

**Active Biotech Group  
Interim Report  
1 January – 30 September 1998**

- **SAIK - for the treatment of multiple sclerosis: ahead of schedule**
- **Collaboration in cancer with BioPhausia**
- **Vaccine for the prevention of hospital acquired infections - new research**
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## **OPERATIONS**

Active Biotech is a biotechnology company with a broad project portfolio and a strong balance sheet with substantial financial resources. The Group's operations are based on knowledge about the human immune defence system. The 185 strong scientific team, based in Solna (Sweden), Cambridge (UK), and Lund (Sweden), is focused on the development of vaccines for the treatment of tourist diarrhoea, cholera, polio and streptococcal infections, and identification of novel pharmaceuticals for the treatment of, among other things, multiple sclerosis, rheumatoid arthritis, cancer and asthma.

## **PROJECT PORTFOLIO**

### **Autoimmune diseases**

The Group's prioritised areas of research are infectious disease, autoimmune disease and inflammatory disease. Autoimmune disease, in which the body's immune defence system turns against its own tissues, is a large and heterogeneous group of diseases which involve many organs in the body.

More than 20 million people are estimated to suffer from autoimmune diseases in the USA alone. At the present time, treatment of patients with autoimmune disease have limited efficacy and only a few of those patients derive any benefit from symptoms and a cure from the disease. The cost of these treatments is high and the market in the USA for drugs to treat these diseases has been estimated at approximately USD 20 billion.

SAIK is Active Biotech's name for various substances for immune defence regulation, a research programme which is undertaken in Lund.

### **SAIK treatment of MS – ahead of schedule**

At present there is no long-term effective treatment for multiple sclerosis (MS) available. More than 20,000 new cases, frequently young people, are diagnosed every year and the total market is estimated to be USD 1,000M.

The research at Active Biotech has advanced ahead of schedule. Selection of a candidate drug will be finalised by the end of this year and not in 1999 as originally planned. The project has already attracted significant interest from potential collaboration partners.

### **SAIK – also for treatment of psoriasis**

Experimental studies towards the development of a treatment for psoriasis with SAIK substances were initiated during the autumn. Psoriasis is a skin disease which affects approximately 1-2 per cent of the global population, i.e. around 10 million people in industrialised countries. The treatment of psoriasis is interesting from the development viewpoint of SAIK, as it should be possible to conduct clinical trials within a short time frame.

Research into SAIK substances for use in the treatment of the major autoimmune diseases such as asthma, diabetes in young people, and rheumatoid arthritis continues according to plan.

### **Vaccines for international launch on track**

The ETEC-vaccine, the polio vaccine (IPV), and the cholera vaccine projects are proceeding according to plan. The main focus is on late clinical trials, the validation of production plants and completing documentation for the regulatory authorities.

Updates on the progress of the Phase III clinical tests for ETEC will be published when the project has passed three milestones; 1) when efficacy studies are completed, 2) when registration is applied for and 3) when registration is approved. The international launch is expected to take place in 2001 as planned.

Test production of rCTB substance has been completed successfully at the production plant in Matfors and by the beginning of 1999 the operation is expected to be capable of producing approximately 5 million doses per annum. Thereafter, it will be possible to increase production capacity significantly with only a limited strengthening of resources.

### **New collaboration on cancer project with BioPhausia**

Active Biotech and BioPhausia have signed a collaborative research agreement focusing on a cancer compound. The collaboration refers to the effect of the enzyme, hyaluronidase, on the treatment of tumours.

The project has significant commercial potential and the objective of the research collaboration is to test the hypothesis within a year. This will, in turn, determine the future direction of the project

The study is in a pre-clinical phase and so far it has been performed under BioPhausia's management. Together with American scientists, the Oncology Group at Active Biotech's facility in Lund will develop the project further.

### **Vaccine for the treatment of hospital-acquired infection - new research collaboration**

For a long time, Staphylococcal infections have been a major cause for concern in a surgical environment. Treatment with antibiotics is often an effective antidote but many strains of staphylococci have become resistant to these drugs. A preventative vaccine targeted against this organism would therefore be beneficial to high risk patient groups about to undergo surgery.

Swedish research groups have come together and formed a joint company with SBL Vaccin and Teknikbrotstiftelsen in Uppsala. SBL Vaccin owns 30 per cent of the new company and has an option to acquire the technologies arising from the research company within 3 years, with a view to initiating the development of a new vaccine product.

### **Peptide drug - a new collaborative agreement**

Actinova's product portfolio has been broadened following an agreement with UMDS, United Medical and Dental Schools (Guys Hospital, London). The parties involved have agreed to terms giving Actinova the exclusive rights to develop a peptide-based drug for the treatment of serious tooth decay caused by a Streptococcus bacterium.

A pilot study including dental student volunteers shows that the effect of the peptide is related to its ability to significantly reduce the ability of the bacterium to multiply in the oral cavity and colonise the teeth. Actinova will carry out the clinical development of the peptide drug in collaboration with Guy's Hospital.

If the results of the clinical tests prove positive, the product will be developed initially for the treatment of bacterial tooth decay in patients where this comes up as a serious side-effect of certain types of treatment. The drug would provide relief from bacterial tooth decay in sufferers from Sjögren's syndrome - an autoimmune disease which destroys the salivary glands.

