

**Active Biotech Group  
Interim Report  
1 January – 30 September 1999**

- **The new annual forecast shows a considerably better result. Sale of the property in Solna expected to be completed before the end of the year**
- **New organisation - annual savings totalling SEK 75m**
- **ETEC vaccine – Phase III clinical trials in final stage. Efficacy data published during Q1, 2000**
- **Great export potential for Dukoral travel vaccine. Record sales in Sweden, +70%**
- **SAIK-MS in extended Phase I – great interest from partners**
- **Extended research partnership with OXiGENE**
- **Available liquid funds: SEK 648m, equivalent to SEK 58 per share**
- **Shareholders' equity SEK 90 per share**

**RESULTS FOR '99 - CONSIDERABLY BETTER THAN PREVIOUSLY FORECAST**

The 1999 results will be considerably improved compared with the estimated loss of approximately SEK –115m previously forecasted. There are three reasons for the improvement: savings measures already effective this year, an improved net financial result and an anticipated higher capital gain on the sale of the property in Solna.

The property negotiations with several parties are in an intensive final phase. For this reason a forecast figure for the whole year is not given, pending a final agreement. There has been enormous interest in the SBL property, with its 100,000 sq m land and 26,000 sq m of building area.

No comparison figures are given for the corresponding period last year. These are misleading due to the changes in the business and the specialisation into biotechnology through the tax-free Wilh. Sonesson distribution in June. The Swedish National Tax Board has assessed the acquisition value after distribution to be allocated 93% to Active Biotech and 7% to Wilh. Sonesson.

## **NEW ORGANISATION – ANNUAL SAVINGS AMOUNTING TO SEK 75M**

Active Biotech has now been organised into an operating unit with a cost-effective and functional organisation with clearly defined responsibilities and tasks.

All preclinical research activities have been brought together in Lund. The group is focusing on, and making further investments in, its three priority products: the cholera vaccine, the ETEC vaccine and SAIK-MS.

The resources of SBL Vaccin in Solna are concentrated on marketing, the distribution of vaccines in the Nordic market and production of the cholera and ETEC vaccines.

The medical, clinical research and registration functions have been strengthened.

The announced annual cost reduction of SEK 75m proceeds as planned, and SEK 20m of this goal has already been achieved during 1999.

## **ETEC VACCINE – EFFICACY DATA DURING Q1, 2000**

Together with our partner SmithKline Beecham, we have started the final part of the Phase III clinical trials in Guatemala/Mexico. The study now involves batches of vaccine produced according to commercial production methods.

The first phase in Guatemala/Mexico, with approximately 750 patients, has ended. Efficacy data are expected to be published during Q1, 2000. The vaccine is drinkable, and protects against the intestinal bacterium ETEC (so-called tourist diarrhoea). No vaccine against the illness is currently available on the market. The first market launch is expected in 2001.

According to the World Tourism Organisation, there were approximately 49 million tourist journeys in 1996, excluding business travel, from Europe, Japan, the USA and Australia to high risk areas for the ETEC bacterium, and approximately 120 million to medium/low risk areas.

## **GREAT EXPORT POTENTIAL FOR DUKORAL TRAVEL VACCINE RECORD SALES IN SWEDEN, +70%**

The travel vaccine Dukoral against cholera is sold in Sweden and Norway, and the vaccine is also approved in these countries for ETEC indications. Dukoral is a drinkable vaccine with the same mode of operation as the ETEC vaccine, which is in the final phase of clinical trials. The protective effect is approximately 85% for 6 months against cholera and approximately 60% for approximately 3 months against ETEC.

Sales in Sweden during the period were 93,000 doses, compared with 56,000 for the same period in the previous year. It is estimated that approximately 800,000 Swedes visit areas at risk of cholera and tourist diarrhoea every year, which gives a penetration for Dukoral of only approximately 10-15% in Sweden so far. Currently, Dukoral is sold only on prescription and at vaccination centres. An application for OTC registration may be considered shortly. The product has been on the market for five years, and no side effects have been reported.

In addition to Sweden and Norway, Dukoral is registered in six South American countries. The registration application has been submitted in Switzerland and is being prepared for several other countries.

Sales of Dukoral during the period totalled SEK 18.1m, representing increases of +70% in Sweden and +405% in export turnover.

Registered only for cholera indication, an equivalent product to Dukoral is marketed internationally under the name "SBL Cholera Vaccine". WHO has recommended SBL Cholera Vaccine as the only available cholera vaccine in the world with a documented protective effect.

A registration application has been submitted recently to WHO for "WHO countries", in preparation for the creation of a stockpile of 1-2 million doses. It will be possible to deliver the vaccine quickly in disaster areas, e.g. countries affected by earthquakes. The selling price per dose is lower in this instance, but still offers a considerable return due to the order volume.

The current production capacity in Solna and Matfors is 4 million doses per year, which can be expanded considerably in the event of increased demand. At higher production volumes, a greater conversion rate is achieved, and hence significantly lower manufacturing costs.

### **SAIK-MS IN EXPANDED PHASE I - GREAT INTEREST FROM PARTNERS**

Active Biotech's research areas are infectious, inflammatory and autoimmune diseases. It is estimated that in the USA alone, more than 20 million people suffer from autoimmune diseases with few satisfactory methods of treatment. SAIK is the generic name for the company's various substances for the control of human immune systems.

During the autumn SAIK-MS, a substance against multiple sclerosis, was tested on a small scale, Phase I in humans, with very promising results. A new application was submitted in November to the Medical Products Agency in Sweden [Läkemedelsverket]. This will enable that an extended Phase I can be carried out during the spring next year, with a larger number of patients and at higher dosages.

