan is the year 2001. SmithKline Beecham is to submit registration applications for both Europe and the USA.

The present situation regarding the clinical trials is as follows:

- In Kenya 700 patients have participated in the study. Patient recruitment has been completed. Laboratory analysis, validation and analysis of the results are currently being made.
- Guatemala/Mexico. In the present situation, 750 patients have been included. The trial continues with vaccine produced according to method used for commercial products.
- In Israel, 500 of the 1600 patients have been recruited to date. The aim of the study is to investigate the ETEC-vaccine's protective effect over a sustained period of time. The study is not intended for inclusion in the first application for registration.

More information regarding the studies will be provided when the effect data from the trials are reported, when SB submits an application for registration and upon approval of the ETEC-vaccine.

## **INCREASED PRODUCTION CAPACITY FOR ETEC**

An investment in SBL Vaccin's production plants in order to ensure adequate volumes prior to the launch of the ETEC-vaccine will start in October. The investment amounts to approx. 30 MSEK. In the existing production plant the cholera vaccine, which, in Sweden, is marketed under the Dukoral trademark, is also manufactured.

Dukoral sales have increased by 125% compared with last year.

## **THE CHOLERA VACCINE – INTERNATIONAL BREAKTHROUGH FOLLOWING WHO RECOMMENDATION**

The subsidiary, SBL Vaccin, has received its first major international order for its oral vaccine against cholera. The World Health Organisation, WHO, has recommended SBL's vaccine as being the only cholera vaccine with a documented high protective effect. The order has been issued by the Madagascan health care authorities. The value of the order amounts to 16 MSEK. It is the authorities' assessment that further orders of the same magnitude are to be expected in the autumn.

From and including this May, Active Biotech took back all the international marketing rights outside of the EU, USA and Australia in order to be able to sell the cholera vaccine under its own management in these markets. The vaccine has already been registered in six South American countries and registration applications are to be submitted in a further ten countries. Negotiations are currently being conducted with distributors in Switzerland, Latin America, Mexico, Africa, Turkey and Canada.

## **SAIK-MS IN PHASE I**

Following approval by the Medical Products Agency in Sweden [Läkemedelsverket] in June, the first clinical trials with a SAIK- compound against multiple sclerosis (MS) have been successfully carried out. SAIK is Active Biotech's generic name for different substances designed to modulate the human immune defence system. During the autumn an increased number of patients are to be included in the study and the result is expected to be available during Q2 of year 2000, which means that the product can be able to enter phase II as early as Q4 of year 2000. The launch is expected to take place in the year 2005/2006. The timing will be determined by the authorities' weighted assessment of the disease's complexity factor and the time required for following up the patients during the Phase III trials.

A new market study shows that the products currently on the market sell for approx. SEK 5 billion, with a strong annual growth rate. The total market potential for MS is estimated as being approx. SEK 20 billion a year and the number of patients is increasing by some 50 000 annually. Only a small proportion of the patients is treated by means of the existing therapy. The need for new and more effective pharmaceuticals is considerable.

## **FOCUSING AND INTEGRATION PROVIDE SAVINGS OF APPROX. SEK 75 MILLION A YEAR**

The integration of Active Biotech from three companies into one operational unit, which was announced by the MD at the shareholders general meeting, has commenced. In this way synergy benefits will be produced at the rate by which the measures are executed.

The Group's pre-clinical research is being increasingly centred upon Lund. Through concentration and reordering priorities within research and development, resources are released for further investments within key projects.

The highest priority for SBL Vaccin, Solna, will be the build-up of increased production capacity for the ETEC and cholera vaccines as well as a strengthening of markets, registration and the pharmaceutical sector.

A total overview of all activities within research and development is under way, with a focusing upon the Group's leading edge expertise area – the human immune defence system. There will be a concentration upon vaccines and pharmaceuticals, which control the immune system, so-called immunomodulators.

By focusing on this area, resources will be freed for further, offensive efforts directed at the Group's three prioritised products: the cholera vaccine, the ETEC-vaccine and SAIK-MS.

Active Biotech will become one operational unit with a cost-efficient organisation. Above measures makes a cost reduction of approx. 75 MSEK possible, of which 20 MSEK external costs. One-off costs are expected to be covered within the forecast result for 1999.

## **STRONG FINANCIAL POSITION**

The Group's available liquid funds amounted to 721 MSEK, or 64 SEK per share. The Group's equity/assets ratio was 75% and the Parent Company's 65%. Net investments for the period amounted to 84 MSEK.