### **Vaccine against tonsillitis - a new collaboration agreement**

Active Biotech's British subsidiary Actinova has signed a collaboration agreement with Vaccine Solutions Pty. - an Australian company representing the Queensland Medical Institute. This agreement gives Actinova the exclusive access to additional technologies for the development of an effective streptococcal vaccine.

### **PROPOSAL FOR DISTRIBUTION OF MOVERA/SONESSON**

In October 1998 the Swedish Government presented a bill to the Swedish Parliament, which among other things includes proposals for the liberalisation of the so-called Lex ASEA. A decision regarding new legislation is expected before the end of the year.

Subject to changed legislation, the Board of Directors today decided to propose that the 1999 Annual General Meeting will decide to distribute Movera/Sonesson to the shareholders.

This means that a new development company, independent of Active Biotech, will be quoted on the O-list during spring 1999.

### **DECISION ON SALE OF REAL ESTATE**

The Board of Directors has decided that the Group will sell the properties in Lund and Solna. The decision should be seen as a strengthening of and focusing on the research operations. Negotiations have started.

### **FINANCIAL POSITION**

Liquid assets amounted to SEK 673M. Interest-bearing liabilities in the biotechnology units amounted to SEK 85M and SEK 154M in other operations. The equity/assets ratio was 71 per cent for the Group and 87 per cent for the Parent Company.

**Investments**

During the period Group investments amounted to SEK 513M, of which investments in Lund Research Center accounted to SEK 351M and in Vitec to 37M.

During the period 909,520 B shares were acquired in Lifco for SEK 32M, equivalent to 10.0 per cent of the capital and 6.2 per cent of the votes.

**Next reporting date**

Preliminary Accounts Report for the 1998 full-year will be published on 25 February 1999.

Lund, 19 November 1998

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<b>Income Statement 1998 (SEK M)</b>	<b>January - September</b>	<b>Biotechnology</b>	<b>Other operations</b>	<b>Total Group</b>
Net sales		186.0	184.4	370.4
Cost of goods sold		-143.5	-123.2	-266.7
<b>Gross profit</b>		<b>42.5</b>	<b>61.2</b>	<b>103.7</b>
Selling expenses		-13.2	-32.9	-46.1
Administrative expenses		-32.1	-9.4	-41.5
Research and development costs		-92.3	-1.0	-93.4
Other operating income and expenses		4.9	0.7	5.5
<b>Operating profit/loss</b>		<b>-90.3</b>	<b>18.5</b>	<b>-71.8</b>
Net financial items		12.1	-5.6	6.5
Deficit on sale of subsidiaries			-13.1	-13.1
<b>Profit/loss after financial items</b>		<b>-78.2</b>	<b>-0.2</b>	<b>-78.4</b>
Minority interest in result for the period		-	0.3	0.3
<b>Profit/loss before tax</b>		<b>-78.2</b>	<b>0.1</b>	<b>-78.0</b>
Tax		-0.5	0.1	-0.4
<b>Profit/loss for the period</b>		<b>-78.6</b>	<b>0.2</b>	<b>-78.4</b>
<i>Depreciation included above</i>		<i>-18.2</i>	<i>-22.3</i>	<i>-40.6</i>
<b>Key ratios</b>				
Group equity/assets ratio		71 %		
Parent Company equity/assets ratio		87 %		
Net debt/equity ratio		0.18		
Average number of employees, total		495		
Average number of employees, biotechnology		306		
Proportion of research staff (biotechnology units)		185		
Number of shares		11 246 292		
Equity/share		SEK 117		
Liquid assets/share		SEK 60		

<b>Balance Sheet</b>	<b>September 1998</b>	<b>1998-09-30</b>	<b>1997-09-30</b>
<b>(SEK M)</b>			
Intangible fixed assets		271.3	213.5
Tangible fixed assets		773.3	890.0
Financial fixed assets		33.6	0.3
<b>Total fixed assets</b>		<b>1 078.2</b>	<b>1 103.8</b>
Inventories		73.7	84.0
Current receivables		126.7	106.0
Cash and bank balances		616.2	331.8
<b>Total current assets</b>		<b>816.6</b>	<b>521.8</b>
<b>Total assets</b>		<b>1 894.8</b>	<b>1 625.6</b>
Total equity		1 319.0	559.7
Minority interest		23.2	23.6
Provisions		61.3	100.4
Long-term liabilities *		265.2	713.2
Current liabilities**		226.2	228.7
<b>Total equity and liabilities</b>		<b>1 894.8</b>	<b>1 625.6</b>

\* Interest-bearing long-term liabilities at 30 September 1998 amounted to SEK 130M, all pertaining to the Group's non-biotechnology operations. In addition, there are interest-bearing pension liabilities of SEK 16.0M in biotechnology and SEK 18.3M in non-biotechnology operations.

\*\* Interest-bearing current liabilities at 30 September 1998 amounted to SEK 74.9M, of which SEK 5.8 pertained to the Group's non-biotechnology operations.

The Interim Report has not been subject to special examination by the Company's Auditors.