SAIK-MS is expected to enter Phase II as early as Q4, 2000, which is faster than planned.

Potential partners have shown substantial and increasing interest in the product. The management, after studying research results obtained so far, has decided not to make partnership agreements in the various markets until 2001.

To negotiate on the basis of Phase II results, "proof of concept", means there will be better opportunities to obtain larger up-front payments, milestones and royalties. Active Biotech has the financial strength to be able to wait for the Phase II study of SAIK-MS.

Current sales of existing drugs against MS are SEK 5bn per year, and with strong growth in excess of 50%. The number of patients, of whom only some can be treated using current therapies, is increasing annually by more than 50,000.

## EXTENDED RESEARCH PARTNERSHIP WITH OXiGENE

During the summer, Active Biotech and OXiGENE signed a research agreement in the inflammatory diseases area. The initial aim of the partnership is that Active Biotech will evaluate new drugs against inflammatory diseases based on OXiGENE's patented technology around the benzamide group of substances in the cancer area.

The partners are currently holding discussions about extending the partnership by allowing OXiGENE to evaluate Active Biotech's patented SAIK substances in order to identify candidate drugs in the cancer area. A positive outcome in both of these areas will create increased resources for more rapid commercialisation.

## PRIORITISED PROJECTS WITH PARTNERS

Project (partner)	2000	2001
<b>ETEC</b> (SmithKline Beecham) Tourist diarrhoea vaccine	Application/ registration	Launch (1st European country)
<b>SBL Cholera Vaccine</b> (SmithKline Beecham) Partnership agreement for the EU, the USA, Australia; other countries under our own management	Registration	Launch (Europe)
<b>Dukoral</b> Cholera travel vaccine with ETEC indication. Own sales in Sweden, Norway. Own export rights exc. EU, USA, Australia	Registration/ launch in several countries	Registration/ launch in several countries
<b>SAIK</b> (Partner chosen in 2001) MS drug	Phase I/Phase II	Phase II
<b>Strep-A</b> (Vaccine Solution PTY) Tonsillitis vaccine	Phase I	Phase II
<b>Dental - 1025</b> (UMDS) Caries treatment	Phase I	Phase II
<b>TTS</b> (Contract research for Pharmacia & Upjohn) Lung cancer drug	Phase II/III New drug candidate	Phase II/III Phase I
<b>Benzamides</b> (OXiGENE) Autoimmune disease treatment	Drug candidate chosen	Phase I

## THE NEW MILLENNIUM

A great amount of work has been done in the form of analysis, planning and measures in the run-up to the year 2000. The risk of possible disruption to IT systems and laboratory technical equipment is considered to have been minimised.

## NEXT REPORT

The final accounts announcement for the operating year 1999 will appear on 18 February 2000.

Lund, 22 November 1999

Active Biotech AB (publ)

Sven Andréasson  
President and CEO

*Active Biotech AB is a biotechnology company focusing on the research and development of pharmaceuticals and vaccines. The core competence is knowledge about human immune systems. We have a high quality project portfolio and substantial financial resources. Important products are a vaccine against cholera, a vaccine against tourist diarrhoea (ETEC) and a drug against MS (SAIK). Active Biotech's turnover in 1998 was SEK 259m.*

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<b>The Group's Profit and Loss Accounts Jan-September 1999</b>		(MSEK)
Net sales		185,2
Cost of sold goods		-101,4
<b>Gross Profit</b>		<b>83,8</b>
Selling expenses		-15,6
Administrative expenses		-43,5
Research & Development costs		-190,5
Items affecting comparability		15,0
Other operating income and costs		-2,0
<b>Operating profit/loss</b>		<b>-152,8</b>
Net financial items		36,2
<b>Profit/loss before tax</b>		<b>-116,6</b>

<b>The Group's balance sheet 30-09-1999</b>		(MSEK)
Intangible fixed assets		299,9
Tangible fixed assets		277,3
Financial fixed assets		95,2
<b>Total fixed assets</b>		<b>672,4</b>
Inventories		60,4
Current receivables		106,4
Cash and bank balances (including short-term investments)		536,3
<b>Total current assets</b>		<b>703,1</b>
<b>Total assets</b>		<b>1375,5</b>
Shareholders' equity		1009,5
Allocations*		26,9
Long-term liabilities**		167,3
Current liabilities***		171,8
<b>Total shareholders' equity and liabilities</b>		<b>1375,5</b>

\* Interest-bearing pension liabilities 30-09-1999 amount to 17.8 MSEK

\*\* Interest-bearing long-term liabilities 30-09-1999 amount to 50.0 MSEK

\*\*\* Interest-bearing current liabilities 30-09-1999 amount to 18.7 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 30-09-1999</b>	(MSEK)
Profit/loss before appropriations and tax	-116,6
Depreciation	28,5
Change in working capital	204,7
<b>Cash-flow before investments</b>	<b>116,6</b>
Net investments in tangible assets	-36,1
Net investments in intangible assets	-18,5
Net investments in financial assets	-53,9
<b>Cash-flow after investments</b>	<b>8,1</b>
Change in long-term liabilities	-15,7
Distribution of goodwill Wilh. Sonesson	-10,3
Other	-3,9
<b>Change in liquid funds</b>	<b>-21,8</b>

The above statement of changes in financial position shows the development as if Active Biotech had been restructured throughout the whole period. All the shares in Wilh. Sonesson AB were distributed on 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.

<b>Key figures 30-09-1999</b>	
Equity/share	90 SEK
Available liquid funds/share	58 SEK
Group equity/assets ratio	73,4 %
Parent Company equity/assets ratio	64,1 %
Average number of employees	349
Total number of shares	11 246 292

The Interim Report has not been subjected to separate investigation by the Company's Auditors.