## **RESULT AND FORECAST 99**

The pre-tax result for January-June amounted to -74.9 MSEK. The forecast for the whole of 1999 remains at -115 MSEK, including estimated one-off costs. As with previous forecasts there is an estimated sales profit for the ongoing sale of SBL Vaccin's property in Solna. No comparative figures for the corresponding period for last year are shown due to change of operations.

## **FORTHCOMING REPORTS**

Q3 report will be issued on 25-11-1999.

The final accounts announcement for 1999 will appear on 24-02-2000.

Lund, 27 August 1999

ACTIVE BIOTECH AB (publ)

Sven Andréasson  
President & CEO

*Active Biotech AB is a Swedish biotechnology group focused on the research and development of pharmaceuticals and vaccines. Our core competence is knowledge of the human immune defence system. We have a high qualitative project portfolio and considerable financial resources. Largest products are the Cholera-vaccine, vaccine against tourist diarrhoea (ETEC), and innovative drugs against MS (SAIK). The turnover of Active Biotech was SEK 259 million in 1998.*

Active Biotech AB (publ) registered number 556223-9227  
PO Box 724, SE-220 07 Lund, Tel +46 46-19 20 00, Fax +46 46 19 20 50  
E-mail [info@activebiotech.com](mailto:info@activebiotech.com)  
Home page: [www.activebiotech.com](http://www.activebiotech.com)

<b>The Group's Profit and Loss Accounts Jan-June 1999</b>	<b>(MSEK)</b>
Net sales	125.9
Cost of sold goods	-70.3
<b>Gross profit</b>	<b>55.6</b>
Selling expenses	-10.4
Administrative expenses	-29.9
Research & Development costs	-126.5
Items affecting comparability	15.0
Other operating income and costs	-1.4
<b>Operating profit/loss</b>	<b>-97.6</b>
Net financial items	22.7
<b>Profit/loss before tax</b>	<b>-74.9</b>
<b>The Group's balance sheet 30-06-1999</b>	<b>(MSEK)</b>
Intangible fixed assets	284.5
Tangible fixed assets	279.7
Financial fixed assets	94.7
<b>Total fixed assets</b>	<b>658.9</b>
Inventories	65.0
Current receivables	85.1
Cash and bank balances (including short-term investments)	599.8
<b>Total current assets</b>	<b>749.9</b>
<b>Total assets</b>	<b>1408.8</b>
Shareholders' equity	1051.0
Allocations*	26.9
Long-term liabilities**	167.3
Current liabilities***	163.6
<b>Total shareholders' equity and liabilities</b>	<b>1408.8</b>

\* Interest-bearing pension liabilities 30-06-1999 amount to 17.8 MSEK

\*\* Interest-bearing long-term liabilities 30-06-199 amount to 50.0 MSEK

\*\*\* Interest-bearing current liabilities 30-06-199 amount to 8.8 MSEK

No comparative figures for the corresponding period for last year are shown, due to change of operations. In Active Biotech's balance sheet for the first half year of 1998, the Wilh. Sonesson companies were included.

<b>The Group's statement of changes in financial position 30-06-1999</b>	<b>(MSEK)</b>
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Profit/loss before appropriations and tax	-74.9
Depreciation	17.7
Change in working capital	213.2
<b>Cash-flow before investments</b>	<b>156.0</b>
Net investments in intangible assets	-20.6
Net investments in tangible assets	-10.1
Net investments in financial assets	-53.4
<b>Cash-flow after investments</b>	<b>71.9</b>
Change in long-term liabilities	-15.6
Distribution of goodwill Wilh. Sonesson	-10.3
Other	-4.2
<b>Change in liquid funds</b>	<b>41.8</b>

The above statement of changes in financial position shows the development as though Active Biotech had been restructured throughout the whole period. All the shares in Wilh. Sonesson AB were distributed the 10<sup>th</sup> of June. The distribution, with a total effect upon the Group's equity of -223.5 MSEK, is thus not shown above.

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**Key figures 30-06-1999**

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Equity/share	93 SEK
Available liquid funds/share	64 SEK
Group equity/assets ratio	75 %
Parent Company equity/assets ratio	65 %
Average number of employees	332
Total number of shares	11 246 292

The final accounts for the half year have not been subjected to separate investigation by the company's auditors.